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Agroscope

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Good food, healthy environment

Lukas Jeker

25. September 2024

Agroscope

Bee risk assessment for the authorization of plant protection products in Switzerland in transition: An overview

Lukas Jeker
25. September 2024

Agroscope

Overview

- Description of Agroscope and the Swiss Bee Research Centre
- Bee risk assessment system for plant protection product (PPP) registration in Switzerland
- PPP issues related to bees in Switzerland
- Current challenges in bee risk assessment e.g. revision of the EFSA bee guidance document
- Regulatory status of neonicotinoid PPPs in Switzerland

Overview

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Agroscope: Key figures 2023

Agroscope is the Swiss center of excellence for agricultural research, and is affiliated with the Federal Office for Agriculture (FOAG)

1115 Employees or **947** full-time employees were employed of which **33** trainees, **37** interns, **62** doctorates, **43** postdocs

1444 Publications, of which **860** were practice-oriented **584** were scientific publications

Organisation of Agroscope: 10 strategic research divisions

Animals, Products of Animal Origin and Swiss National Stud

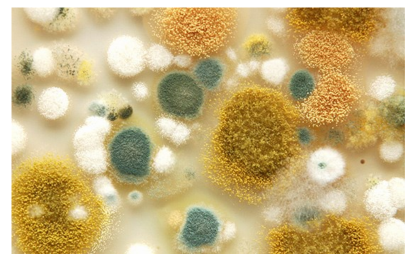
Plants and Plant Products

Methods Development and Analytics

Plant Breeding

Plant-Production Systems

Plant Protection

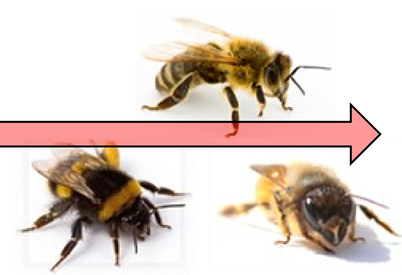


Food Microbial Systems

Agroecology and Environment

Sustainability Assessment and Agricultural Management

Animal Production Systems and Animal Health



Swiss Bee Research Centre

Agroscope

Swiss Bee Research Centre

Head:
MSc. Jean-Daniel Charrière

Team:
Bee research centre

Organisation of the Swiss Bee Research Centre in Switzerland

Bee Research Centre
Agroscope

Applied research

Basic Research

Institute for Bee Health
(IBH)

Training / Education
Knowledge Transfer

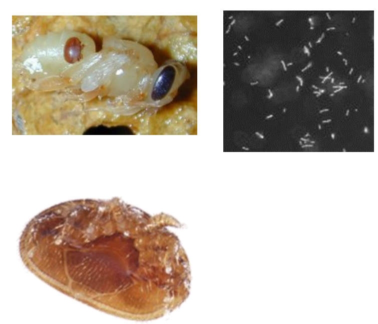
Bee health service

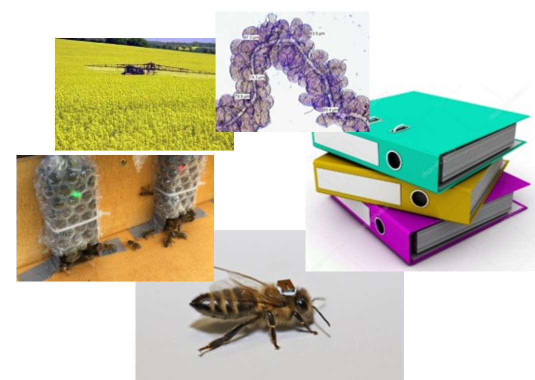
Organisation of the Swiss Bee Research Centre in Switzerland

Swiss Bee Research Centre Activities

Head:
Jean-Daniel Charrière

- National reference laboratory for bee diseases
- Bee products
- Bee disease and pest control
- Bee protection and beekeeping practices





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Activities at Swiss Bee Research Centre
National Reference Laboratory for bee diseases

- Reliable partner for routine diagnostic laboratories as well as for Swiss and European veterinary authorities (EURL)
- Maintenance, development and, where appropriate, adaptation of diagnostic methods recognised at European level

European Foulbrood (EFB)

Small hive beetle (*Aethina tumida)*

Varroa destructor

Tropilaelaps spp.

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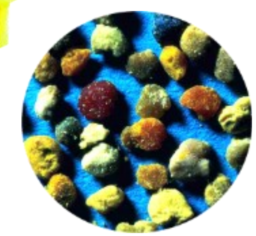
Activities at Swiss Bee Research Centre

Bee products

- Authenticity and origin of the products
- Monitoring pyrrolizidine alkaloids in honey and bee pollen

- National quality monitoring of Swiss honey / wax
  e.g. contamination pesticides, heavy metal, paraffin and stearin

- Honeybees as bio indicators,
  monitoring environmental toxins in bee matrices



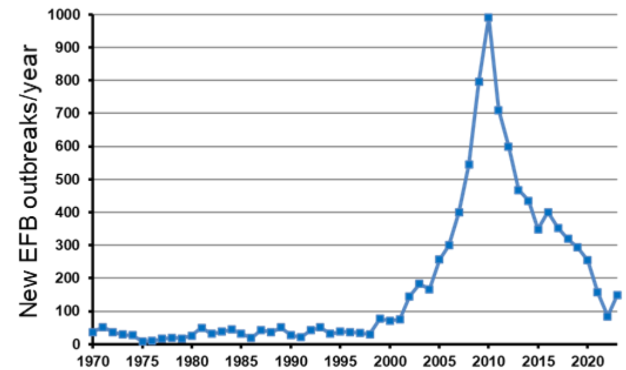
- Method development for the detection of honey fraud
- Supporting the practice in technological issues (e.g. pollen preservation)

Activities at Swiss Bee Research Centre

Bee disease and pest control

- Development of control methods for current and future pests. New ways (RNAi) to combat diseases and reduce colony losses

- *Varroa destructor* mites



- European Foulbrood (EFB)

  Brood disease caused by the bacterium *Melissococcus plutonius*

- Monitoring of colony losses

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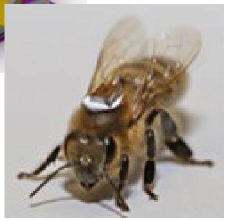
Activities at Swiss Bee Research Centre

Bee protection and beekeeping practices

- Plant protection product testing (enforcement + research)
- Risk assessment, new authorisation of PPP > 100 expertises / year
- Re-evaluation of old products (after 10 years)
- Development / validation of new test methods
- New measures for drift reduction
- Influences of agricultural practice on bees (e.g. impact of flower strips)



- Selection / queen breeding / artificial insemination
- Method testing/development for best beekeeper practices

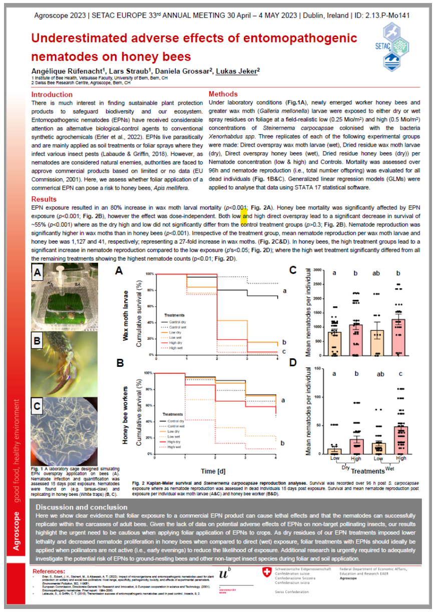
Method development and international connections

International connections

- **ICPPR**
  - Bee brood working group (co-chair Lukas Jeker)
  - Non-Apis working group and microbials (Daniela Grossar)
  - Congress 2019 in Bern Switzerland
- **COLOSS - APITOX task force** → Member
- **Expert Group on Pollinator Testing and Assessment (EG-PTA)** → co-chair Lukas Jeker
- **German bee protection working group** → Member

Method development

- Co-lead revision OECD 75 brood test under semi-field conditions
- Homing flight test (OECD 332)
- Honey bee adult chronic test (OECD 245)
- Honey bee larvae (OECD 237/239)
- Bumble bee acute oral and contact (OECD 246/247)
- Solitary bee *Osmia bicornis* acute oral, contact under evaluation (OECD) and chronic ring-test **ongoing**
- Method development for testing entomopathogenic nematodes on bees **ongoing**



Agroscope 2023 | SETAC EUROPE 33rd ANNUAL MEETING 30 April – 4 MAY 2023 | Dublin, Ireland | ID: 2.13.P-Mo141

Underestimated adverse effects of entomopathogenic nematodes on honey bees

Angélique Rüfenacht[1], Lars Straub[1], Daniela Grossar[2], Lukas Jeker[2]

1 Institute of Bee Health, Vetsuisse Faculty, University of Bern, Bern, CH
2 Swiss Bee Research Centre, Agroscope, Bern, CH

Introduction

There is much interest in finding sustainable plant protection products to safeguard biodiversity and our ecosystem. Entomopathogenic nematodes (EPNs) have received considerable attention as alternative biological-control agents to conventional synthetic agrochemicals (Erler et al., 2022). EPNs live parasitically and are mainly applied as soil treatments or foliar sprays where they infect various insect pests (Labaude & Griffin, 2018). However, as nematodes are considered natural enemies, authorities are faced to approve commercial products based on limited or no data (EU Commission, 2001). Here, we assess whether foliar application of a commerical EPN can pose a risk to honey bees, *Apis mellifera*.

Methods

Under laboratory conditions (**Fig.1A**), newly emerged worker honey bees and greater wax moth (*Galleria mellonella*) larvae were exposed to either dry or wet spray residues on foliage at a field-realistic low (0.25 Mio/m²) and high (0.5 Mio/m²) concentrations of *Steinernema carpocapsae* colonised with the bacteria *Xenorhabdus spp*. Three replicates of each of the following experimental groups were made: Direct overspray wax moth larvae (wet), Dried residue wax moth larvae (dry), Direct overspray honey bees (wet), Dried residue honey bees (dry)) per Nematode concentration (low & high) and Controls. Mortality was assessed over 96h and nematode reproduction (i.e., total number offspring) was evaluated for all dead individuals (**Fig. 1B&C**). Generalized linear regression models (GLMs) were applied to analyse that data using STATA 17 statistical software.

Results

EPN exposure resulted in an 80% increase in wax moth larval mortality ($p<0.001$; **Fig. 2A**). Honey bee mortality was significantly affected by EPN exposure ($p<0.001$; **Fig. 2B**), however the effect was dose-independent. Both low and high direct overspray lead to a significant decrease in survival of ~55% ($p<0.001$) where as the dry high and low did not significantly differ from the control treatment groups ($p>0.3$; **Fig. 2B**). Nematode reproduction was significantly higher in wax moths than in honey bees ($p<0.001$). Irrespective of the treatment group, mean nematode reproduction per wax moth larvae and honey bee was 1,127 and 41, respectively; representing a 27-fold increase in wax moths. (**Fig. 2C&D**). In honey bees, the high treatment groups lead to a significant increase in nematode reproduction compared to the low exposure (p's<0.05; **Fig. 2D**); where the high wet treatment significantly differed from all the remaining treatments showing the highest nematode counts ($p<0.01$; **Fig. 2D**).

Fig. 1 A laboratory cage designed simulating EPN overspray application on bees (A). Nematode infection and quantification was assessed 15 days post exposure. Nematodes were found on (e.g. tarsus-claw) and replicating in honey bees (White traps) (B, C).

Fig. 2 Kaplan-Meier survival and *Steinernema carpocapsae* reproduction analyses. Survival was recorded over 96 h post *S. carpocapsae* exposure where as nematode reproduction was assessed in dead individuals 15 days post exposure. Survival and mean nematode reproduction post exposure per individual wax moth larvae (A&C) and honey bee worker (B&D).

Discussion and conclusion

Here we show clear evidence that foliar exposure to a commercial EPN product can cause lethal effects and that the nematodes can successfully replicate within the carcasses of adult bees. Given the lack of data on potential adverse effects of EPNs on non-target pollinating insects, our results highlight the urgent need to be cautious when applying foliar application of EPNs to crops. As dry residues of our EPN treatments imposed lower lethality and decreased nematode proliferation in honey bees when compared to direct (wet) exposure, foliar treatments with EPNs should ideally be applied when pollinators are not active (i.e., early evenings) to reduce the likelihood of exposure. Additional research is urgently required to adequately investigate the potential risk of EPNs to ground-nesting bees and other non-target insect species during foliar and soil application.

