Semiochemical active substances as Plant Protection Products

Remote, 11 June 2026

3rd Workshop on innovative biopesticides (BioNAS)

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AGENDA

Section 1 – Introduction

- Biology of semiochemicals
- Semiochemicals when used as Plant Protection Products
- Efficacy considerations

Q&A

Section 2 – Implications for the risk assessment

- Natural background calculation
- Human Health Risk Assessment
- Enviromental Risk Assessment

Q&A

SECTION 1 – INTRODUCTION

- Biology of semiochemicals
- Semiochemicals when used as Plant Protection Products
- Efficacy considerations

Q&A

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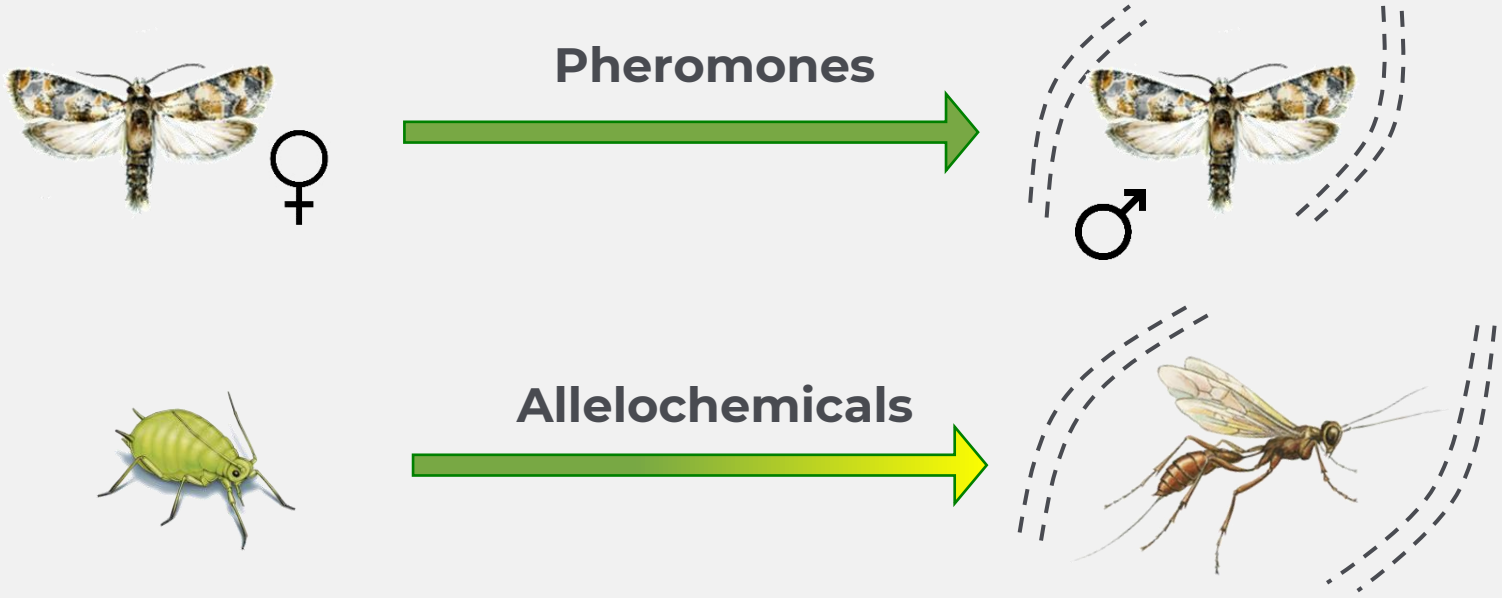
What are semiochemicals?

Nature's first communication tool

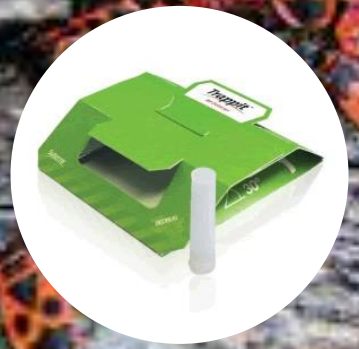
*"Semiochemicals are substances emitted by plants, animals and other organisms which are used for intra- and inter-species communication, have a **target-specific** and **non-toxic** mode of action and are **naturally occurring**.*
They are generally effective at very low rates, often comparable to levels that occur naturally" (Regulation (EU) No. 2017/1432)



Types of PHEROMONES

Types of PHEROMONES

Aggregation



Alarm

Sex

Trail

Types of ALLELOCHEMICALS

Synomone
Receiver (+), Emitter (+)

Kairomones
Receiver (+), Emitter (–)

Allomone
Receiver (-), Emitter (+)

Types of ALLELOCHEMICALS

Synomone
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Kairomones
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Allomone
Receiver (-), Emitter (+)

SEMIOCHEMICALS, ACTUALLY

We're outnumbered:
a field guide to chemical eavesdropping

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KAIROMONES
Human skin and sweat releases CO_2, lactic acid, ammonia and fatty acids that attract mosquitos, ticks and horseflies.

SYNOMONES
Floral scent blends attract pollinators, which benefit from nectar while helping the plant reproduce .

ALLOMONES
When plants are chewed by caterpillars, they release HIPVs that attract parasitoid wasps.

KAIROMONES
Ripening fruit releases ethylene and ester volatiles which attract fruit flies and wasps.

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QUEEN PHEROMONE

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SEX PHEROMONES
Female moths emit sex pheromone for mating purposes

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ALARM PHEROMONES
When threatened, aphids release (E)-β-farnesene.

AGGREGATION PHEROMONES
Beetles release aggregation pheromones to attracts other beetles to suitable habitats.

TRAIL PHEROMONES
Ants laid trail pheromones to guide other colony members to food sources.

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SYNOMONES
Floral scent blends attract pollinators, which benefit from nectar while helping the plant reproduce .

GREEN LEAF VOLATILES
These substances are released when grass is crushed or cut.

ALLOMONES
When plants are chewed by caterpillars, they release HIPVs that attract parasitoid wasps.

ALARM PHEROMONES
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Ripening fruit releases ethylene and ester volatiles which attract fruit flies and wasps.

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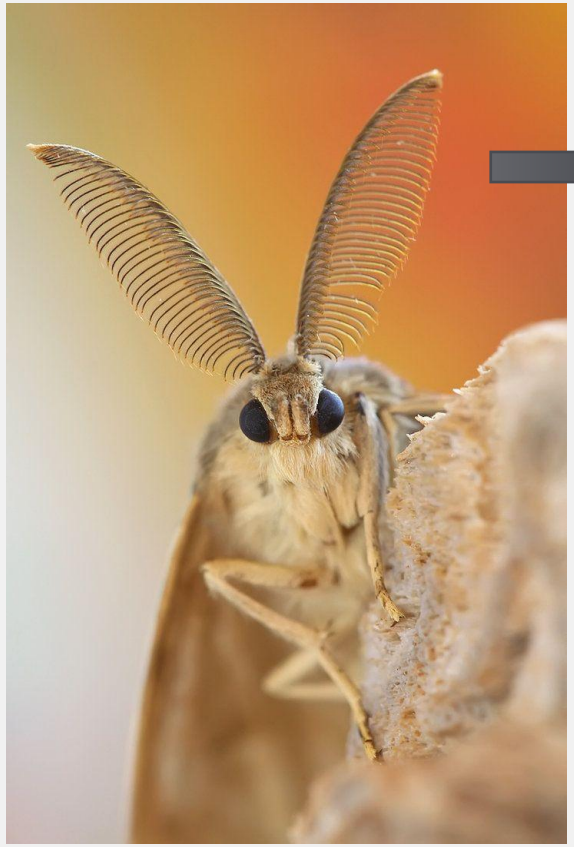
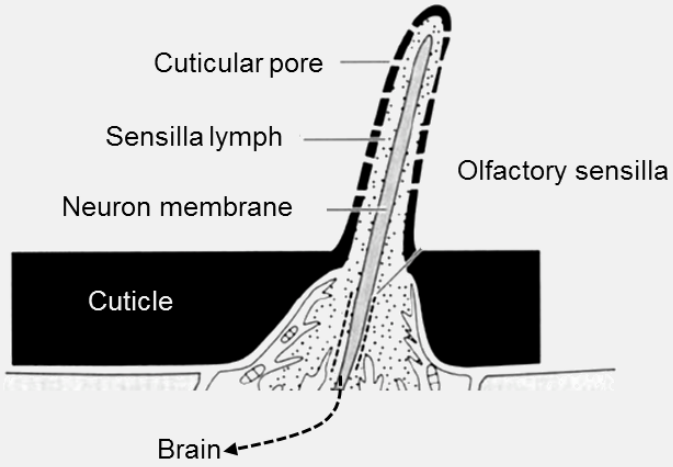
What are semiochemicals characteristics?

