



AGENCE FRANÇAISE  
DE SÉCURITÉ SANITAIRE  
DES ALIMENTS

# **Current Developments on Environmental Risk Assessment for Plant Protection Products in Europe NTA including bees**

**Dr Anne ALIX**

**AFSSA - French Food Safety Agency  
Plant and Environment Department (DiVE)  
Environmental Fate and Ecotoxicology Unit**

**1. Introduction**

**2. Evaluating risks to bees**

**3. Evaluating risks to other Non Target Arthropods**

**Conclusions**

# 1. Introduction



# Directive 91/414/EEC and regulation to come:

Before authorization and placing on the market MS shall ensure that for each use:



- The product is sufficiently effective
- It has no harmful effects on humans (user, operator, consumer)
- It has no unacceptable influence on the environment

# Directive 91/414/EEC: trigger for a risk assessment

*Directive 91/414/EEC (Annex II point 8.3.1.1, Annex III point 10.4):*

*Potential impact on bees must be investigated, except where preparations containing the active substance are for exclusive use in situations where bees are not likely to be exposed such as:*

- food storage in enclosed spaces\*,*
- non-systemic seed dressings,*
- non-systemic preparations for application to soil,*
- non-systemic dipping treatments for transplanted crops and bulbs,*
- wound sealing and healing treatments\*,*
- rodenticidal baits\*,*
- use in glasshouses without pollinators.*

# Potential risks to non target arthropods



# Potential risks to pollinators



Extrapolation?

# Current regulation and guidance documents

## Bees

- Regulation:

Directive 91/414/EEC (Annex II point 8.3.1.1, Annex III point 10.4)

Directive 91/414/EEC (Annex VI point 2.5.3.2)

- Guidance document :

Sanco 10329/2002 rev 2 chapter 4

- Test guidelines OECD (acute), EPPO (semi-field and field experimentations)

- Published protocols: Oomen et al. (1992), Aupinel et al. (2005) for brood test, Decourtye et al. (2005)...



# Current regulation and guidance documents

## Non Target Arthropods

- Regulation:

Directive 91/414/EEC (Annex II point 8.3.2, Annex III point 10.5)

Directive 91/414/EEC (Annex VI point 2.5.3.4)

- Guidance document :

Sanco 10329/2002 rev 2 chapter 5

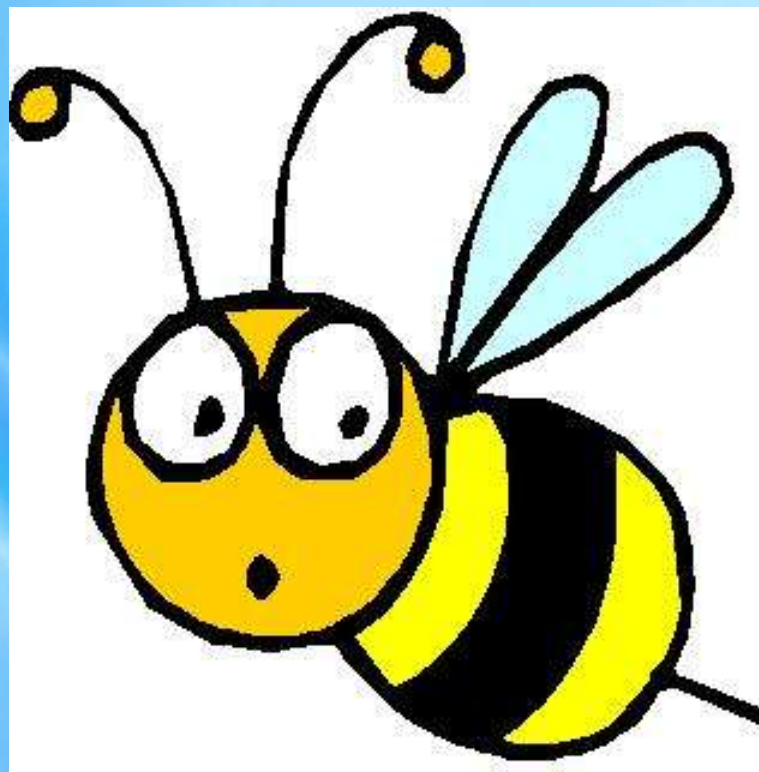
Escort 2 (risk assessment in and off-field)

- Test guidelines: Escort 1

# Need for an update

- **Update of the regulation and discussion on related protection aims**
- **Evolution of Plant Protection Products:**
  - **uses**
  - **modes of action**
  - **formulations**
- **Identification of unexpected exposure routes (dusts...)**
- **assessing the long-term risks and related recovery issue**

## 2. Evaluating risks to bees



# Directive 91/414/EEC: protection aims

## *Directive 91/414/EEC (2.5.2.3.)*

*Where there is a possibility of honeybees being exposed, no authorization shall be granted if the hazard quotients for oral or contact exposure of honeybees are greater than 50, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product according to the proposed conditions of use.*