References:

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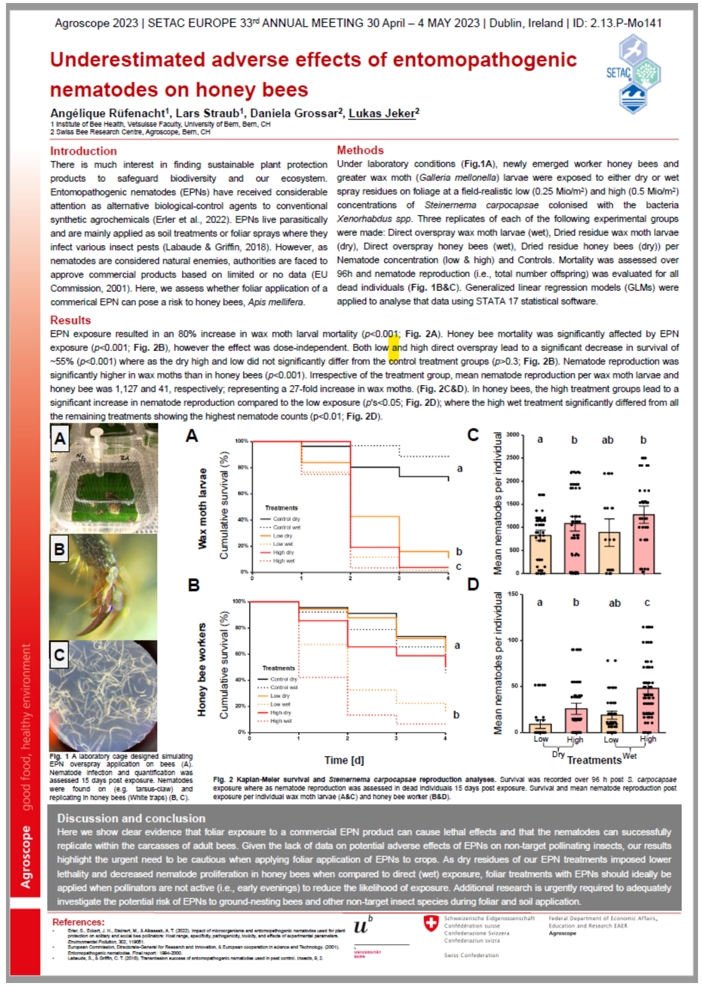
Underestimated adverse effects of entomopathogenic nematodes (EPN) on honey bees



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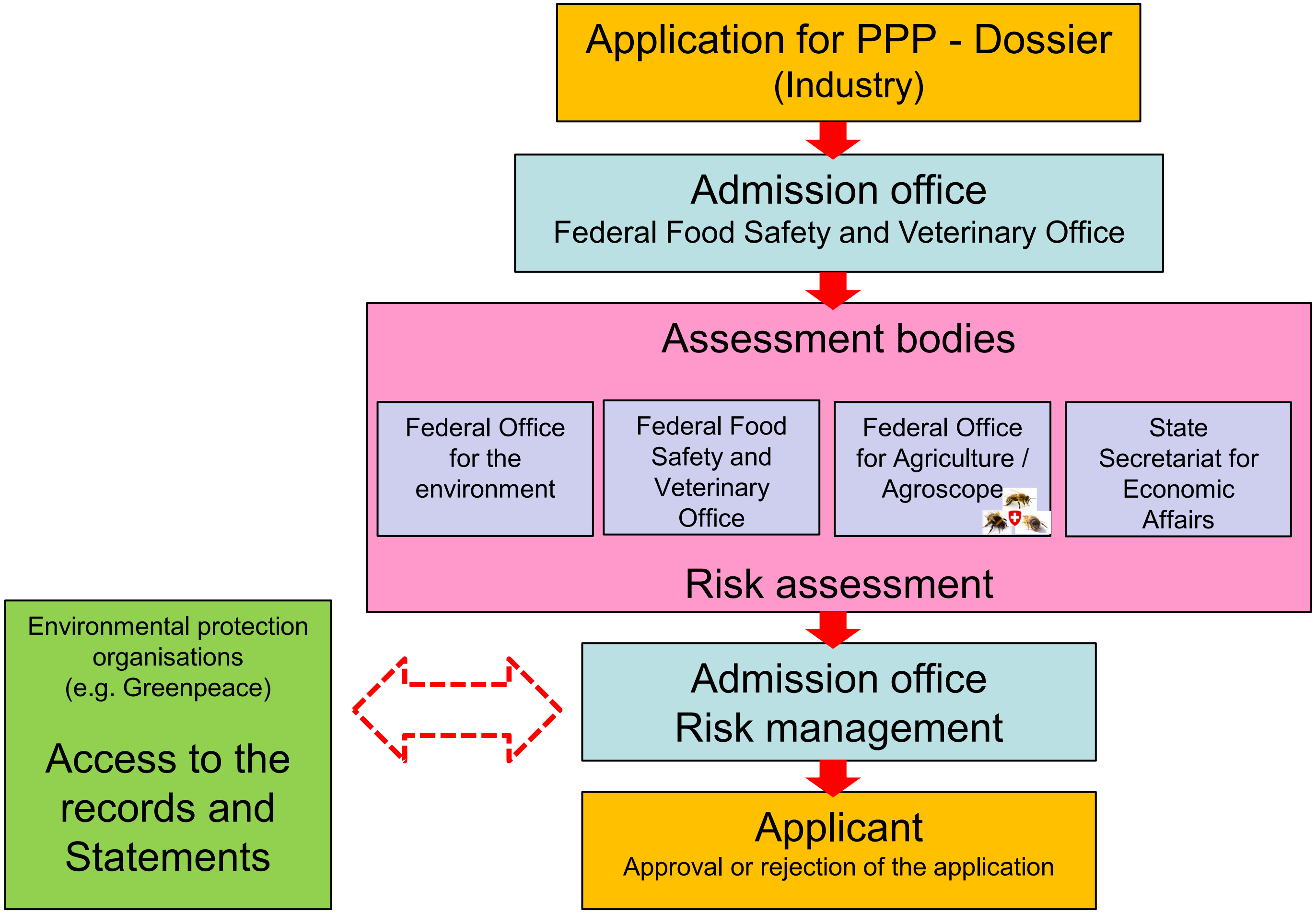
Authorisation procedure of PPP in Switzerland

Simplified scheme



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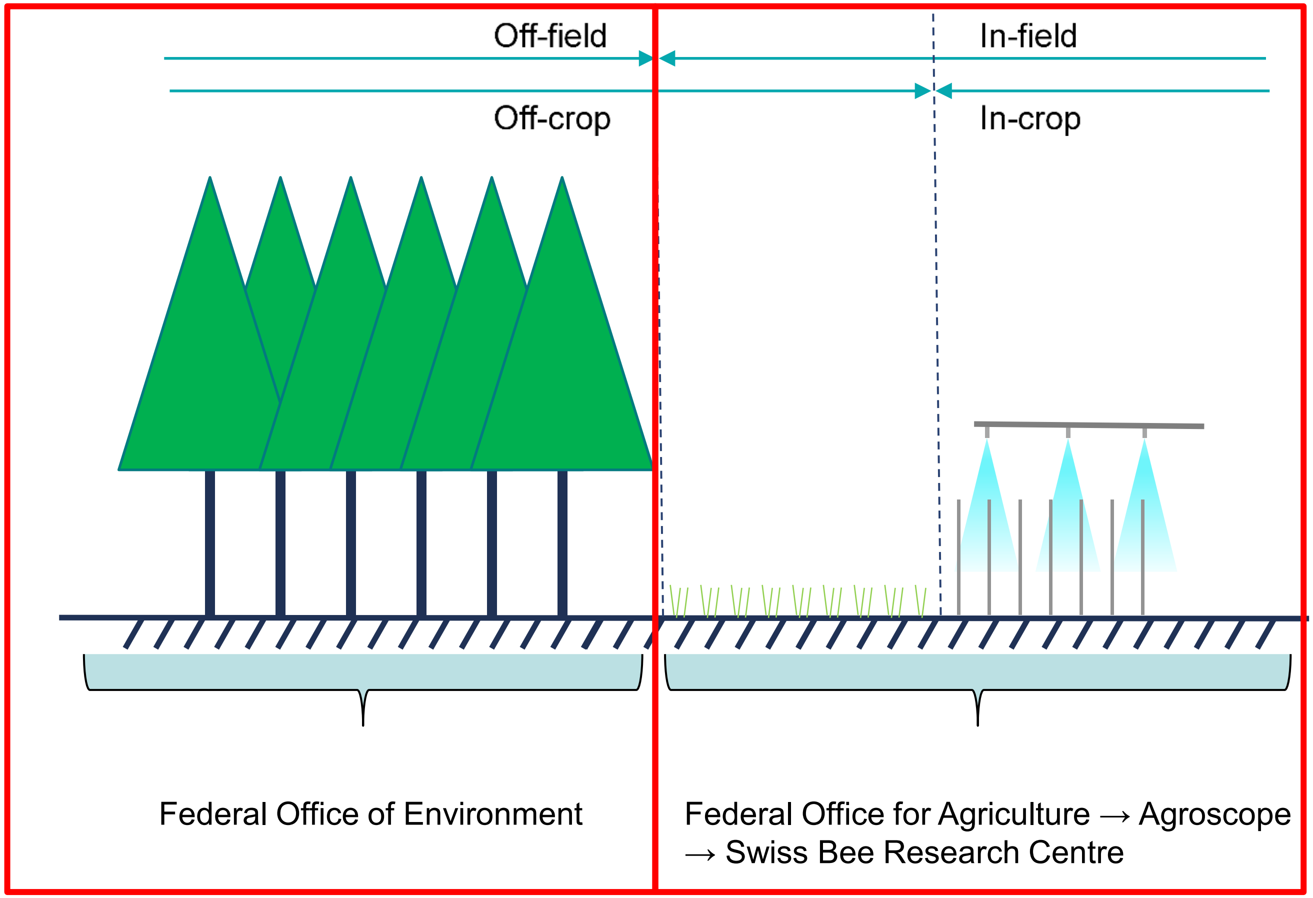
Shared responsibility for bee risk assessment and management in Switzerland



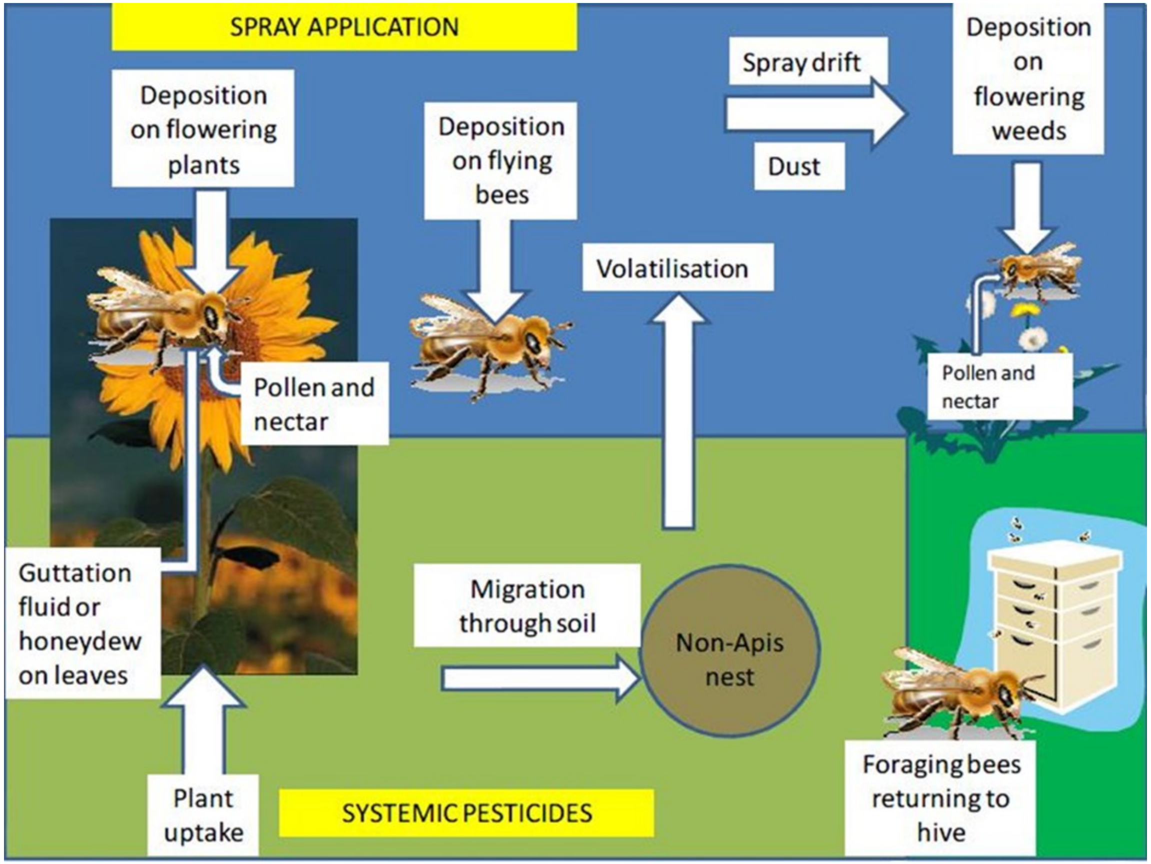
Ordinance concerning the placing of plant protection products on the market

- Swiss plant protection product ordinance (SR 916.161) refers to the European Regulation 1107/2009 with the corresponding Annexes EU 283/2013 (AS) - 284/2013 (PPP)

- Current bee risk assessment scheme in Switzerland:
  - Combination of Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002),
  - European plant protection organization (EPPO 170 (4))
  - EFSA Bee guidance document (2013)
  - Stepwise approach from laboratory (lower tier) to semi-field to field (higher tier).