- Semiochemicals are substances **naturally emitted** by plants, animals and other organisms used for intra-species and/or inter-species **communication**
- They are **poorly soluble in water**, **volatile** and **rapidly degrade** in the environment (according to their biological function).
- When used for pest control purposes, **they do not have a -cydal mode of action**, i.e. they are not killing agents, and they are used at **concentrations comparable to those occurring during a natural infestation**
- Semiochemicals are intrinsically characterised by a low toxicity: they have a **non-toxic** and **target specific** mode of action

How do they work in nature? Let’s look pheromones

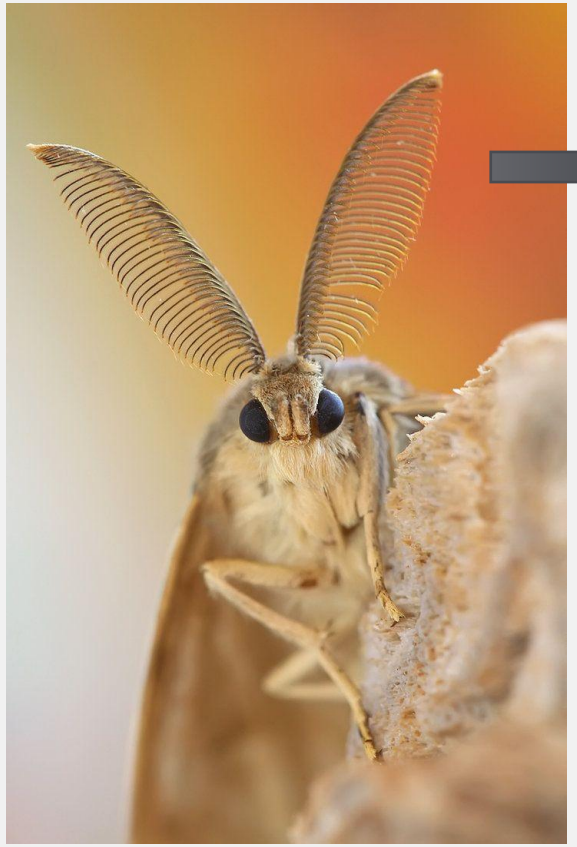
Pheromone perception happen in the antennae

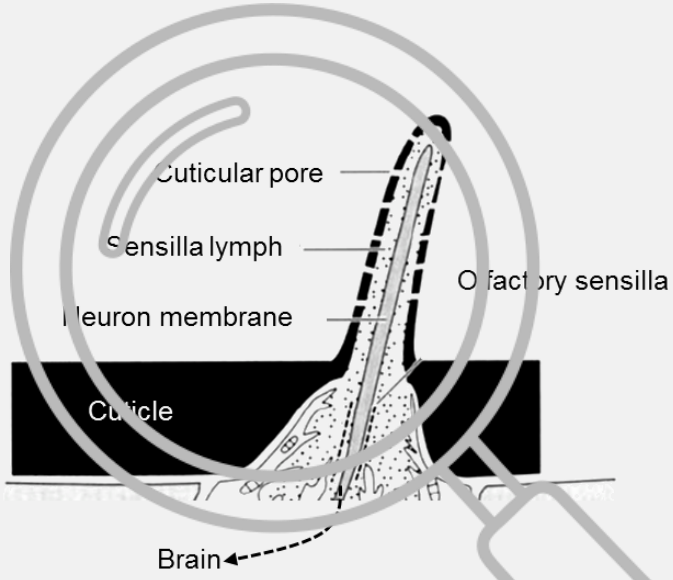


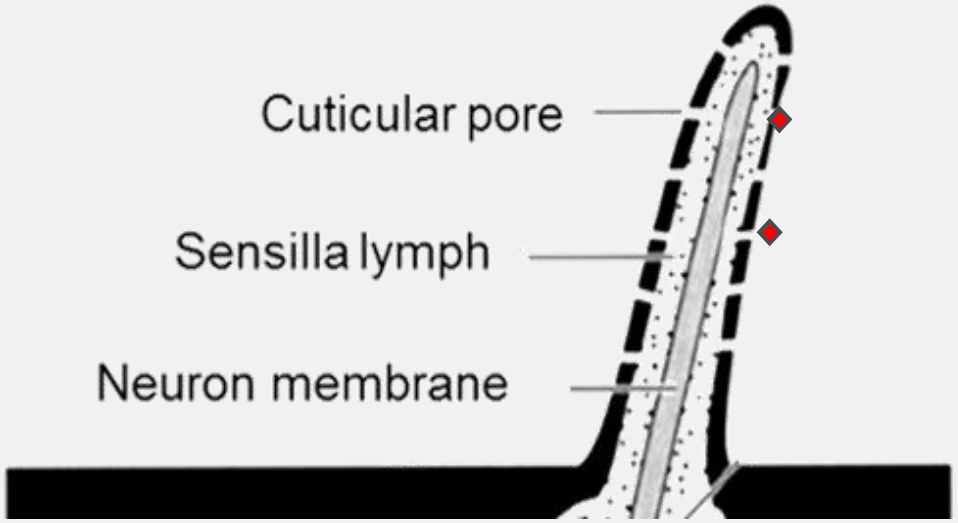


How do they work in nature? Let’s look at pheromones

Pheromone perception happen in the antennae







Pheromone molecule

How do they work when used as PPPs?

- They retain the same intrinsic characteristics

It is key to develop **controlled-release technologies** to emit the semiochemical in the air over a longer period of time

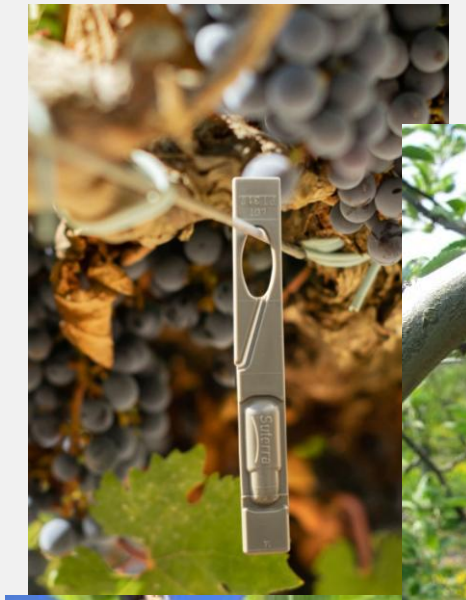
Platforms currently authorised in MD PPPs

VP formulations

AE formulations

CS formulations

Platforms currently authorised in MD PPPs



VP formulations

MACRO Passive Dispensers

They are ALL dispensers

All these technologies allow for a slow controlled release of the pheromone over time