Risk for bumble bees and solitary bees are currently covered by the honey bee risk assessment scheme

Exposure scenarios considered in the risk assessment of PPPs for bees



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Bee toxicity data requirement for PPP registration in Switzerland

Effect data	Methode	AS	Formulation	Metabolites
Honey bee adult acute oral/contact	OECD 213/214	**Always**	**Always**	Triggered
Honey bee adult chronic	OECD 245[1]	**Always**	**Always**	Triggered
Honey bee larval development	OECD 239[1]	**Always**	Triggered	Triggered
Honey bee sub-lethal effects	OECD 332	Triggered	Triggered	Triggered
Bumble bee adult acute oral/contact	OECD 247/246	**Always**	Triggered	Triggered
Solitary bee adult acute oral/contact	Method validation ongoing	N.A.	N.A.	N.A.
Options for refinement:				
Higher-tier testing	OECD 75 (revised 2024) EPPO PP 1/170 (4) Oomen-deRuijter 1992 Residues (SANTE/11956/2016 rev.9)	no	yes	no






[1]data requirement for microbials (PPPs)






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Calculating the risk of PPPs to bees according to SANCO and EPPO

- <u>Hazard quotient calculation (HQ):</u>

$$HQ_{oral/contact} = \frac{Application\ rate}{LD_{50}}$$

Where:

- Application rate: Is the maximum single application rate expressed in g a.s./ha or g product/ha
- LD_{50}: Derived from oral and contact acute toxicity tests, respectively, expressed in µg a.s./bee or µg product/bee
- The risk is considered to be acceptable if oral and contact **HQ < 50**

- <u>Toxicity exposure ratio calculation (TER):</u>

$$TER_{oral} = \frac{NOED\ \ \mu g\ a.s./\ bee}{\mu g\ residue/kg(nectar\ or\ pollen)}$$

Where:

- No observed effect dose (NOED): Derived from oral chronic toxicity tests (adult or larvae), respectively, expressed in µg a.s./bee or µg product/bee
- Max. residues (µg a.s./kg matrices): Is the maximum concentration of residues that may be ingested by a bee in one day
- The risk is considered to be acceptable if **TER ≥ 10** (generic values) or **TER ≥ 1** (measured residue values)

Calculating the risk of PPPs to bees according to EFSA (2013)

Contact risk:

$$HQ_{contact} = \frac{AR \times \left(\frac{f_{dep}}{100}\right)}{LD_{50,contact}}$$

HQ = Hazard Quotient,
f_{dep} = deposition factor (values in EFSA GD, appendix x)

Oral risk:

$$oral\ ETR_{acute/chronic} = \frac{ERC_{acute/chronic}}{Endpoint}$$

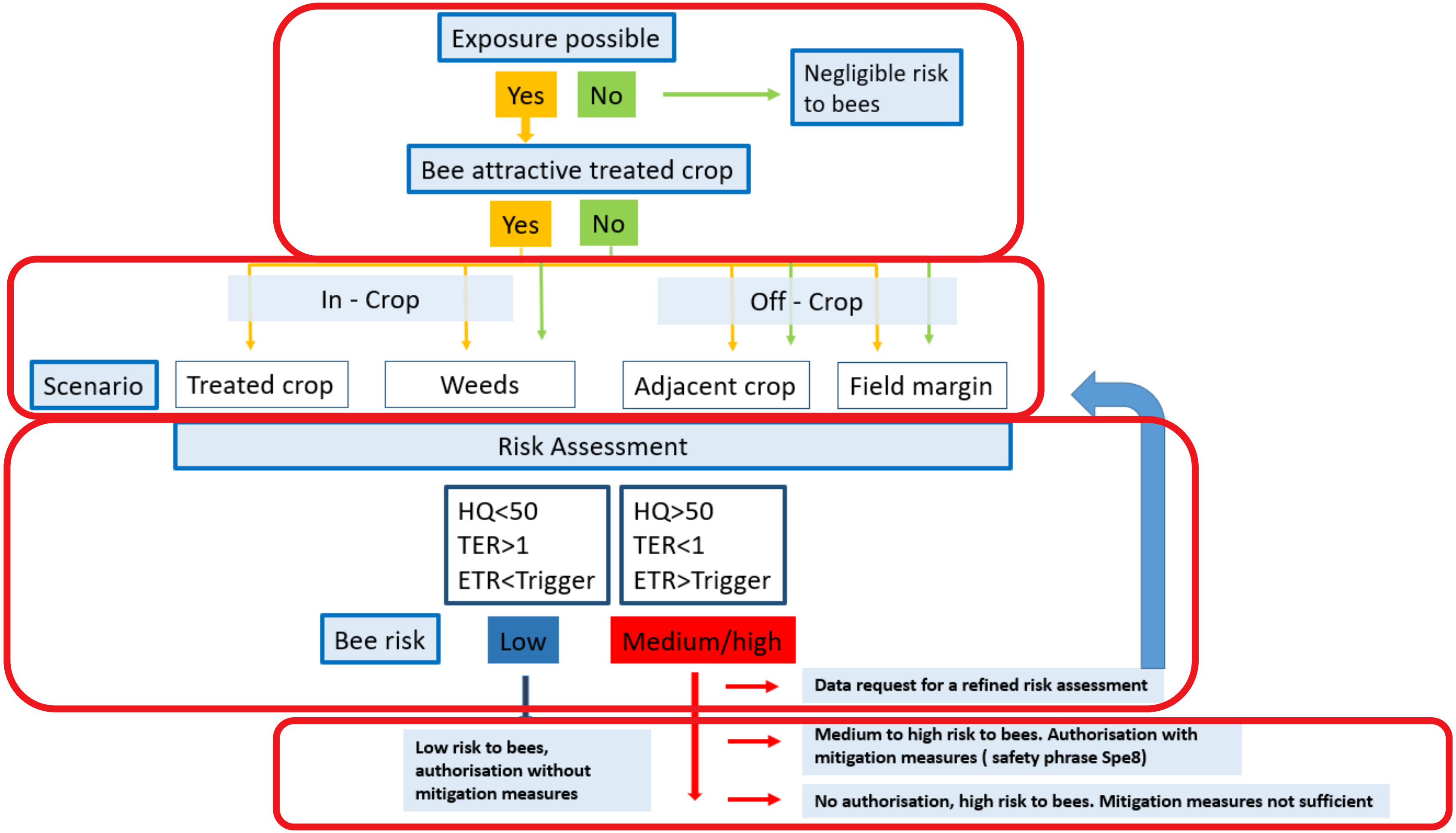
ETR = Exposure Toxicity Ratio,
ERC = ecotoxicologically relevant concentration

Trigger values:

Scenario	Honeybees	Bumblebees[1]	Solitary bees[1]
Acute adult contact toxicity	>42^{dw} / >85^{suw} / >14^{sol}	>7^{dw} / >14^{suw} / >2.3^{sol}	>8^{dw} / >16^{suw} / >2.6^{sol}
Acute adult oral toxicity	>0.2	>0.036	>0.04
Chronic adult oral toxicity	>0.03	>0.0048	>0.0054
Chronic adult sub-lethal effects	>1	-	-
Larva toxicity	>0.2	>0.2	>0.2

- [1] If the honeybee endpoint is used as a surrogate in the assessment of bumblebees and solitary bees then divide the endpoint by assessment factor of 10

Swiss bee risk assessment scheme



Risk assessment scheme using hazard quotient (HQ), toxicity-exposure ratio (TER) and exposure-toxicity ratio (ETR) with corresponding risk factors and risk decisions (L. Jeker)

Published:
Data Requirements and Method Development of a New Bee Risk Assessment Scheme for Plant Protection Product Registration / L.Jeker, D. Grossar 2020 /
DOI: https://doi.org/10.2533/chimia.2020.176

Risk mitigation safety phrases (SPe8)

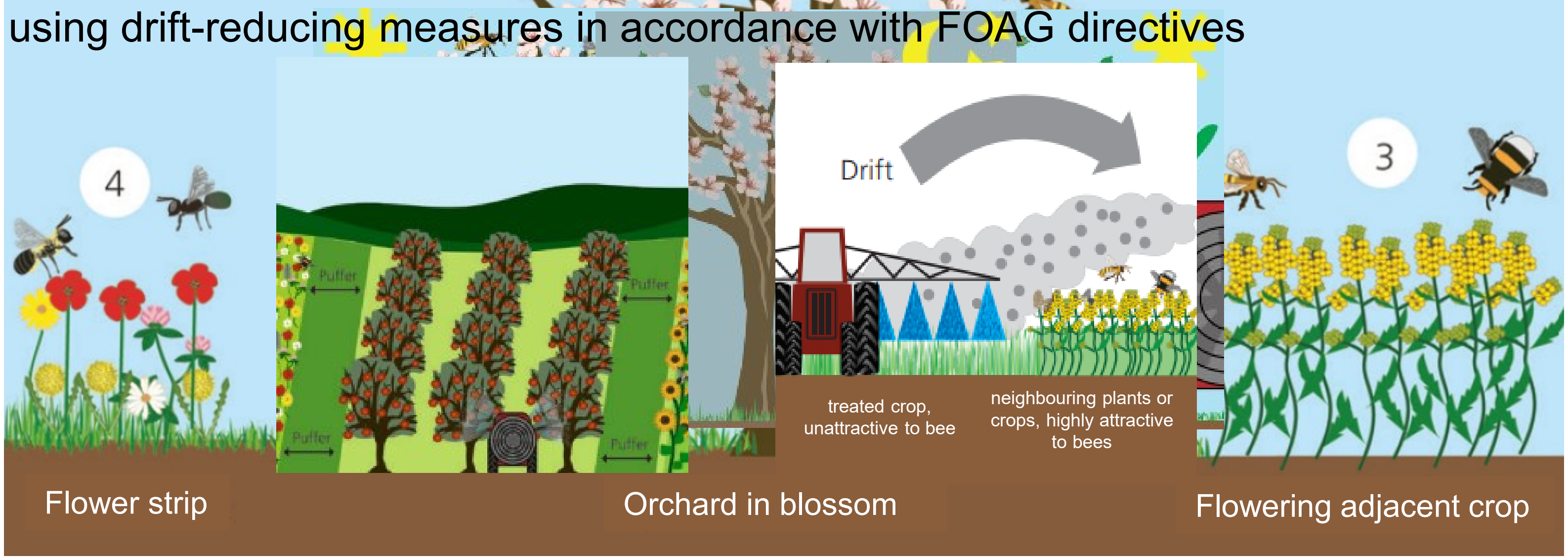
in-crop

off-crop

SPe 8: Dangerous for bees - Must only be applied to flowering plants or plants with honeydew outside of the bee flight in the evening

SPe 8: Dangerous for bees - Remove flowering weeds before treatment (mowing or mulch).

SPe 8: Dangerous for bees - Must not come into contact with flowering plants in neighbouring plots. Maintain an untreated buffer zone of 3, 6, 20 or 50 m from flowering plants in neighbouring plots. This distance can be reduced when using drift-reducing measures in accordance with FOAG directives



1: exposure on treated crop
2: exposure on weeds below the treated crop

3: exposure on flowering adjacent crop
4: exposure on flowering flower strip

Cooperation: Agridea, FOAG and Swiss bee research center 2018

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Trap or haven: Assessing the spray drift deposition of insecticides into flower-strips ?

- Increased demand of **Spinosad, Acetamiprid Pyrethroids** as alternative for neonicotinoids

- The Federal Office for Agriculture financially supports the cultivation of flower strips in agriculture in order to promote biodiversity in farmland

- Recent bee poisoning incidence with **Spinosad**

- Are current mitigation measures sufficient to adequately safeguard wild and managed bees in non-treated off-crop areas (e.g., flower-strips)?

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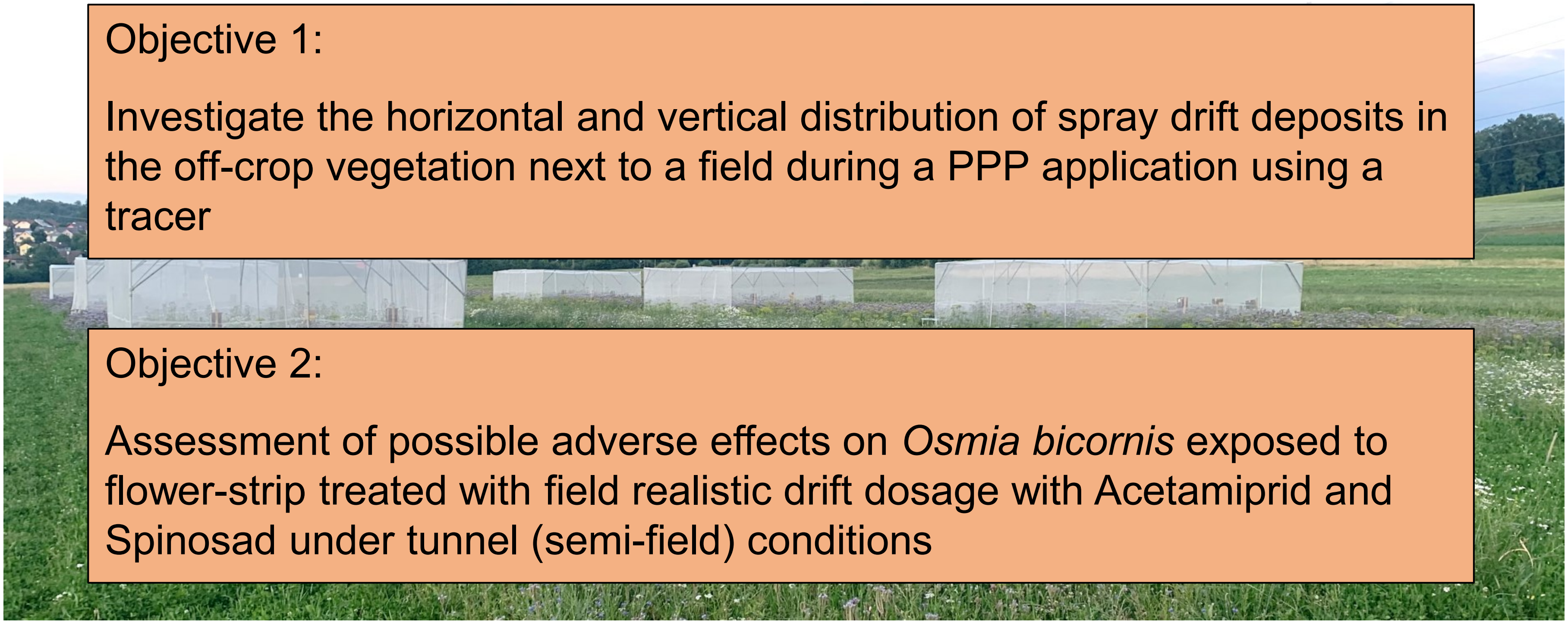
Risk assessment for bees: Spray drift into flower-strips

Objectives



Objective 1:

Investigate the horizontal and vertical distribution of spray drift deposits in the off-crop vegetation next to a field during a PPP application using a tracer

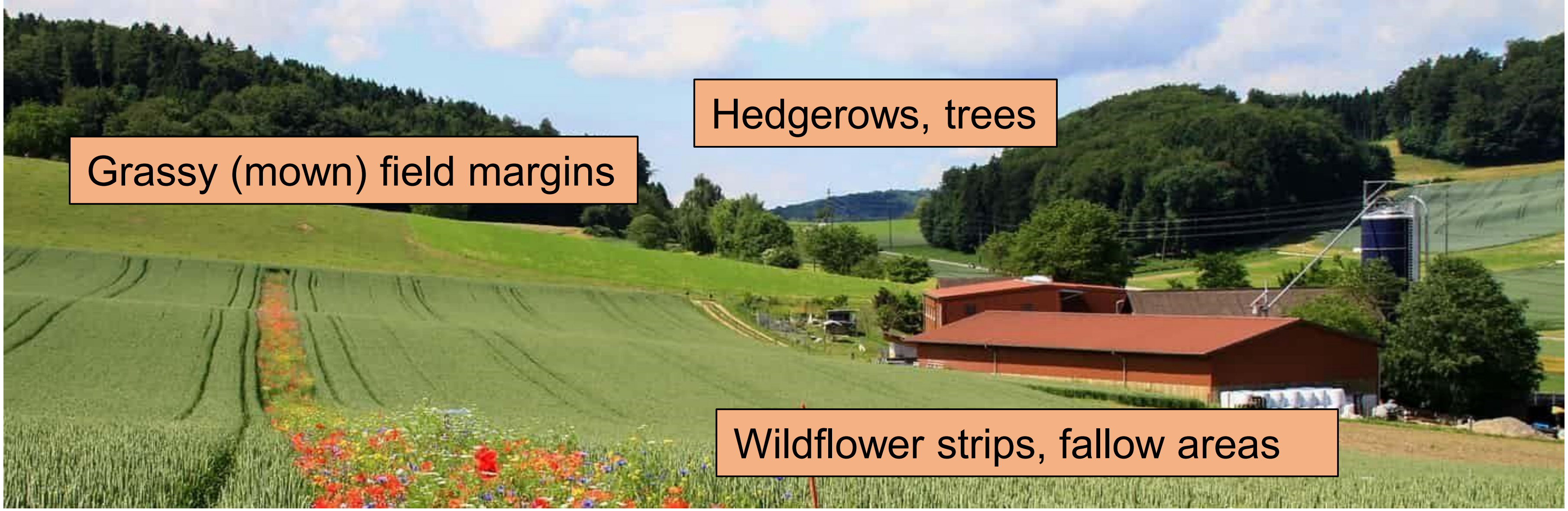
Objective 2:

Assessment of possible adverse effects on *Osmia bicornis* exposed to flower-strip treated with field realistic drift dosage with Acetamiprid and Spinosad under tunnel (semi-field) conditions

Risk assessment for bees: Spray drift into flower-strips

Introduction

Flower strips – biodiversity promotion in Switzerland



Wildflower strips, which are very close to the crops, or even within the crops → are prone to get in contact with drift of PPPs used to treat adjacent crops

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Risk assessment for bees: Spray drift into flower-strips

Flower-strip

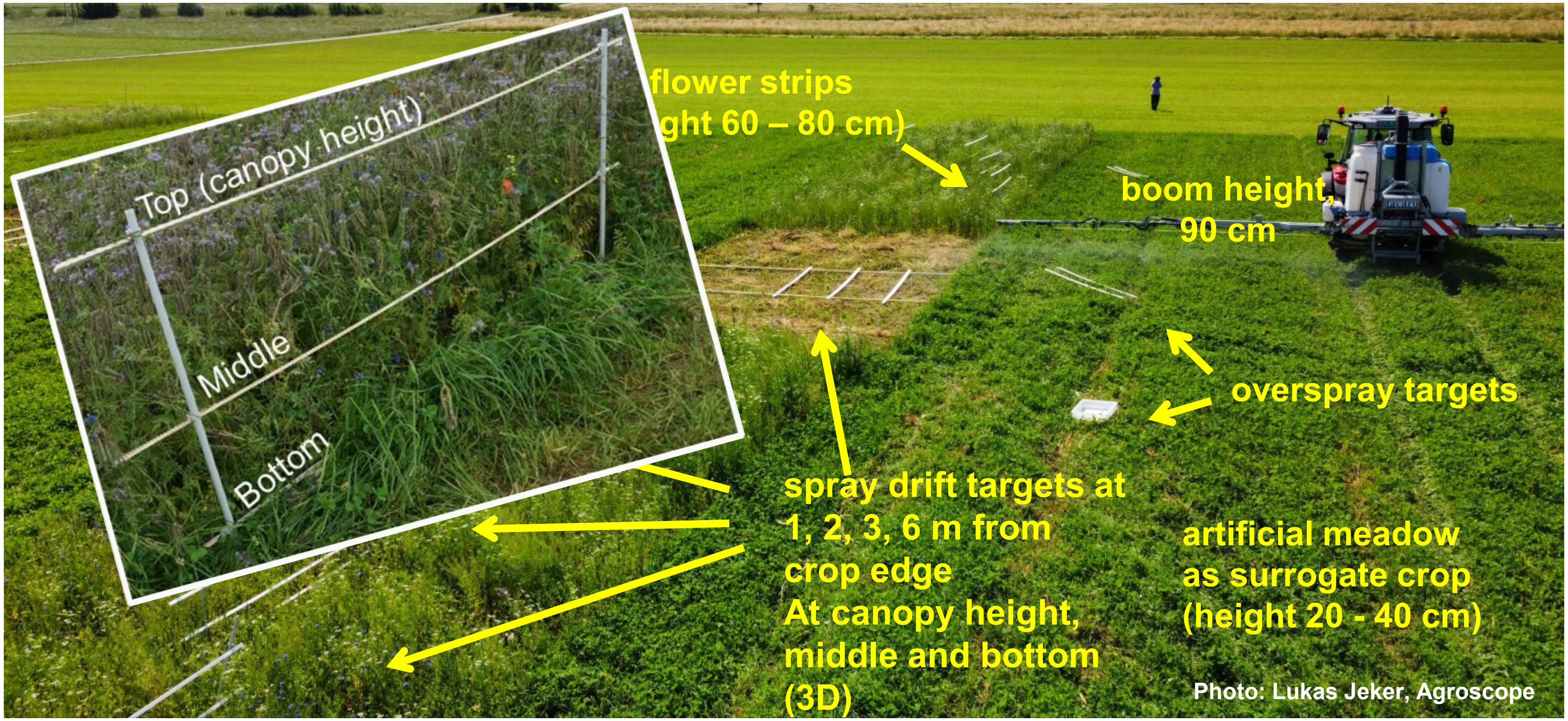
- Provide habitat and resources for biodiversity