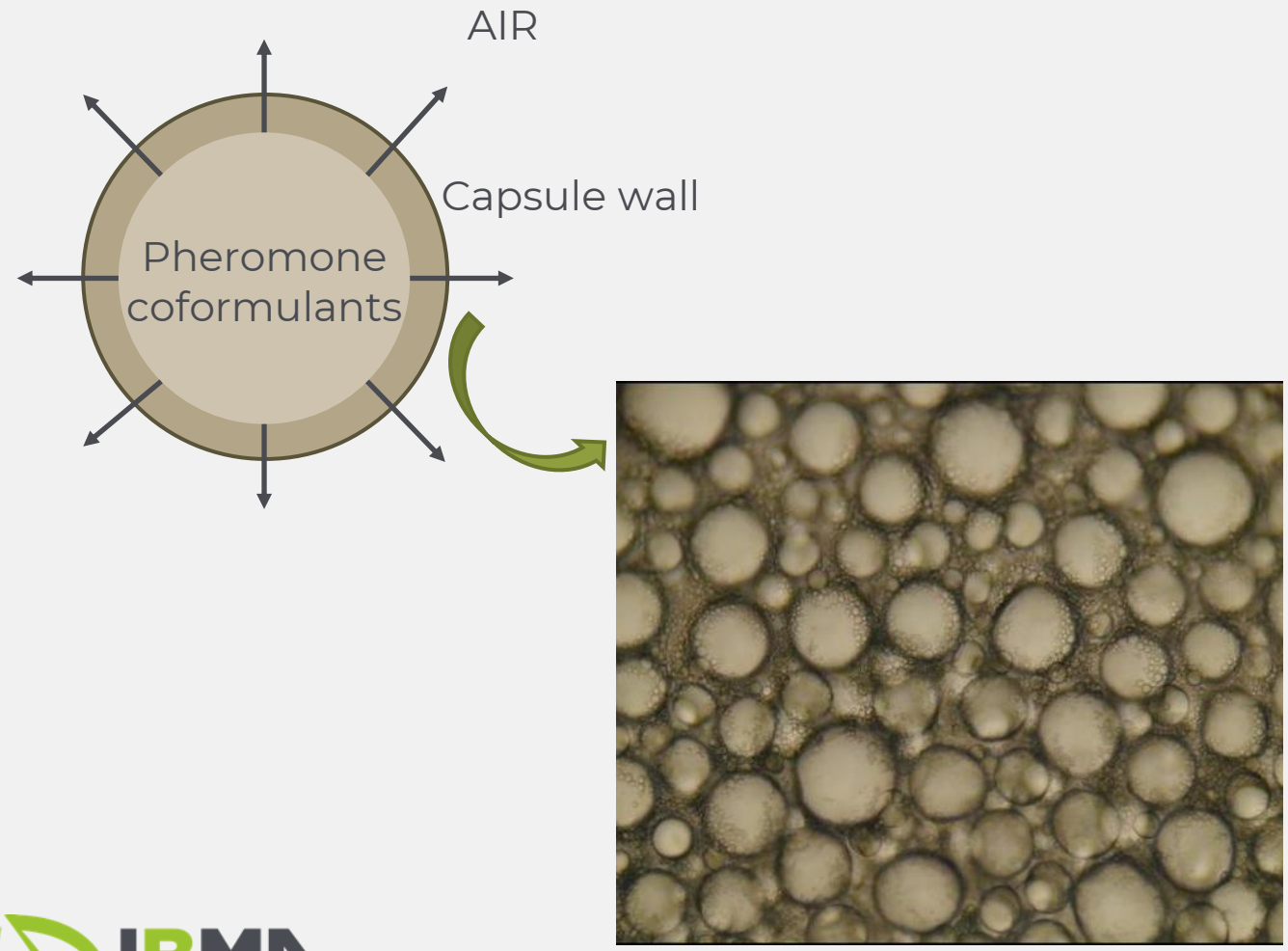
AE formulations

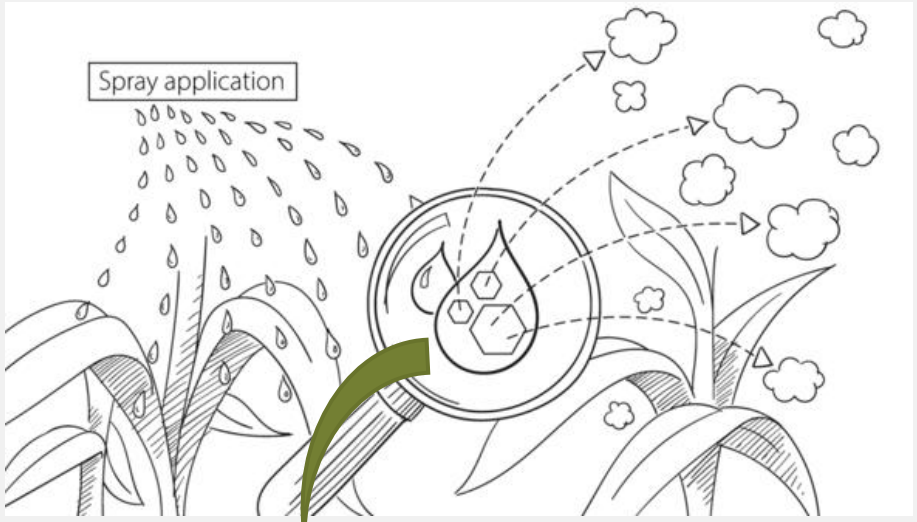
Active Dispensers

MICRO Passive Dispensers

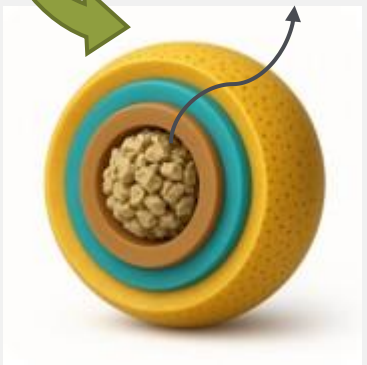
CS formulations

Controlled release into the air





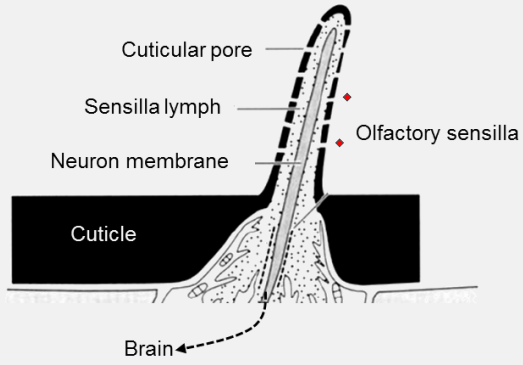
Contolled release
into the air



Pheromone with co-formulants

How do they work when used as PPPs?

- They retain the same intrinsic characteristics
- They interact with the olfactory system of the receiving organism exactly in the same way they do in nature.



It is key to replicate synthetically the naturally occurring **pheromone component** or **pheromone blend**

Why are blends important?

- Many pheromones, including the sex pheromones of a number of lepidopteran species, are not single compounds but a species-specific combination of molecules in a precise ratio.
- This is particularly important to achieve **species specificity starting from shared building blocks**: components are frequently common across species, so identity is encoded combinatorially through which components are present and in what *ratio*.

Thaumatotibia leucotreta

False codling moth

(Z)-8-dodecenyl acetate	~ 30
(E)-8-dodecenyl acetate	**~ 70**

Grapholita molesta

Oriental fruit moth

(Z)-8-dodecenyl acetate	**~ 80**
(E)-8-dodecenyl acetate	~ 6
(Z)-8-dodecen-1-ol	~ 1

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Blends & Efficacy

- For the EU renewal of SCLPs EFSA based its conclusion only on the 37 individual substances (listed in Appendix I A of the Review Report SANTE/10828/ 2021), considering the blends as mixtures of these substances that would be covered during the authorisation of plant protection products.

- However, efficacy has to be demonstrated for an active substance for it to be approved under Art. 4 of Reg. EC 1107/2009.

  Article 4(1) approves an active substance only where it may be expected that PPPs containing it satisfy Article 4(2) and (3). Article 4(3)(a) then states that such a product, applied consistently with good plant protection practice and under realistic conditions of use, *"shall be sufficiently effective."*

- For future evaluations it is strongly recommended to also consider pheromone blends as whole blends and not to solely evaluate them as single components.