Risk assessment for bees: Spray drift into flower-strips

Objective 1 (2022): Experimental setup

Risk assessment for bees: Spray drift into flower-strips

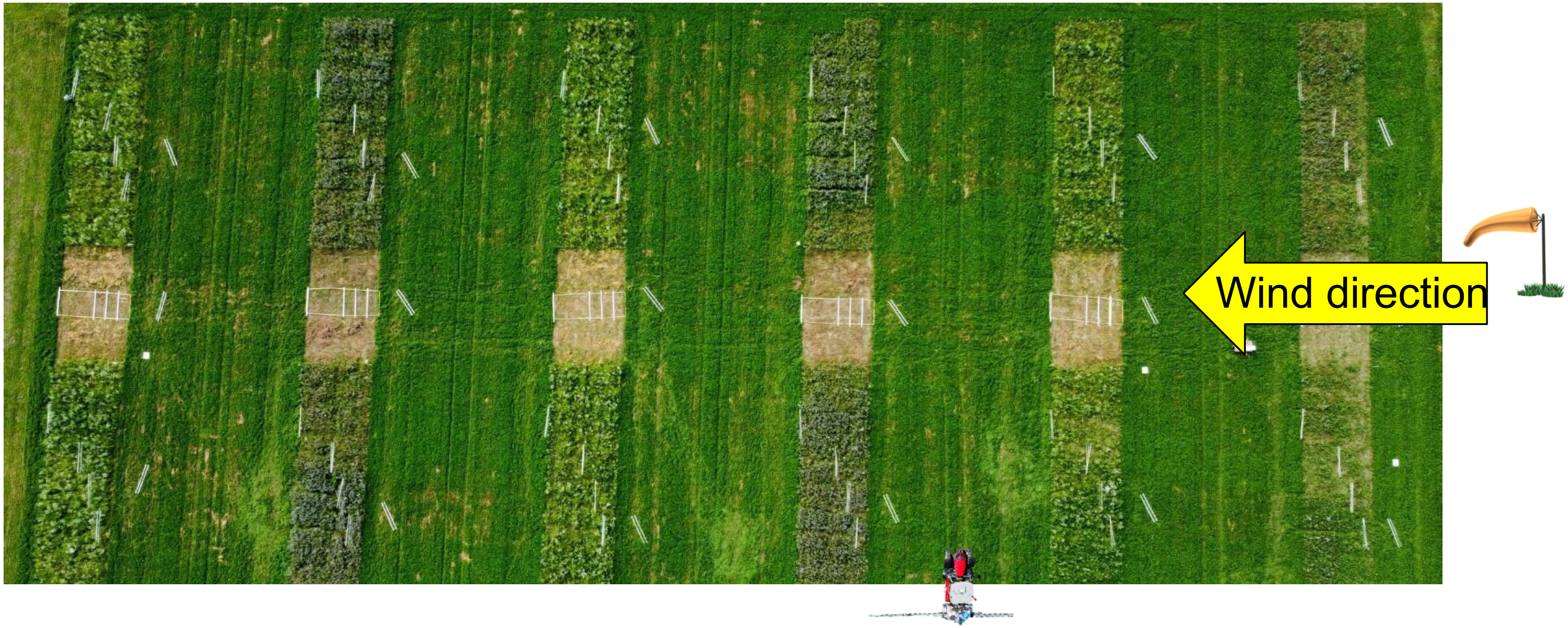
Objective 1 (2022): Experimental setup



Risk assessment for bees: Spray drift into flower-strips

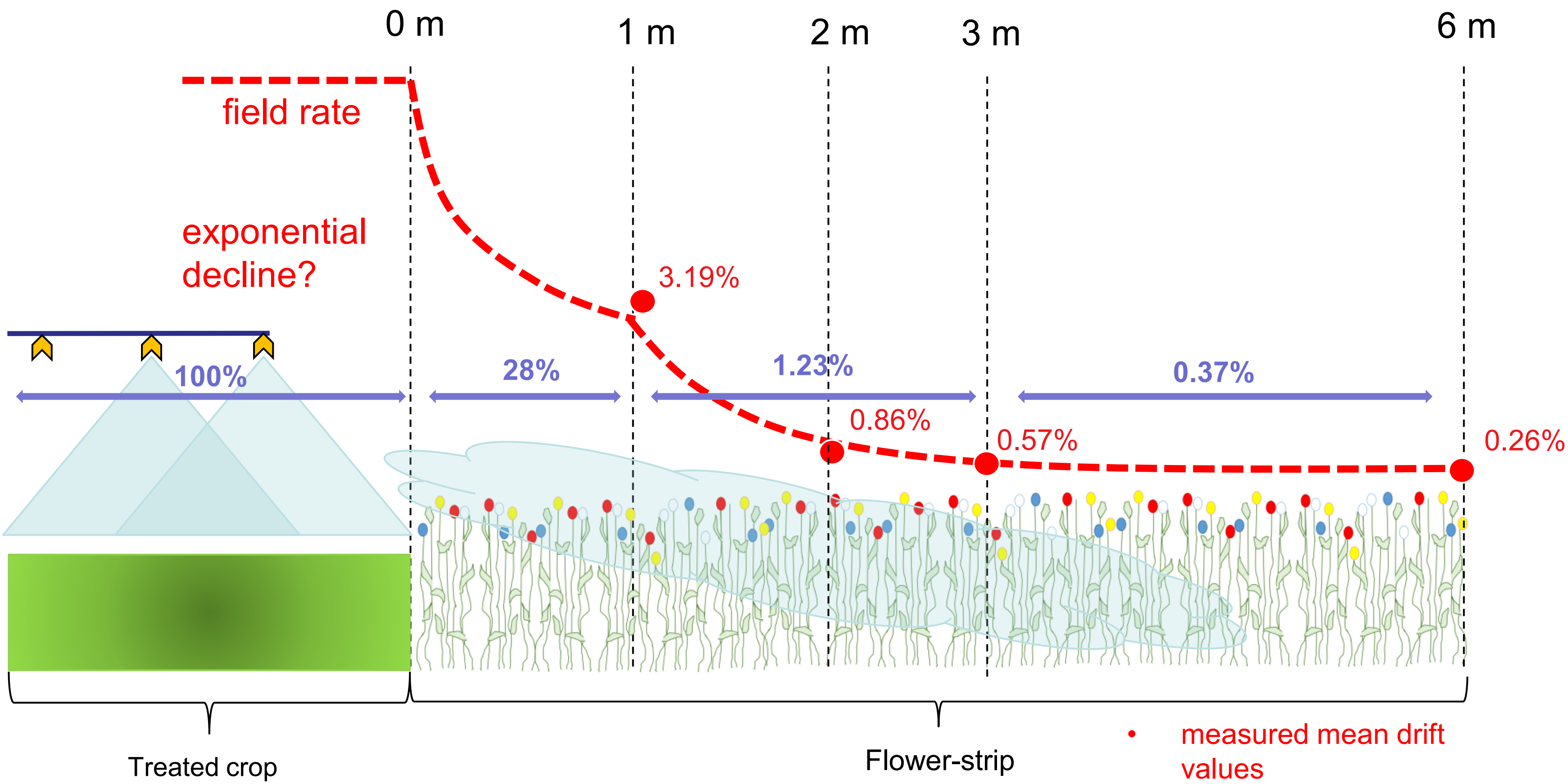
Objective 1 (2022): Experimental setup

3 days, 2 repetitions per day, 1400 targets (2/3 valid)
Tracer (Fluorescent marker)



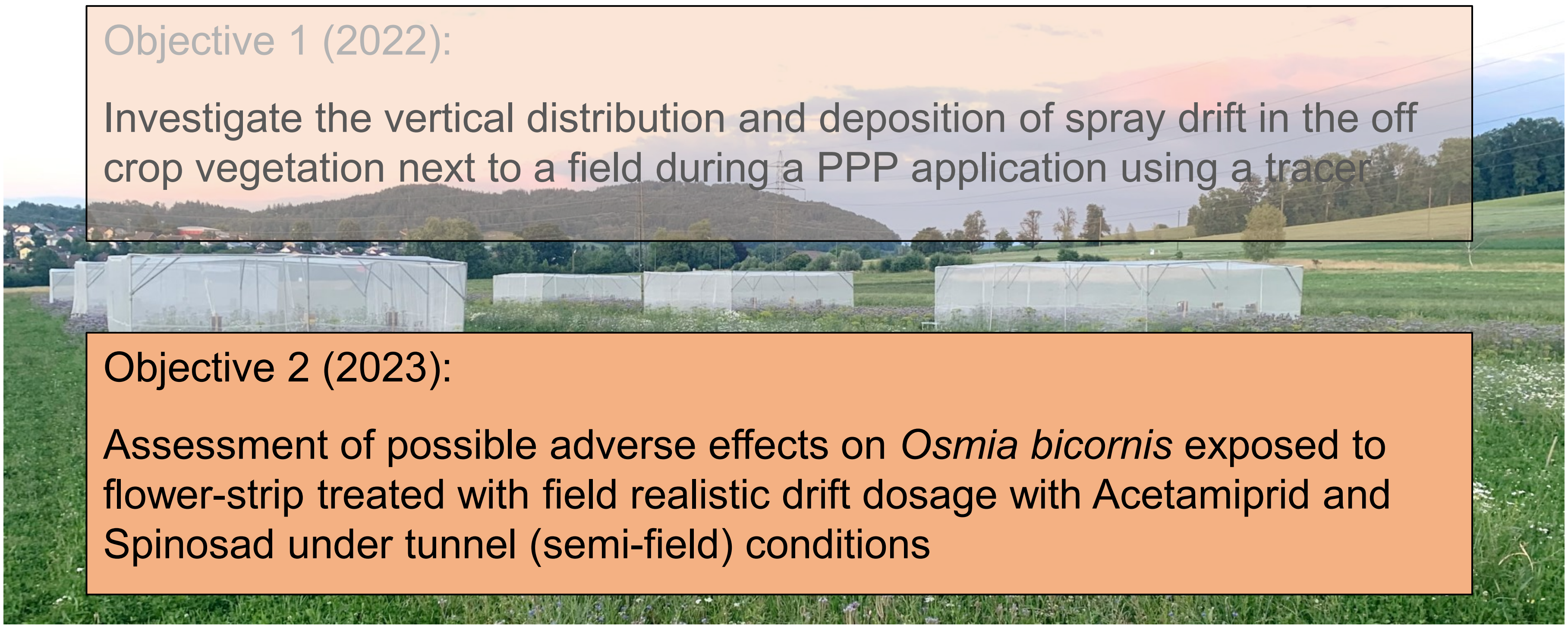
Risk assessment for bees: Spray drift into flower-strips

Objective 1 (2022): Results – Drift gradient concentration in flower-strip



Risk assessment for bees: Spray drift into flower-strips

Objectives



Objective 1 (2022):

Investigate the vertical distribution and deposition of spray drift in the off crop vegetation next to a field during a PPP application using a tracer

Objective 2 (2023):

Assessment of possible adverse effects on *Osmia bicornis* exposed to flower-strip treated with field realistic drift dosage with Acetamiprid and Spinosad under tunnel (semi-field) conditions

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Risk assessment for bees: Spray drift into flower-strips

Tested Insecticides

Acetamiprid (40 g a.s./ha)

is a systemic insecticide from the active substance group of neonicotinoids

Field of application: Vegetables, orchard, berries, field crops and ornamentals

Acute toxicity (oral/contact) for honey bees is LD50: **8.85 / 9.26** µg/bee.

Therefore classified as low toxic to honey bees

Spinosad (90 g a.s./ha)

is a broad-spectrum contact and oral insecticide derived from the bacterium *Saccharopolyspora spinosa* and is authorised for use in organic farming

Field of application: Vegetables, orchard, berries, field crops and ornamentals

Acute toxicity (oral/contact) for honey bees is LD_{50} **0.060** / **0.045** µg/bee

According to higher-Tier studies, spinosad is considered to be less toxic to bees at 76-96 g a.s./ha if the product is applied after bee flight and honey bees (*Apis mellifera*) are thus exposed to dry residues (spinosad) after treatment.

Therefore classified as highly toxic to bees
*bee protection based on honey bee toxicity data

No risk mitigation measures applied (SPe8)

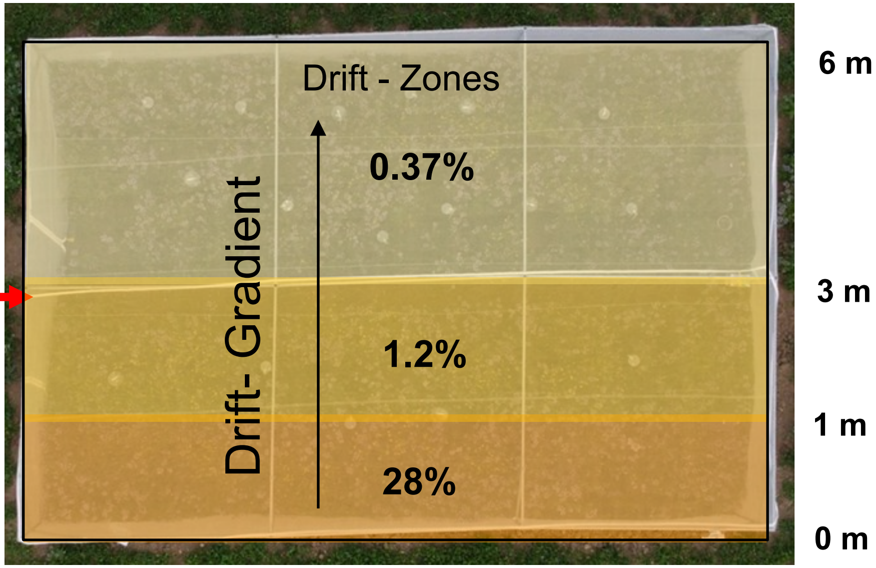
Risk mitigation measures must be applied (SPe8) to reduce risk to bees