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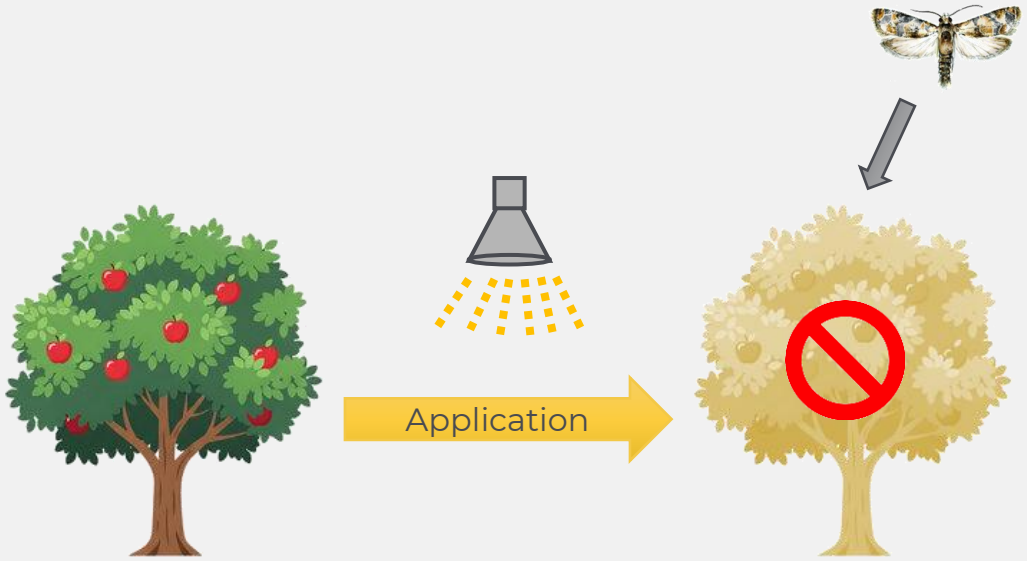
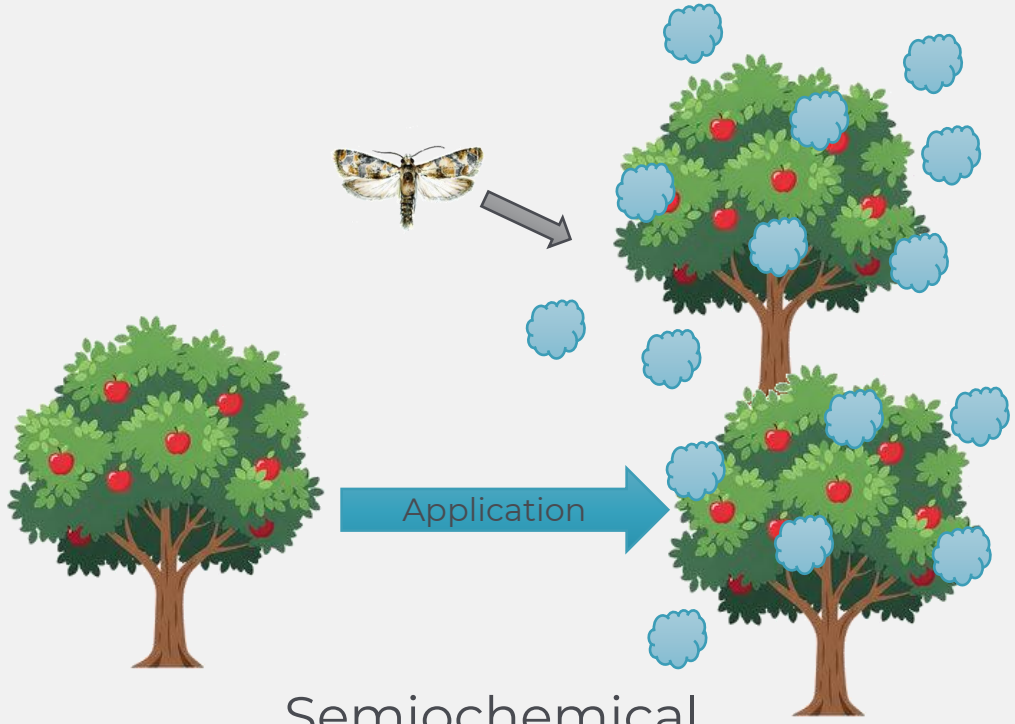
Efficacy considerations

Why standard designs are not suitable?

Because individual plants are not protected, the plot (or field) is



Regular pesticide



Semiochemical

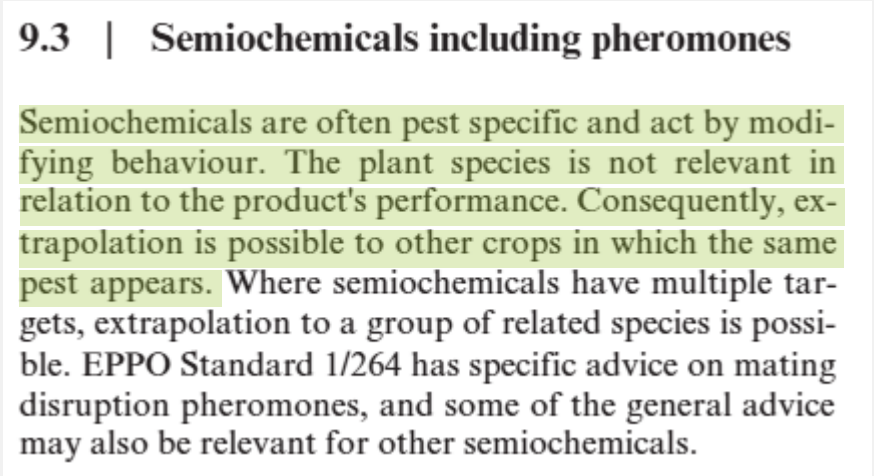
Efficacy trials set up

Principles

- The trial set-up needs to account the specific MoA of the product
- The trial set-up needs to account for the target pest biology and behaviour
- Non-efficacy benefits should be weighed/tested within an IPM context

Existing international guidelines

- EPPO PP1/264 - ‘Mating disruption pheromones’
- EPPO PP1/296 - ‘Principles of efficacy evaluation for low-risk plant protection products’
- EPPO PP1/269 - ‘Comparable climates at global level’
- Species-specific EPPO Standards



9.3 | Semiochemicals including pheromones

Semiochemicals are often pest specific and act by modifying behaviour. The plant species is not relevant in relation to the product's performance. Consequently, extrapolation is possible to other crops in which the same pest appears. Where semiochemicals have multiple targets, extrapolation to a group of related species is possible. EPPO Standard 1/264 has specific advice on mating disruption pheromones, and some of the general advice may also be relevant for other semiochemicals.

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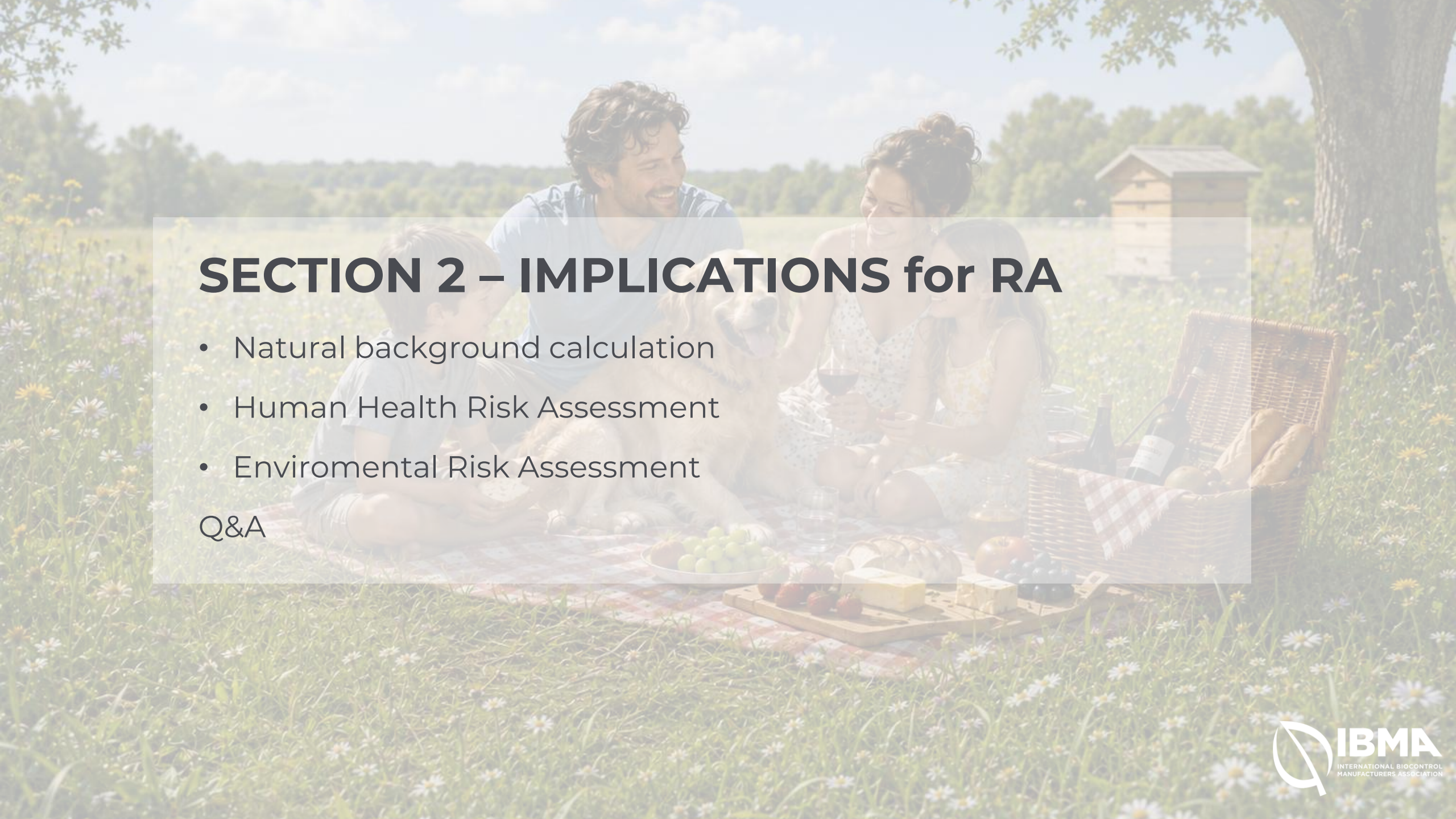
Time for Q&A