Risk assessment for bees: Spray drift into flower-strips

Objective 2 (2023): Experimental (tunnel) setup with *Osmia*

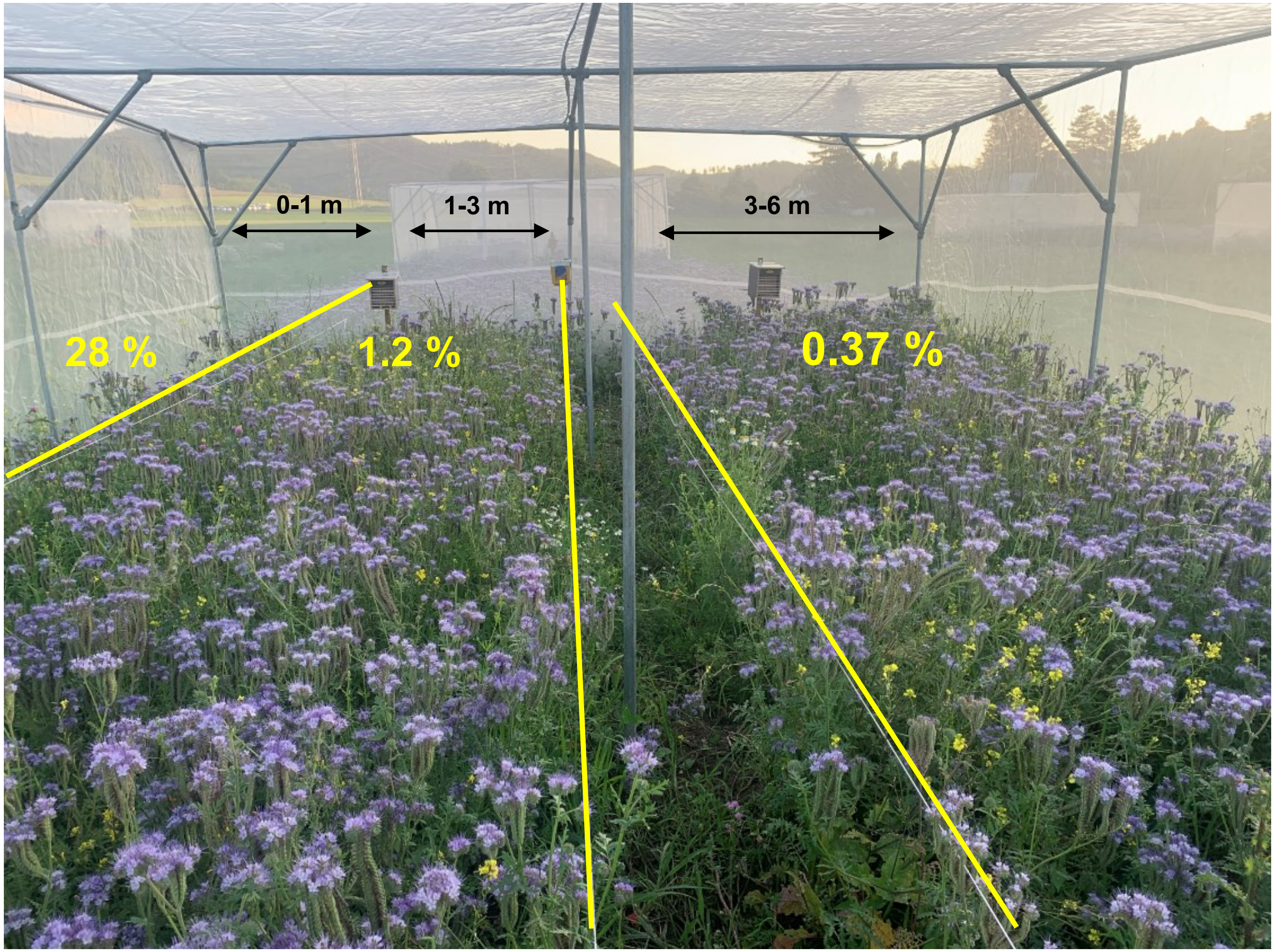
- 3 flower strips → replicates
- 9 randomized tunnels 54 m^2 (6 x 9 x 2.5 m)
- Artificial meadow and strips with different seed mixture in between
- 3 tunnels per treatment (Untreated Control, Acetamiprid and Spinosad)
- Gradient treatment for Acetamiprid and Spinosad

% Drift Rate	Acetamiprid (PPP Gazelle SG, 0.2 kg/ha)	Spinosad (PPP Audienz 0.19 L/ha)
100% (Field rate)	**40 g a.s./ha**	**90 g a.s./ha**
0.37%	**0.148** g a.s./ha	**0.33** g a.s./ha
1.2%	**0.48** g a.s./ha	**1.08** g a.s./ha
28%	**11.2** g a.s./ha	**25.2** g a.s./ha



Risk assessment for bees: Spray drift into flower-strips

Objective 2 (2023): Designated drift areas within tunnel



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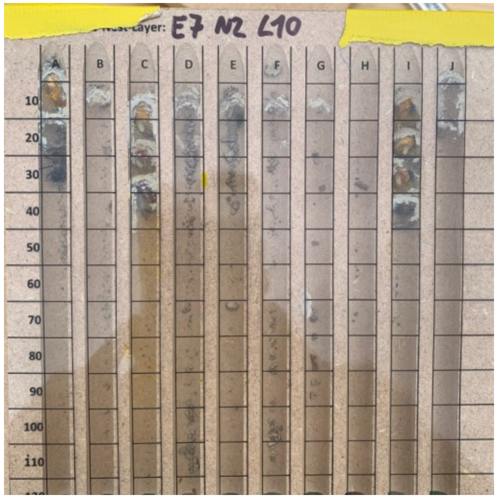
Risk assessment for bees: Spray drift into flower-strips

Objective 2 (2023): Test species *Osmia bicornis* and its nesting units



10 cavities / wooden plate

10 wooden plates / nesting unit

2 nesting units / tunnel

<u>Osmia nesting unit:</u>

- Consisting of ten wooden plates each offering ten nesting cavities 100 nesting cavities per nesting unit
- Per tunnel two nesting units one for reproduction assessment and one for residue analysis

Risk assessment for bees: Spray drift into flower-strips

Objective 2 (2023): Test species *Osmia bicornis* and nesting units

Introduction of synchronized newly emerged *Osmia bicornis* (**65** females and **100** males) **10 days prior** to treatment application or at DAT -10 (Days after treatment)

Density 1.2 nesting female/m^2

ICPPR non-*Apis* working group Franke et al., 2021

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Risk assessment for bees: Spray drift into flower-strips

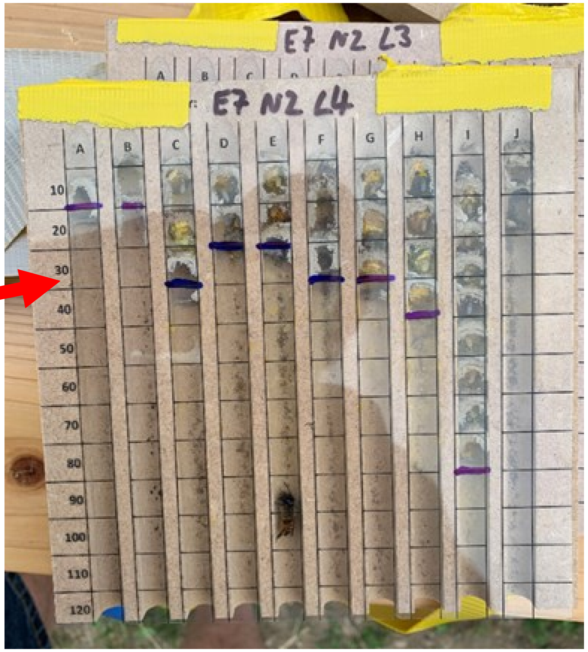
Objective 2 (2023): Application SPe8 after bee flight and after sunset

Risk assessment for bees: Spray drift into flower-strips

Objective 2 (2023): Assessment and Sampling in the Field

- **DAT 0, 1, 3 and 7**: Assessment: Established provisions and presence of female in nesting unit
- **DAT 7:** Removal of one *Osmia bicornis* nest for residue analysis
- **DAT 14, 21, 30 and 41:** Further monitoring of development of *O. bicornis* larvae/offspring within the nesting units

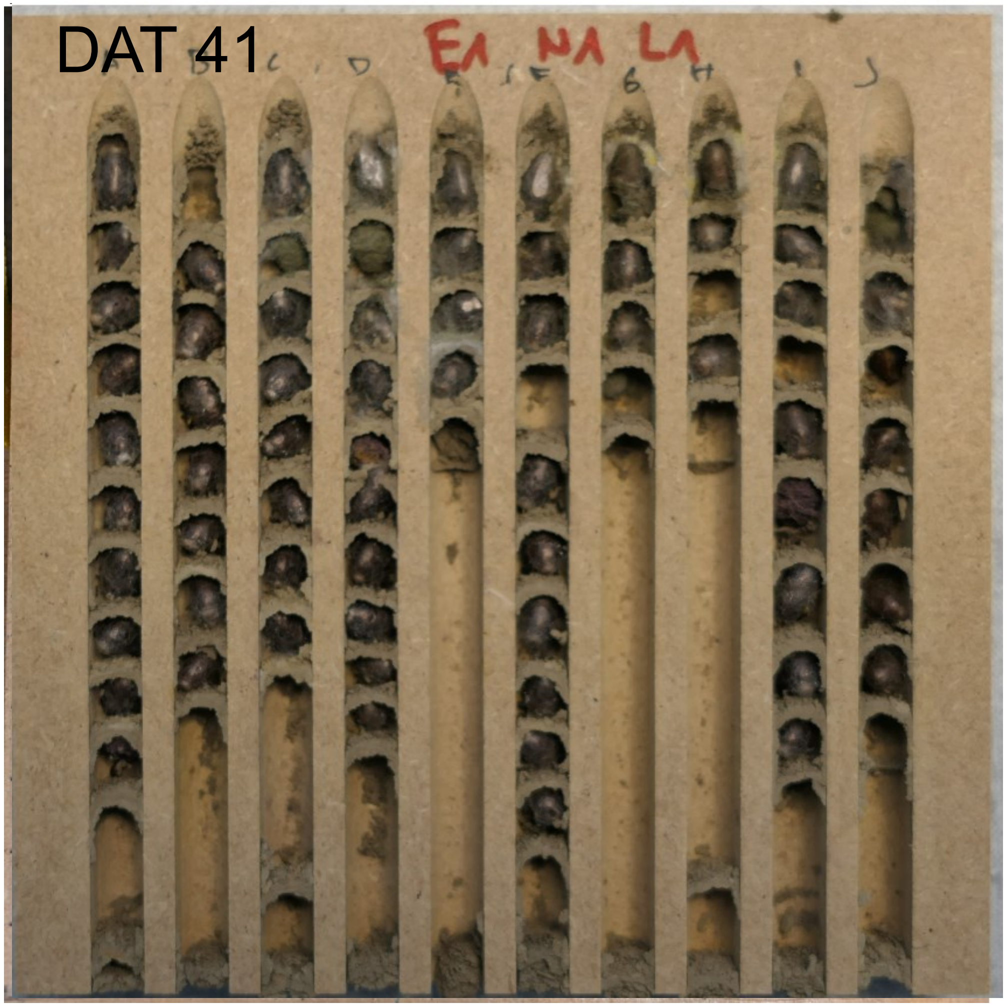
Daily marking and photo shooting of each nest layer (new provisions) and females



Nesting cavities covered with acetate sheet: Marking of new pollen provisions and assessment of *O. bicornis* females

Risk assessment for bees: Spray drift into flower-strips

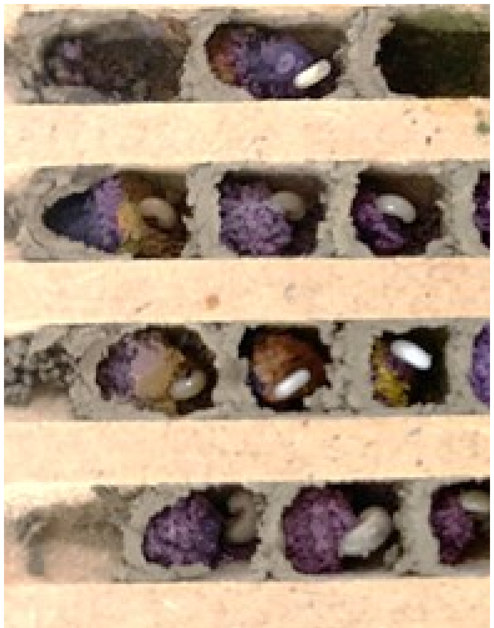
Objective 2 (2023): Brood development assessment



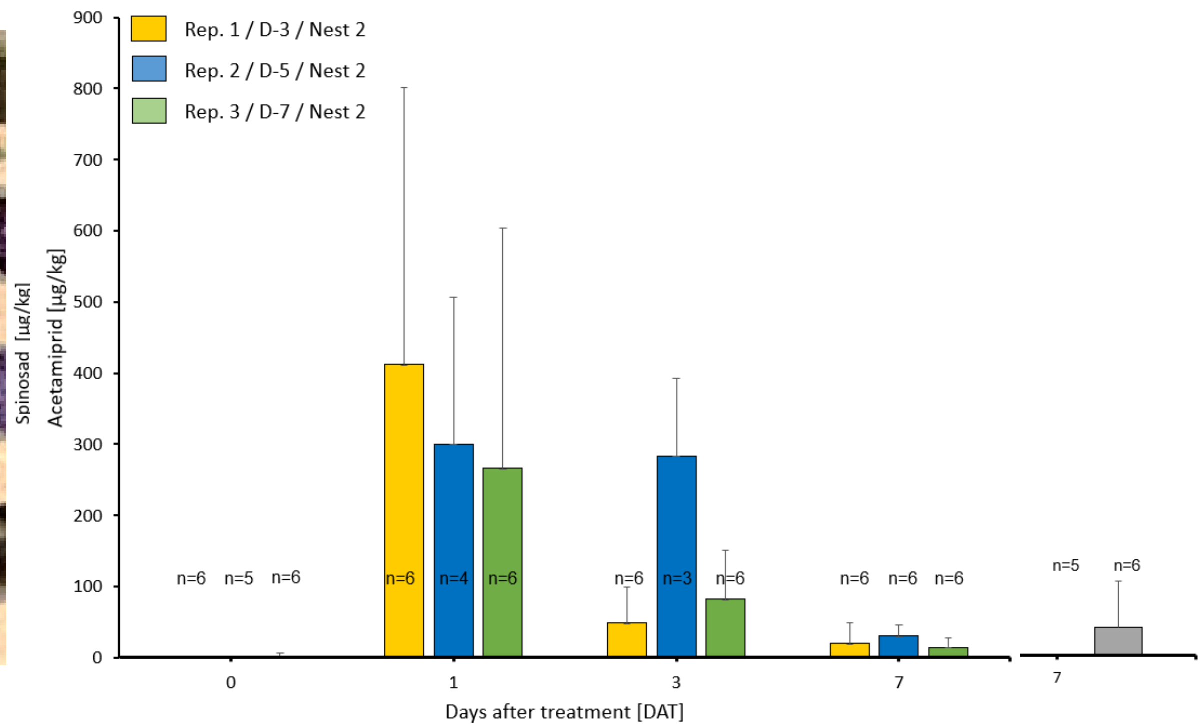
Risk assessment for bees: Spray drift into flower-strips

Results: Residues in pollen provisions

Pollen provision (*O. bicornis*)



Acetamiprid
Spinosad



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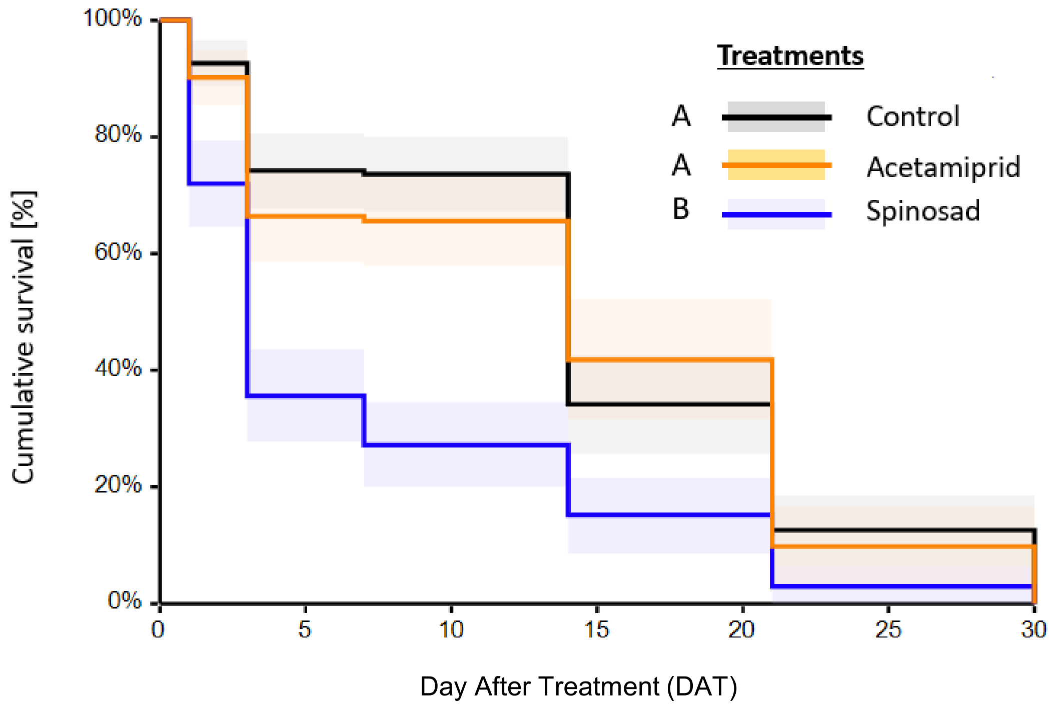
Risk assessment for bees: Spray drift into flower-strips

Results: Survival adult females / presence in nesting units

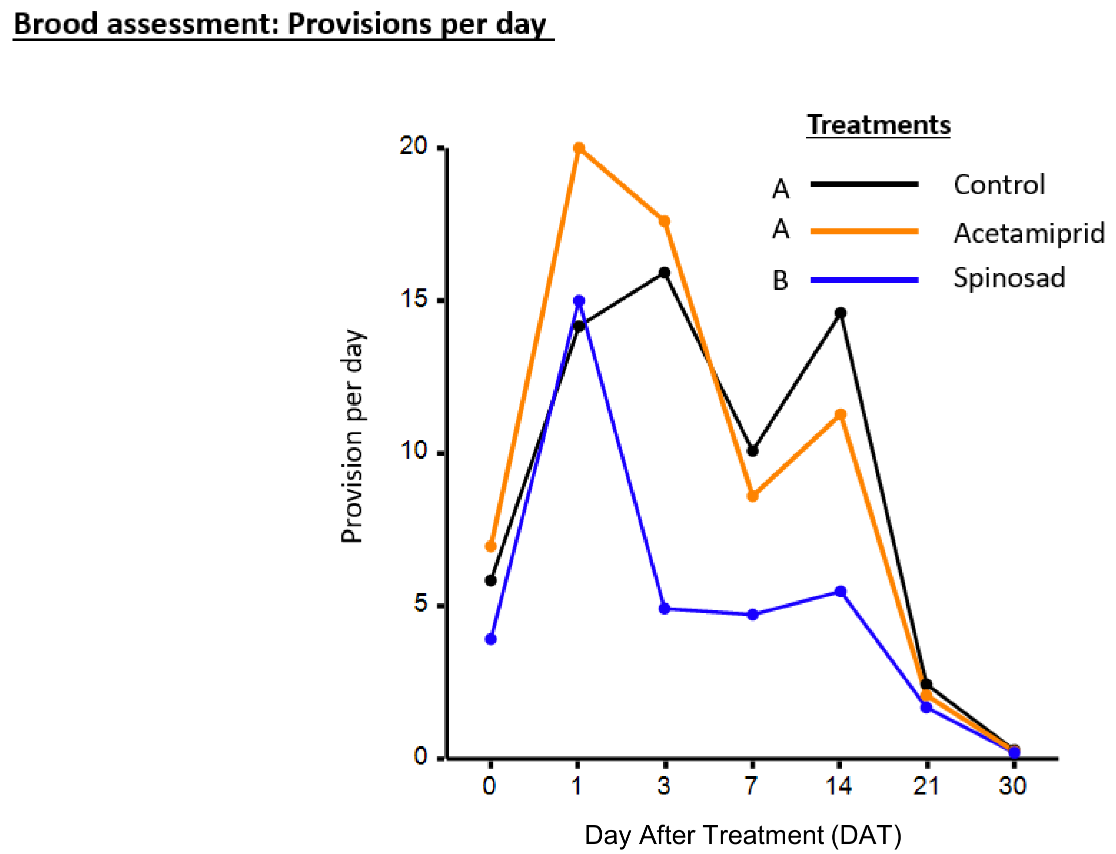
Survival adult females



Cox-regression with Bonferroni corrections: Letters indicate significant differences (i.e., $p < 0.01$).

Risk assessment for bees: Spray drift into flower-strips

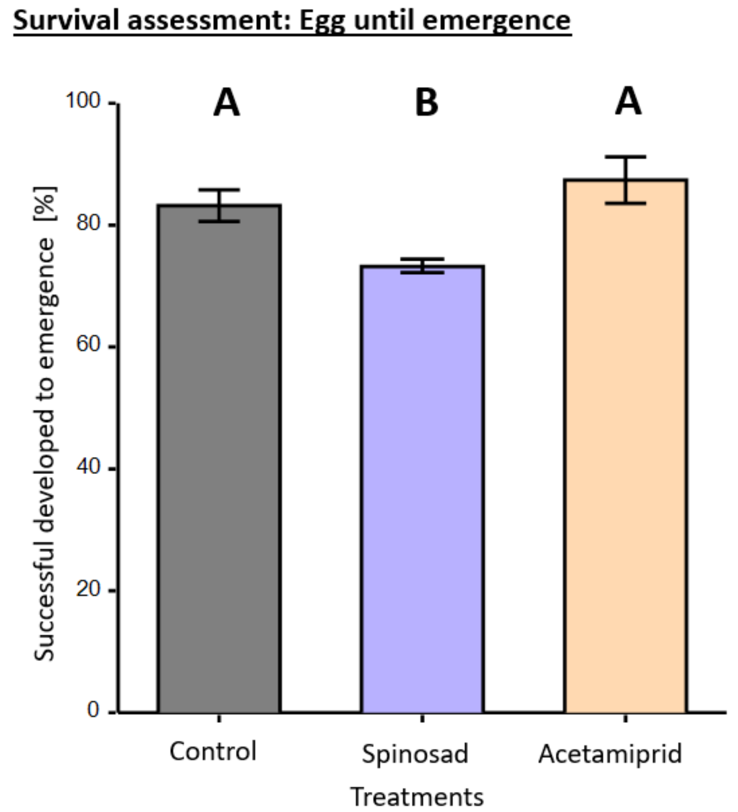
Results: Reproduction / Provisions per day



Generalized linear regression mixed model (GLMM); Letters indicate significant differences (i.e., $p < 0.05$)

Risk assessment for bees: Spray drift into flower-strips

Results: Successful brood development / egg to emergence



GLMM with Bonferroni corrections; Letters indicate significant differences (i.e., $p < 0.05$)

Risk assessment for bees: Spray drift into flower-strips

Conclusion

Spinosad treatment: Female survival, reproduction performance and brood development statistically significantly reduced

Acetamiprid showed no adverse effects

Measured drift deposition in vegetation 3-D compared to 2-D values: Vegetation dilution factor (vdf) 1.5 (top), 3.0 (middle), 8.0 (bottom)

Based on our data and available honey bee data, the SPe8 mitigation measure for Spinosad (night application, after bee flight) is not sufficiently protective for solitary bees

Buffer zones to adjacent crops/flower strips must be applied

Further studies with non-*Apis* bees are needed to develop and issue sufficient protection measurements for the safe use of Spinosad

Beside the positive aspects (e.g, food source for bees), drift contaminated flower-strips can also adversely affect bees

A detailed publication of our data is in preparation

Overview

- Description of Agroscope and the Swiss Bee Research Centre
- Bee risk assessment system for plant protection product (PPP) registration in Switzerland
- PPP issues related to bees in Switzerland
- Current challenges in bee risk assessment e.g. revision of the EFSA bee guidance document
- Regulatory status of neonicotinoid PPPs in Switzerland

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New revised EFSA bee guidance document 2023

A brief history: Evolution of bee risk assessment in Europe

2002

SANCO Guidance on Terrestrial Ecotoxicology EPPO, 2002

Bees: 2 pages

2013

First EFSA Bee Guidance

≈300 pages

- Not endorsed by a majority of Member States so was never officially noted at EU level
- European Commission mandated EFSA to review it in 2019…

2023

"Revised" EFSA Bee Guidance

74 Documents
≈1600 pages

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New revised EFSA bee guidance document 2023

Overview of major changes since EFSA 2013

- Drinking water assessment no longer required
- Hypopharyngeal gland (HPG) assessment is no longer required
- New specific protection goals
- Updated list of crop attractiveness
- Completely new lower tier risk assessment approach
- Extrapolation factors for non-*Apis* bees
- New assessments for time-reinforced toxicity and sublethal effects
- Tier 2 options for exposure refinement

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New revised EFSA bee guidance document 2023

Specific protection goals (SPGs)

- New specific protection goal (SPG) for honey bees of 10 %
- Undefined threshold approach for setting specific protection goals for both bumble bees and solitary bees

Table 1: Overview of the agreed SPGs for honey bees, bumble bees, solitary bees

Dimensions	Honey bees	Bumble bees	Solitary bees
Ecological Entities	Colony	Colony	Population
Attribute	Colony strength**	Colony strength**	Population abundance
Magnitude*	$\leq$ 10%	Undefined	Undefined
Temporal scale	Any time	Any time	Any time
Spatial scale	Edge of field	Edge of field	Edge of field

*: This was the only dimension reviewed and agreed by risk managers. The definition of the other dimensions was retained as in EFSA (2013). For bumble bees and solitary bees, a defined threshold will be decided by risk managers when more data will become available.
**: Operationalised as colony size reduction.