SECTION 2 – IMPLICATIONS for RA

- Natural background calculation
- Human Health Risk Assessment
- Enviromental Risk Assessment

Q&A

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Exposure considerations: SANTE/21815/2014 rev. 11

"When the exposure route is **by the vapour phase** *only and where the exposure (by the same route) caused by the use of the plant protection product is similar (within one order of magnitude) to natural exposure levels of the semiochemical (or a group of related semiochemicals when justified) the risk characterisation is concluded"*

Exposure considerations

Route of exposure depends on the **formulation type** of the PPP

CIPAC formulations

AE	Aerosol dispenser
AL	Other liquids to applied undiluted
AP	All other products to be applied undiluted
BR	Briquette
CB	Bait concentrate
CP	Contact powder
CS	Capsule suspension
DC	Dispersible concentrate
DP	Dustable powder
DS	Powder for dry seed treatment
DT	Tablets for direct application
EC	Emulsifiable concentrate
EG	Emulsifiable granule
EO	Emulsion, water in oil
EP	Emulsifiable powder
ES	Emulsion for seed treatment
EW	Emulsion, oil in water
FS	Flowable concentrate for seed treatment
FU	Smoke generator
GA	Gas
GE	Gas generating product
GL	Emulsifiable gel
GR	Granule
GS	Grease
GW	Water soluble gel
HN	Hot fogging concentrate
KK	Combi-pack solid/liquid*
KL	Combi-pack liquid/liquid*
KN	Cold fogging concentrate
KP	Combi-pack solid/solid*
LN	Long-lasting insecticidal net
LS	Solution for seed treatment
MC	Mosquito coil
ME	Microemulsion
OD	Oil dispersion
OF	Oil miscible flowable concentrate (oil miscible suspension)
OL	Oil miscible liquid
OP	Oil dispersible powder
PA	Paste
PR	Plant Rodlet
PS	Seed coated with a pesticide
RB	Bait (ready fore use)
SC	Suspension concentrate (= flowable concentrate)
SD	Suspension concentrate for direct application
SE	Suspo-emulsion
SG	Water soluble granule
SL	Soluble concentrate
SO	Spreading oil
SP	Water soluble powder
ST	Water soluble tablets
SU	Ultra- low volume (ULV) suspension
TB	Tablet
TC	Technical material
TK	Technical concentrate
UL	Ultra-low volume (ULV) liquid
VP	Vapour releasing product
WG	Water dispersible granule
WP	Wettable powder
WS	Water dispersible powder for slurry treatment
WT	Water dispersible tablets

VP Macro-passive dispenser

AE Active dispenser

WP /CS Micro-passive dispenser

Exposure considerations: SANTE/21815/2014 rev. 11

"When the exposure route is **by the vapour phase** *only and where the exposure (by the same route) caused by the use of the plant protection product is similar (within one order of magnitude) to natural exposure levels of the semiochemical (or a group of related semiochemicals when justified) the risk characterisation is concluded"*

VP Macro-passive dispenser

AE Active dispenser

CS WP Micro-passive dispenser

Exposure considerations: SANTE/12815/2014 rev. 11

Exposure considerations: SANTE/12815/2014 rev. 11

Semiochemicals Natural Background Level

- When semiochemicals are used in plant protection products the actual emissions to envirommment are comparable to those occurring during a natural infestation
- Therefore, definition of the **natural background level** is a key parameter during the risk assessment of semiochemical-based PPPs.
- The natural background level corresponds to the exposure that might occur naturally in the environment from a high-density population of emitting organisms and thus, expected to be **experienced by humans and other non-target organisms** and not having any effect
- The natural background level can either be a **fixed threshold value** (i.e. 375 g semiochemical/ha (150 g/acre) per year) or it can be **calculated separately per each species**

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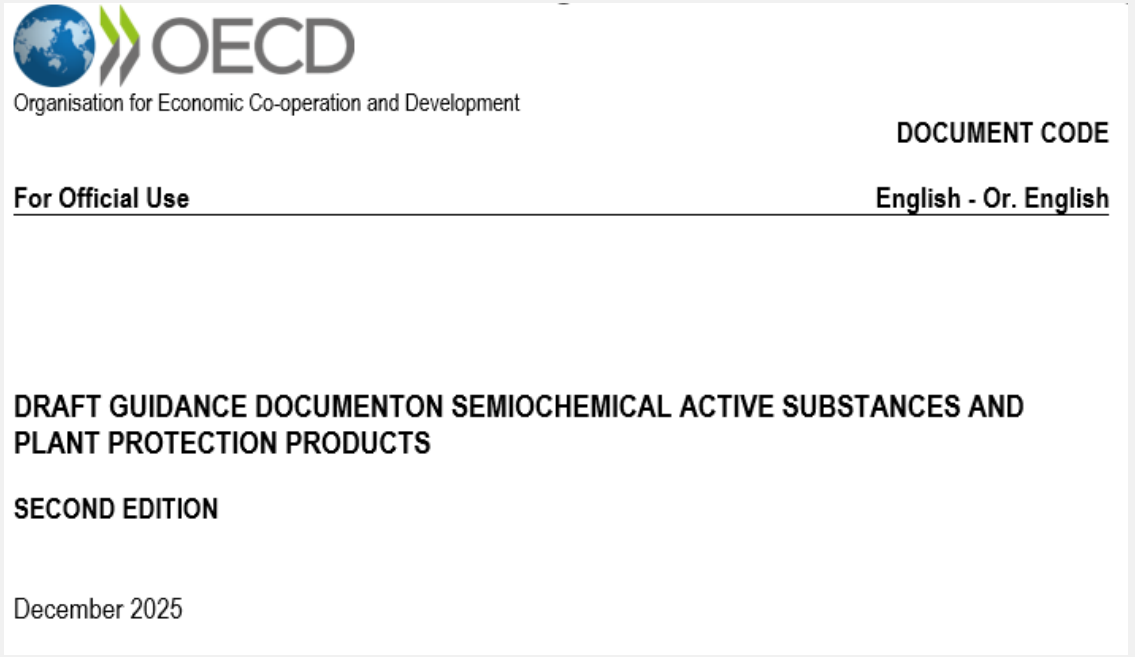
Current calculation method

There is a calculation method for the determination of the natural background levels of semiochemicals based on available peer-reviewed literature reported in three official guidance documents:

- 'Guidance document on semiochemical active substances and plant protection products'. **DG SANTE**, SANTE 12815/2014; rev. 11 of January 2024
- 'Guidance document on semiochemical active substances and plant protection products'. **OECD**, OECD ENV/JM/MONO(2017)33; **- under revision**
- 'Guidelines for the registration of microbial, botanical and semiochemical substances for both plant protection and public health uses'. **FAO/WHO** International Code of Conduct on Pesticide Management, 2017, WHO/HTM/NTD/WHOPES/2017.05



OECD

Organisation for Economic Co-operation and Development

DOCUMENT CODE

For Official Use

English - Or. English

DRAFT GUIDANCE DOCUMENTON SEMIOCHEMICAL ACTIVE SUBSTANCES AND PLANT PROTECTION PRODUCTS

SECOND EDITION

December 2025

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OECD Semiochemicals Background project outline

01 Confirm method suitability with experimental phase

02 Refine the process including an additional step of verifying the reliability of the peer-reviewed input data

03 Provide examples of the applicability of the method

04 Propose harmonised natural background levels for a set of semiochemicals commonly uses in plant protection in OECD countries (e.g. SCLPs, Mealybugs, ...)

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Current calculation method

All the input data come from published peer-reviewed literature and/or official sources

$$PRR = RIO \times NRO$$

Where:

PRR (Population Release Rate) = release rate of the semiochemical from a justified high population of the source organism in nanograms per hectare and hour (**ng/ha/h**).

RIO (Release of an individual organism) = release rate of the semiochemical by an individual organism in one hour (**ng/h**).

NRO (Number of Releasing Organisms) = number of releasing organisms per hectare.

$$NRO = \frac{YLD}{MPY} \times \frac{\%\ INF}{100} \times OCC \qquad \text{or} \qquad NRO = PPH \times EIP$$

Where:
YLD (Yield) = total yield of the crop in one cropping cycle (Kg/ha)
MPY (Mass per yield unit) = average mass of a standard unit (Kg) of the crop
% INF (Infestation rate) = % of harvested units affected by the target organism
OCC (Occupancy) = no. of releasing individuals per individual plant part

Where:
PPH (Plants per hectare) = number of plants per one hectare.
EIP (Emitting individuals per plant) = number of individual emitting per single plant

Assignment of criteria for reliability assessment

RIO (Release of Individual Organism) Assessment

Criteria	Reliable without restriction	Reliable with restrictions	Not reliable
Source	• Peer reviewed literature	• Company reports • Dissemination magazines • Not peer reviewed literature	• Companies web pages
Analytical method	• Volatile collection with adsorbents using internal standard	• Gland extraction (solvent or thermal) • Body extraction • Volatile collection with adsorbents using external standard	• Measurements without any calibration

EIP (Emitting Individuals per Plant) or NRO Assessment

Criteria	Reliable without restriction	Reliable with restrictions	Not reliable
Source	• Peer reviewed literature • National competent authorities reports	• Company reports • Dissemination magazines • Not peer reviewed literature	• Companies web pages

PPH (Plants per Hectare) Assessment

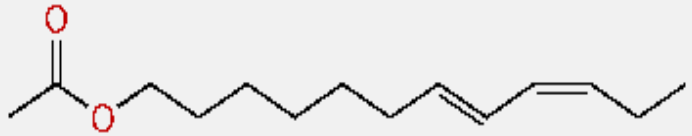
Criteria	Reliable without restriction	Reliable with restrictions	Not reliable
Source	• Peer reviewed literature • National competent authorities reports • FAO Statistics	• Dissemination magazines/ webpages • Not peer reviewed literature	• Companies web pages

Lepidoptera – *Lobesia botrana* – European grapevine moth

L. botrana adult

L. botrana larvae

- It is considered a major vineyard pest in its native range, as the larvae feed on the interior of grapes.
- Pheromones are released by females like in all Lepidopterans.
- Pheromone release consists of a lead SCLP component of 7(*E*),9(*Z*)-dodecadienyl acetate



7E,9Z-dodecadienyl acetate

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Lobesia botrana - Input data scoring

Endpoint	Value used for calculations	Scoring/Rationale	Source
RIO	• 0.36 ng/h	1 Reliable without restrictions Volatile collection with adsorbents using internal standard / Peer reviewed literature	Tasin, (2005)
EIP	• 60% infestation • 90% infestation • 50% took for calulations (1 individual per berry with ♂/♀ ratio of 1:1	1 Reliable without restrictions Peer reviewed literature	Shoukat, (2012) Pavan and Sbrissa, (1994)
PPH	• 25000 kg /ha • 1 g weight of single grape	1 Reliable without restrictions Peer reviewed literature	FAO, (2000) Calderón-Orellana et al., (2014)

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Lobesia botrana - Calculation

$$PRR = RIO \times EIP \times PPH$$

Where:

PRR (Population Release Rate) = release rate of the semiochemical from a justified high population of the source organism in nanograms per hectare and hour (ng/ha/h).

RIO (Release of an individual organism) = release rate of the semiochemical by an individual organism in one hour (ng/h).

EIP (Emitting individuals per plant) = number of individual emitting per single plant.

PPH (Plants per hectare) = number of plants per one hectare.

$$\text{PRR} = 0.36\ \text{ng/h} \times 0.5 \times (2500000\ \text{kg/ha} / 0.001\ \text{kg}) = 4\ 500\ 000\ \text{ng/ha/h}$$

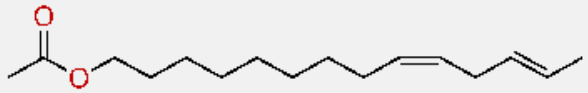
4.5 mg /ha /h

Lepidoptera - *Spodoptera exigua* - Beet armyworm

S. exigua adult

S. exigua larvae

- It is native to Asia but has been introduced worldwide. Has a very broad range of hosts: asparagus, beans and peas, sugar and table beets, celery, cole crops, lettuce, potato, tomato, cotton, cereals, oilseeds, tobacco, cannabis.
- Pheromones are released by females like in all Lepidopterans.
- Pheromone blend release consists of a lead SCLP component of (Z)9,(E)12-tetradecadienyl acetate



(*Z*)9,(*E*)12-tertadeanienyl acetate

Spodoptera exigua – Input data scoring

Endpoint	Value used for calculations	Scoring/Rationale	Source
RIO	• 0.26 ng/h	1 Reliable without restrictions Volatile collection with adsorbents using internal standard / Peer reviewed literature	Acín et al, (2010).
EIP	• 50% took for calulations (1 individual per cottonball with ♂/♀ ratio of 1:1)	1 Reliable without restrictions Peer reviewed literature	Smith, (1989)
PPH	• 1500000 kg /ha • 3.5 g weight of single cotton ball	1 Reliable without restrictions Peer reviewed literature	Banuri, (1998)

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Spodoptera exigua - Calculation

$$PRR = RIO \times EIP \times PPH$$

Where:

PRR (Population Release Rate) = release rate of the semiochemical from a justified high population of the source organism in nanograms per hectare and hour (ng/ha/h).

RIO (Release of an individual organism) = release rate of the semiochemical by an individual organism in one hour (ng/h).

EIP (Emitting individuals per plant) = number of individual emitting per single plant

PPH (Plants per hectare) = number of plants per one hectare.

$$\text{PRR} = 0.26\ \text{ng/h} \times 0.5 \times (1500000\ \text{kg} / 0.0035\ \text{kg}) = 55\ 710\ 000\ \text{ng/ha/h} =$$

55.7 mg /ha / h

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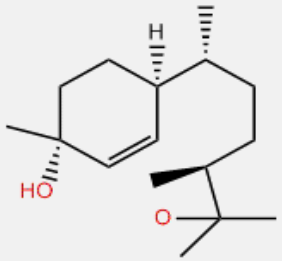
Hemiptera - *Halyomorpha halys* - Brown marmorated stink bug

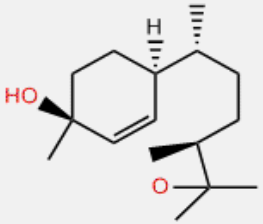
H. halys adult

H. halys eggs and nymphs

- Ubiquitous and invasive species - feed on a wide array of plants including apples, apricots, Asian pears, cherries, corn, grapes, lima beans, peaches, peppers, tomatoes, and soybeans.
- Pheromones are released by **males** which in combination with vibrational signals attract females for mating.
- Pheromone release consists of 2 main components being a mixture of enentiomeres of: (3S,6S,7R,10S)-10,11-epoxy-1-bisabolen-3-ol and (3R,6S,7R,10S)-10,11-epoxy-1-bisabolen-3-ol.



(3R,6S,7R,10S)-10,11-epoxy-1-bisabolen-3-ol



(3S,6S,7R,10S)-10,11-epoxy-1-bisabolen-3-ol

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Halyomorpha halys – Input data scoring

Endpoint	Value used for calculations	Scoring/Rationale	Source
RIO	• 125 ng/h	1 Reliable without restrictions Volatile collection with adsorbents using internal standard / Peer reviewed literature	Harris et. al. (2015)
EIP	• 160 per plant (320/2) (Based on number of individuals per plant of 320 and ♂/♀ ratio of 1:1)	1 Relialable without restrictions Peer reviewed literature	Bergmann et. al. (2016)
PPH	• 1000 trees/ha	1 Reliable without restrictions Peer reviewed literature	Wang et. al. (2015)

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Halyomorpha halys - Calculation

$$PRR = RIO \times EIP \times PPH$$

Where:

PRR (Population Release Rate) = release rate of the semiochemical from a justified high population of the source organism in nanograms per hectare and hour (ng/ha/h).

RIO (Release of an individual organism) = release rate of the semiochemical by an individual organism in one hour (ng/h).