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Risk assessment – Lower Tier

Specific Protection Goals for wild bees

To proceed at this stage and in the absence of sufficiently robust evidence, with an undefined threshold approach for both bumblebees and solitary bees until further data becomes available and to require by default (in case of potential exposure of bees) field studies on bumblebees and solitary bees unless:

- the lower tier risk assessments for honeybees and non-target arthropods other than bees show no effects for the active substance, or
- semi-field (cage or tunnel studies) with bumblebees and solitary bees show absence of effects.

Furthermore, semi-field or field testing with bumblebees would also not be needed if laboratory studies according to OECD test methods No 246 and 247, show an LD50 > 100 µg active substance/bumblebee.

5

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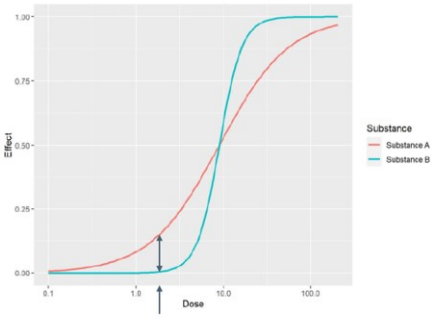
Toxicity endpoints - Lower tier

- In general, no new study types required
- For existing studies statistical re-analysis may be needed, with some different endpoints required for risk assessment and potential to trigger repeat studies to address new requirements
- The new GD stopped relying on point estimates for the hazard characterisation (e.g. LD_{50}, NOED). The newly supported hazard characterisation is the full dose-response



- No specific requirements to conduct laboratory toxicity tests for non-*Apis* bees (but very conservative extrapolation factors from honey bee endpoints)

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Exposure assessment

- Completely different to EFSA 2013 – different short-cut values, parameters, calculations → added complexity
- Now considers multiple applications, and accounts for whether applications are **before** or **during flowering**
  - Pre-flowering factor (PFF) – how many days before flowering (dilution and dissipation considered)
- Same main scenarios as EFSA 2013 - treated crop, weeds in the treated field, field margin, adjacent crop, succeeding / permanent crop [but drinking water, including guttation, no longer required]
- New terminology – "PEQ" predicted exposure quantity and three types of dietary exposure models

Through soil contamination

$$PEQ_{di} = SV_{po,soil} + SV_{ne,soil}$$

Pre-flowering contamination

$$PEQ_{di} = \frac{AR}{1000} EF_{di}\, PFF \left(SV_{po,be} + SV_{ne,be}\right)$$

During flowering contamination

$$PEQ_{di} = \frac{AR}{1000} EF_{di} \left(SV_{po,du} + SV_{ne,du}\right)$$

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Body surface factor (BSF)

- BSF translates the application to bee level
- The bigger the bee the higher the surface the higher the exposure
- For the Risk assessment the smaller the bee the higher the risk
- In HQ values only the PPP application rate per area was considered

$$PEQ_{co} = AR\ EF_{co}\ BSF$$

Where:

PEQ_{co}: Predicted Exposure Quantity for contact exposure - µg/bee

AR: application rate – g/ha

EF_{co}: exposure factor for contact exposure (-)

BSF: body surface factor - dm^2/bee

For Tier 1, PEQ_{co} can routinely be estimated for the 5^{th}% small bumble bee and solitary bee species.

Category for the risk assessment	Representative species	Bsf (dm^2/bee)
Honey bee	*Apis mellifera*	0.0114
Bumble bee	5th percentile (by body surface) bumble bee species	0.0146
Solitary bee	5th percentile (by body surface) solitary bee species	0.00184

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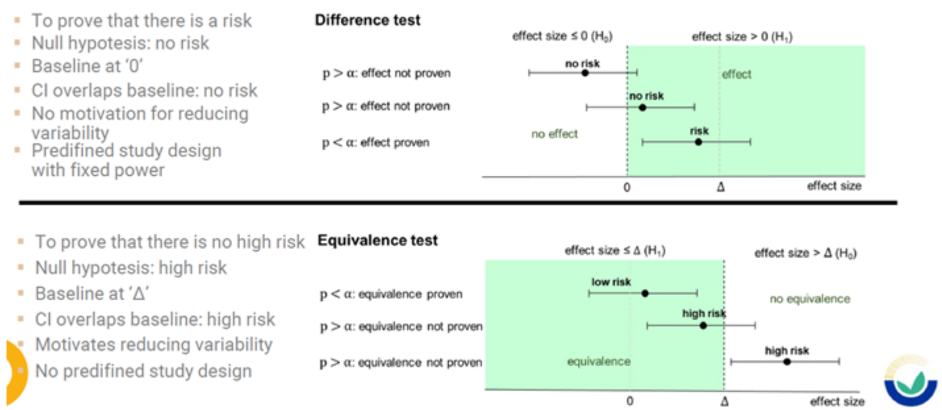
New revised EFSA bee guidance document 2023

Equivalence test - Statistical paradigm

<u>EFSA BG 2013:</u>

- General Difference test: Treated group compared with a control group. Aim is to prove that there is a risk / statistical significant difference



<u>EFSA BG 2023:</u>

- The equivalence test is the opposite approach. The aim is to prove that there is no risk for bees due to the application of a PPP. It needs to demonstrate that the two treated groups are equivalent to the untreated group is

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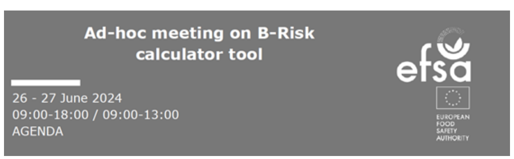
Key improvements since EFSA 2013

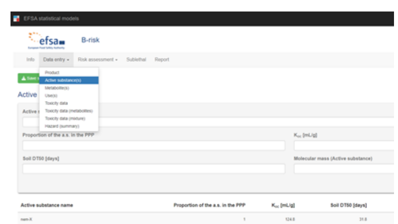
- More realistic quantification of exposure for honey bees (winter/summer bees)
- More realistic values for food intake for adult bees
- Better estimation of pesticide residues and their behaviour in pollen and nectar
- Chronic oral exposure assessment is more realistic
- Drinking water/guttation assessment no longer required (negligible exposure route)
- Updated list of crop attractiveness
- Revised succeeding crop assessment (persistence and toxicity considered)
- Revised metabolite risk assessment (toxicity included in determination of triggers)

New revised EFSA bee guidance document 2023

Conclusion - Key challenges

- Increased complexity at all tiers
- At the lower tier individual effects from lab studies are translated 1:1 to colony level effects and risk cases (acute contact/oral, chronic, larvae) are combined
- Expected that higher tier studies (including field studies) will be triggered more often, but practical study designs still challenging (not even feasible?)
- Uncertainty in how to best address the risk assessment for non-*Apis* bees
- B-Risk calculator, beta testing currently on-going





B-risk

Bees Risk Calculator

New revised EFSA bee guidance document 2023

Info session new EFSA bee guidance document

Recording

[Online info session on bee guidance document (youtube.com)]<

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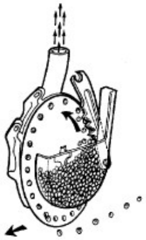
Regulatory status of Neonicotinoids in Switzerland

A brief review: 2008, Bee poisoning incidence in southern Germany

What has happend:

- Compulsory control against *Diabrotica virgifera* (eradication)
- Corn seed treatment (coating) with Poncho Pro® (Clothianidin) was of poor quality

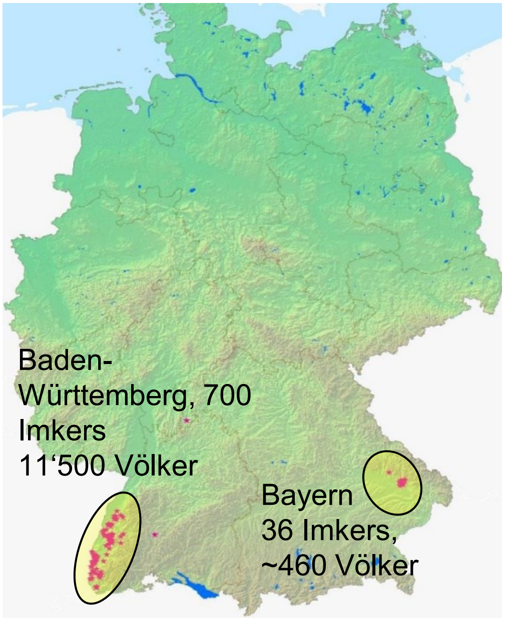


During drilling:

➔ poor coating quality ➔ use of pneumatic sowing machines ➔ resulted in high dust formation

➔ late seasonal treatment and windy conditions ➔ increased drift deposition into adjacent crops (oilseed rape and orchards) in full flower

➔ Clothianidin residues on bees and bee matrices (pollen nectar, bread), poisoned 12174 honey bee colonies



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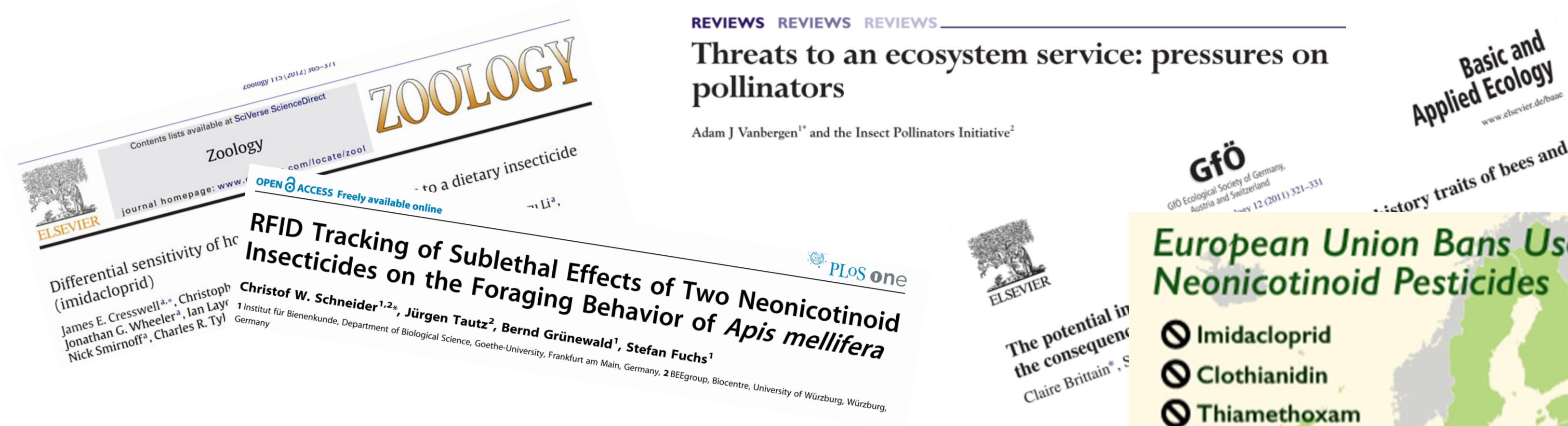
Regulatory status of Neonicotinoids in Switzerland

A brief review: Clear evidence

- Until 2012, a high number of publications showing clear evidence for adverse and sublethal effects of neonicotinoids on bees



- 2013, The EU imposed a two year moratorium on neonicotinoid application as a seed-treatment for certain bee-attractive crops (Maize, sunflower and oilseed rape)

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Regulatory status of Neonicotinoids in Switzerland

Conclusion

Since 2018, the outdoor use of the three neonicotinoids **Clothianidin**, **Thiamethoxam** and **Imidacloprid** in agriculture has been banned throughout the EU and Switzerland

In May 2020, another neonicotinoid, **Thiacloprid**, lost its authorisation

Acetamiprid, the only neonicotinoid active ingredient still authorised in Switzerland

Laboratory tests have shown that **Acetamiprid** is more than 1000 times less harmful to honey bees than the banned neonicotinoids

The above mentioned and banned neonicotinoids are now replaced by **Pyrethroids**, **Acetamiprid** and **Spinosad** when possible

The reduction in authorised insecticides in Switzerland and the lack of alternatives are leading to an increased number of 'emergency authorisations' of insecticides to protect agricultural crops in Switzerland

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Acknowledgments

- Firstly I would acknowledge all the people that assisted in preparing and collecting data
  Daniela Grossar, Benoit Droz and Domenic Camenzind (Agroscope)

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  Daniela Grossar, Thomas Poiger, Christina Kast, Michael Meissle, Jean-Daniel Charrier (Agroscope), Lars Straub (IBH), Katja Knauer (FOAG) and Stefan Kimmel (Corteva Agriscience)

- All the funding bodies that enable us to work daily, financed our projects (Swiss Federal Office for Agriculture and Agroscope)

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Rural Development Administration
National Institute of Agricultural Sciences

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Thank you / 감사합니다