EIP (Emitting individuals per plant) = number of individual emitting per single plant

PPH (Plants per hectare) = number of plants per one hectare.

$$\text{PRR} = 125\ \text{ng/h} \times 160 \times 1000 = 20\ 000\ 000\ \text{ng/ha/h}$$

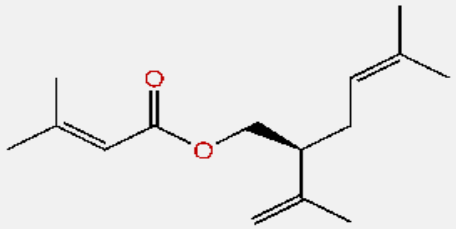
20 mg/ha/h

Hemiptera - *Planococcus ficus* - Vine mealybug

P. ficus female

P. ficus winged males

- Important vineyard pest that feed on all parts of the grape vine plant and weedy plants. They are found on apples, avocados, banana, date palm, fig, mango, and citrus fruits.
- Pheromones are released by **females**, which are sessile attracting mobile males.
- Pheromone release consists of 2 main components being a mixture of enentiomeres of: (S)-Lavandulyl senecioate and (R)-Lavandulyl senecioate



(*S*)-Lavandulyl senecioate

Planococcus ficus - Input data scoring - (*S*)-Lavandulyl senecioate

Endpoint	Value used for calculations	Scoring/Rationale	Source
RIO	• 1.5 ng/h	1 Reliable without restrictions Volatile collection with adsorbents using internal standard / Peer reviewed literature	Levi-Zada et al., (2014).
EIP	• 750 per plant	1 Reliable without restrictions Peer reviewed literature	Lentini et al. (2008)
PPH	• 10000 vines/ha	1 Reliable without restrictions Peer reviewed literature	Hunter, (1998); Grainger, (2009)

Planococcus ficus - Input data scoring - (*R*)-Lavandulyl senecioate

Endpoint	Value used for calculations	Scoring/Rationale	Source
RIO*	• 0.3 ng/h**	1 Reliable without restrictions Volatile collection with adsorbents using internal standard / PhD Thesis	Dublon, (2009)
EIP	• 540 per plant (1080/2) (based on number of individuals per plant of 1080 and ♂/♀ ratio of 1:1)	1 Reliable without restrictions Peer reviewed literature	Seal et al., (2013) Araújo et al. (2007)
PPH	• 350000 plants/ha	1 Reliable without restrictions Peer reviewed literature	Canko, (2014)

* *P. ficus* pheromone contains (R)-Lavandulyl senecioate, however it was not investigated in this species. A vicinal positional isomer [(R)-Lavandulyl 3-methyl-3-butenoate] has been described to be the aggregation pheromone of the Melon thrip (*Thrips palmi* Karny) . As based on QSAR evaluation both (R)-Lavandulyl senecioate and [(R)-Lavandulyl 3-methyl-3-butenoate shall be extremely similar in terms of toxicology and environmental fate it can be used as a **SURROGATE** for calculations.
** Due to lack of data for *P. ficus* values are taken from a **closely-related species** of *Frankliniella occidentalis*.

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Planococcus ficus – Calculation - (*S*)-Lavandulyl senecioate

$$PRR = RIO \times EIP \times PPH$$

Where:

PRR (Population Release Rate) = release rate of the semiochemical from a justified high population of the source organism in nanograms per hectare and hour (ng/ha/h).

RIO (Release of an individual organism) = release rate of the semiochemical by an individual organism in one hour (ng/h).

EIP (Emitting individuals per plant) = number of individual emitting per single plant

PPH (Plants per hectare) = number of plants per one hectare.

$$\text{PRR} = 1.5\ \text{ng/h} \times 750 \times 10000/\text{ha} = 11\ 250\ 000\ \text{ng/ha/h}$$

11.3 mg /ha / h

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Planococcus ficus – Calculation - (*R*)-Lavandulyl senecioate

$$PRR = RIO \times EIP \times PPH$$

Where:

PRR (Population Release Rate) = release rate of the semiochemical from a justified high population of the source organism in nanograms per hectare and hour (ng/ha/h).

RIO (Release of an individual organism) = release rate of the semiochemical by an individual organism in one hour (ng/h).

EIP (Emitting individuals per plant) = number of individual emitting per single plant

PPH (Plants per hectare) = number of plants per one hectare.

$$\mathrm{PRR} = 0.3\ \mathrm{ng/h} \times 540 \times 350000/\mathrm{ha} = 56\,700\,000\ \mathrm{ng/ha/h}$$

56.7 mg /ha / h

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Harmonised Natural Background levels

In the proposed update of OECD Semiochemical Guideline in Appendix VI the calculation method has been applied to derive natural exposure levels for 16 Straight-Chained Lepidopteran Pheromones (SCLPs) and for the pheromones emitted by 7 Hemiptera species.

LEPIDOPTERA		
Species	**Sex pheromone molecule**	**Natural background (mg/ha*h)**
Anarsia lineatella	(E)-5-decen-1-yl acetate	7.8
Anarsia lineatella	(E)-5-decen-1-ol	1.4
Trichoplusia ni	(Z)-7-dodecen-1-yl acetate	**99.0**
Grapholita molesta	(E)-8-dodecen-1-yl acetate	0.7
Grapholita molesta	(Z)-8-dodecen-1-yl acetate	16.9
Grapholita molesta	(Z)-8-dodecenol	5.1
Eupoecilia ambiguella	(Z)-9-dodecen-1-yl acetate	31.3
Lobesia botrana	(E,Z)-7,9-dodecadien-1-yl acetate	4.5
Adoxophyes orana	(Z)-9-tetradecen-1-yl acetate	9.7
Platynota stultana	(Z)-11-tetradecen-1-yl acetate	3.5
Spodoptera exigua	(Z, E)-9,12-tetradecadien-1-yl acetate	55.7
Plutella xylostella	(Z)-11-hexadecen-1-yl acetate	7.5
Cydia pomonella	(E,E)-8,10-dodecadien-1-ol	9.1
Helicoverpa assulta	(Z)-9-hexadecenal	36.4
Helicoverpa armigera	(Z)-11-hexadecenal	10.8
Eoreuma loftini	(Z)-13-octadecenal	4.34

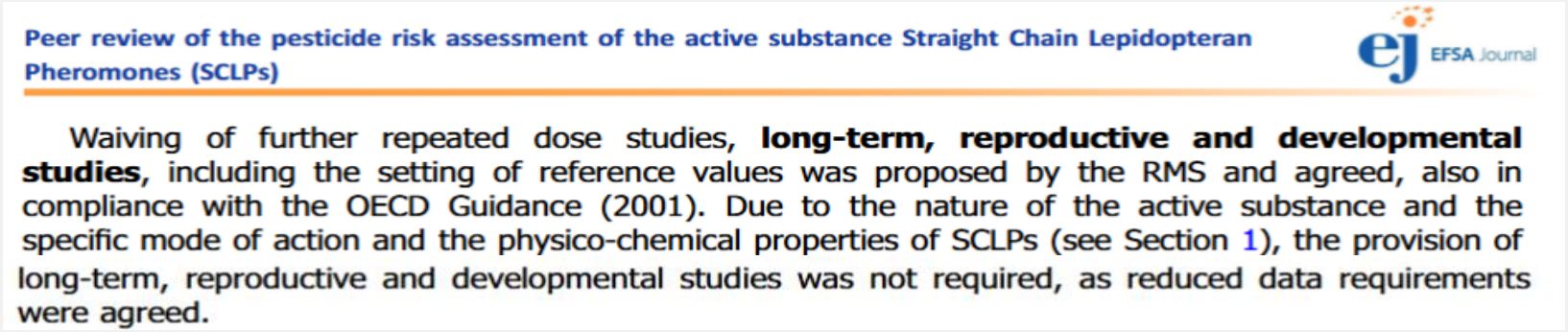
HEMIPTERA		
Species	**Sex pheromone molecule**	**Natural background (mg/ha*h)**
Pseudococcus longispinus	(2-(1,5,5-trimethylcyclopent-2-en-1-yl)ethyl acetate)	1.31
Pseudococcus viburni	(1*R**,2*R**,3*S**)-(2,3,4,4-tetramethyl cyclopentyl) methyl acetate	0.57
Delottococcus aberiae	(4,5,5-trimethyl-3-methylenecyclopent-1-en-1-yl) methyl acetate	0.59
Planococcus citri	(1*R*,3*R*)-cis-2,2-Dimethyl-3-isopropenyl-cyclobutanemethanol acetate	2.24
Planococcus ficus	(S)-Lavandulyl senecioate	11.2
Planococcus ficus	(R)-Lavandulyl senecioate	56.7
Aonidiella aurantii	Rescalure	2.23 to **25.3**
Halyomorpha halys	(3S,6S,7R,10S)-10,11-epoxy-1-bisabolen-3-ol	20
Halyomorpha halys	(3R,6S,7R,10S)-10,11-epoxy-1-bisabolen-3-ol	20

Conclusions: let's harmonise

- The highest natural background level observed for SCLPs is 99.0 mg/ha*h, derived from *Trichoplusia ni*. In contrast, Hemiptera pheromones present greater challenges in data availability, with the highest value recorded being 25 mg/ha*h for *Aonidiella aurantii*.
- Given these findings, it is proposed to extend the group approach to align with natural background levels. A harmonized threshold value of **99.0 mg/ha per hour** is recommended for *SCLPs*, while a threshold of **25 mg/ha per hour** is suggested for *Hemiptera* and terpenoid-like sex pheromones. In practice those values can be used in conjunction with duration of infestation to propose a yearly thresholdd to compare with the GAP table proposed for a given product.
- It is important to note that multiplying the threshold value identified for SCLPs by the expected duration of a pest infestation (approximately 160 days, covering three generations) results in a value of **380 g/ha per year**. This is consistent with the threshold values adopted in several geographies for SCLPs, such as 375 g/ha per year specified in the Chilean Resolución Extenta 2082-2022 and the U.S. EPA threshold of 150 g/acre per year (equivalent to 375 g/ha per year) under FIFRA 40 CFR 158.2050 and 40 CFR 180.1153.

Human Health considerations

- Repeated dose, long-term, reproductive and developmental toxicity studies can generally be waved due to semiochemicals specific mode of action, intrinsic properties and natural exposure.



Peer review of the pesticide risk assessment of the active substance Straight Chain Lepidopteran Pheromones (SCLPs)

EFSA Journal

Waiving of further repeated dose studies, **long-term, reproductive and developmental studies**, including the setting of reference values was proposed by the RMS and agreed, also in compliance with the OECD Guidance (2001). Due to the nature of the active substance and the specific mode of action and the physico-chemical properties of SCLPs (see Section 1), the provision of long-term, reproductive and developmental studies was not required, as reduced data requirements were agreed.

- Exposure of consumers through diet is not expected to occur as all the GLP trials conducted to date with different types of micro-dispensers according to the products GAP have demonstrated absence of any residue on the treated crops.
- In light of the above, toxicological reference values should generally be waved for these substances.

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ERA - Aquatic endpoints for semiochemicals

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What are semiochemicals characteristics?

- Semiochemicals are substances **naturally emitted** by plants, animals and other organisms used for intra-species and/or inter-species **communication**
- They are **poorly soluble in water**, **volatile** and **rapidly degrade** in the environment (according to their biological function).
- When used for pest control purposes, **they do not have a -cydal mode of action**, i.e. they are not killing agents, and they are used at **concentrations comparable to those occurring during a natural infestation**
- Semiochemicals are intrinsically characterised by a low toxicity: they have a **non-toxic** and **target specific** mode of action

Semiochemicals intrinsic characteristics

- **Poorly soluble in water**
  → Solvents need to be added
- **Highly volatile**
  → Closed systems may be used
- **Rapidly degrade in the environment**
  → Semi-static systems (not always possible)

Substance	Water solubility 20°C	Vapour pressure at 20°C
Rescalure[1]	0,2 mg/L	26 mPa
Lavandulyl senecioate[2]	0,71 mg/L	3100 Pa
SCLP Acetates e.g.: (Z)-11-tetradecenyl acetate[3]	0,13 mg/L	0,16 mPa
SCLP Aldehydes e.g.: 11-tetradecenal[4]	0,4 mg/L	0,171 mPa
SCLP Alcohols e.g.: 1-dodecanol[5]	1,9 mg/L	130 mPa

[1] https://sitem.herts.ac.uk/aeru/bpdb/Reports/2894.htm
[2] https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/3127.htm#none
[3] https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/1959.htm
[4] https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/1952.htm
[5] https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/1379.htm

SCLP (E,E)-8,10-dodecadienol		
Experimental DT_{50} SOIL	**Experimental DT_{50} WATER**	**Calculated DT_{50} AIR**
1.33 hours	0.13 days (ca. 3 hours)	0.83 hours (ca. 50 minutes)

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EU aquatic toxicity assessments of semiochemicals

Substance	Experimental data		European assessment
	Total	Valid	
Rescalure	0 (3 QSAR)	**0**	**EFSA Conclusion** The **risk** to birds, mammals, aquatic organisms, bees, earthworms and soil macro- and microorganisms, terrestrial non-target plants and methods for sewage treatment plants was **considered as low**, being the exposure from the representative use in the range of natural occurrence.
Lavandulyl senecioate	3	**0**	**EFSA Conclusion** The available studies on aquatic organisms were not considered sufficiently reliable due to shortcomings (i.e. **test concentrations not fully maintained**).
SCLPs	32	**4**	**Review Report** 7. List of studies to be generated No further information was identified which is at this stage considered necessary in relation to the approval of Straight Chain Lepidopteran Pheromones. **EFSA Conclusion** [...] In the absence of any valid studies, this approach could not be followed for fish and aquatic invertebrates and, thus, the risk assessment could not be finalized. **EU RAR Vol 3 B9** Some studies [...] were not considered valid or acceptable due to the **lack of analytical measurements** or in the case the validity criteria set in the current guidelines were not fulfilled. In other studies [...] the maintenance of the exposure concentrations during the tests was not demonstrated, since **the measured concentrations were detected at the beginning of the tests but were below the LOQ or LOD** at the end of the tests.

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EU aquatic toxicity assessments of semiochemicals, case

Substance	Aquatic Classification and Algal Study Design	
Pheromone **Non-SCLP** **Acetate** Low water solubility	**OECD 201: algal toxicity study** **Closed-bottle design with PTFE lined cups** **Acetone** used as carrier **solvent** Acetonitrile for analytical sample stabilisation Algae driven **CLP classification** Acute 1 (H400), Chronic 1 (H410)	**Study validity:** • OECD validity criteria fulfilled • Concentration analytically verified • Closed-bottle system scientifically justified because of adaptation to volatility and solubility • No relevant effect of solvent control • Used for hazard classification but under forced conditions
Environmental exposure context The study is considered technically valid; however, the exposure regime does not represent environmentally realistic aquatic exposure conditions for risk assessment purposes. The test was specifically designed to maximise and maintain exposure of a volatile, poorly soluble substance.		

EU aquatic toxicity assessments of semiochemicals, case

Substance	Environmental relevance	
Pheromone Non-SCLP Acetate	**Limitations** • Exposure concentrations declined rapidly • Sustained exposure not always maintained (<LOD/<LOQ) • Test may reflect a transient pulse exposure rather than environmentally realistic exposure	**Actual risk** • **Low risk** to aquatic organisms **for the proposed use of the product** even at worst case ecotox endpoints • Exposure via the vapour phase is within an order of magnitude of natural exposure → Risk is considered low according to SANTE/12815/2014 rev. 11.
The limitations are substance-driven **Artificial exposure conditions have been implemented due to challenging physicochemical properties.** **Actual risk to be considered low.**		

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Is there a more appropriate path?

Point 1.5 of the introductions of the Annexes of Regulations (EU) No 283/2013 and No 284/2013 **allow to provide justifications in cases where experimental data would not be necessary owing to the nature of the active substance**

> 1.5. The information shall include a full and unbiased report of the studies conducted as well as a full description of them. Such information shall not be required, where a justification is provided showing that:
>
> (a) it is not necessary owing to the nature of the plant protection product or its proposed uses, or it is not scientifically necessary; or
>
> (b) it is technically not possible to supply.

If exposure of aquatic organisms to the a.s. is expected to be very low due to its physicochemical properties, is it appropriate to conduct artificially forced studies that do not satisfy current validation criteria?

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Conclusion: Is there a more appropriate path?

- Standard aquatic tests may not reflect realistic environmental exposure and risk and may overestimate hazard.
- However aquatic studies are required for CLP and RA for some formulation types (SANTE/12815/2014 rev. 11)

IBMA proposes…

- Studies should reflect **realistic exposure conditions** and the intended use pattern of the product.
- Allowing accepted OECD **test deviations for semiochemicals** (e.g. as for microorganisms), to avoid artificially forced exposure scenarios.
  E.g. for a deviation: lack of presence of test item in the testing media under normal conditions should not invalide the OECD study.

Generating data where needed, but under environmentally realistic conditions. Semiochemical testing should be exposure-driven and scientifically fit for purpose, rather than based on artificially forced aquatic exposure.

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CONCLUSIONS

- Semiochemicals are naturally occurring communication tools. They are **poorly soluble in water**, **volatile** and **rapidly degrade in the environment** (according to their biological function).
- When used as PPPs they retain the same intrinsic characteristics. They are biological tools; hence **biology should be considered when conducting the RA**.
- If the semiochemicals emitted naturally and effective in generating a response in field situations is a blend, then the blend should be approved as the AS and not the single components.
- The calculation method developed in SANTE/12815/2014 and refined in OECD GD on semiochemicals is the best tool available to calculate natura background exposure levels for semiochemicals.
- Higher tier tox studies and reference values can generally be waved due to semiochemicals specific mode of action, intrinsic properties and natural exposure.
- Aquatox data should be generated under environmentally realistic conditions. Semiochemical **testing should be exposure-driven and scientifically fit for purpose**, rather than based on artificially forced aquatic exposure.

Time for Q&A

THANK YOU FOR YOUR ATTENTION

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