# Criteria of effects according to Annexes II and III

## Acute test on adults:

*The test should provide the LD50 values (by oral and contact exposure).*

## Residue tests:

*The test should provide sufficient information to evaluate possible risks to foraging bees from residual traces of plant protection products remaining on crops.*

## Cage tests:

*The test should provide sufficient information to evaluate possible risks from the plant protection product for bee survival and behaviour.*

## Field tests:

*The test should provide sufficient information to evaluate possible risks from the plant protection product on bee behaviour, colony survival and development.*

## Tunnel tests:

*The test should provide sufficient information to evaluate the impact on bees resulting from feeding on contaminated honey dew or flowers.*



# Criteria of effects according to Annexes II and III

## •Criteria:

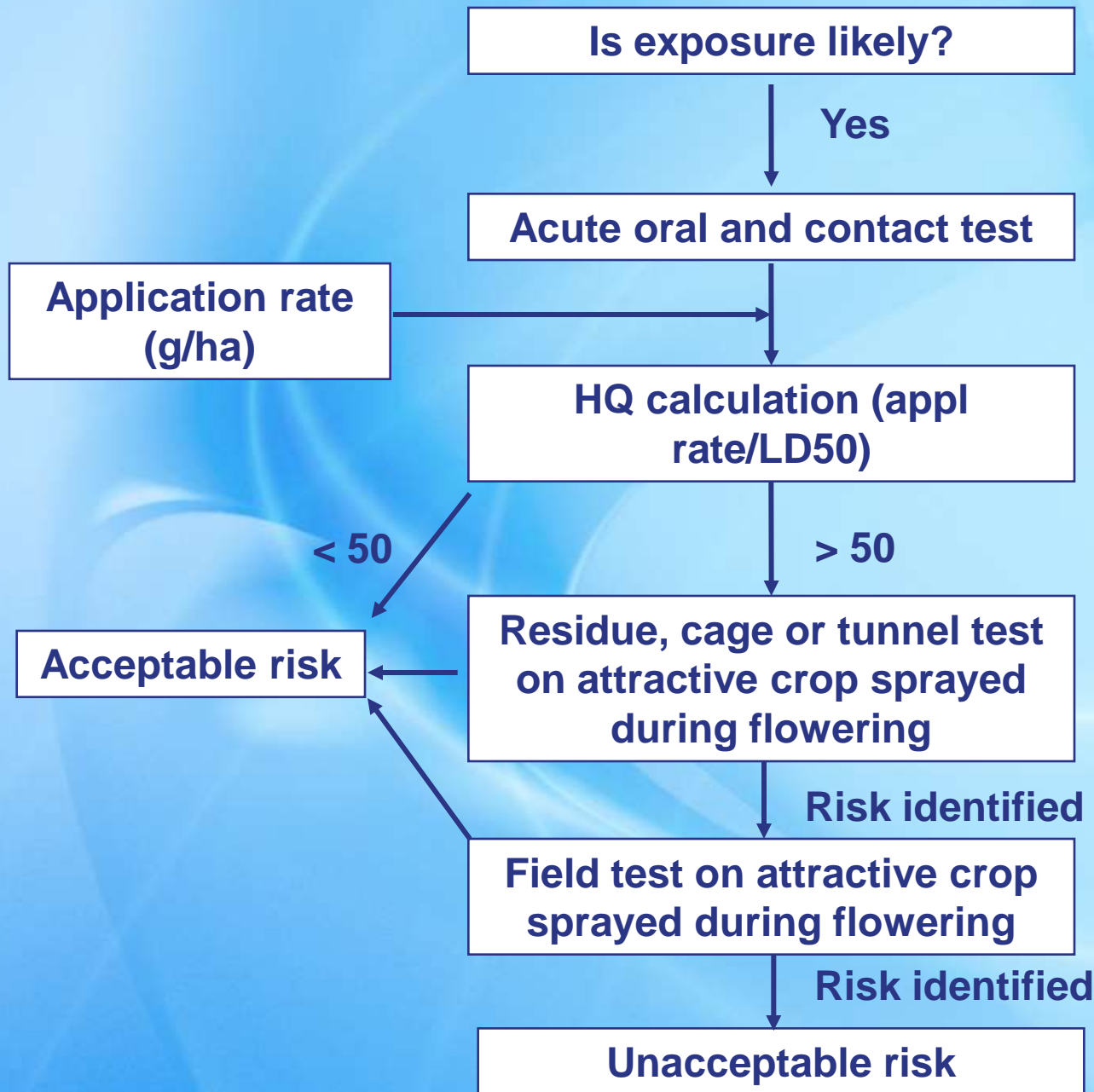
- Survival
- Behaviour (foragers)
- Colony development (and thus larvae)

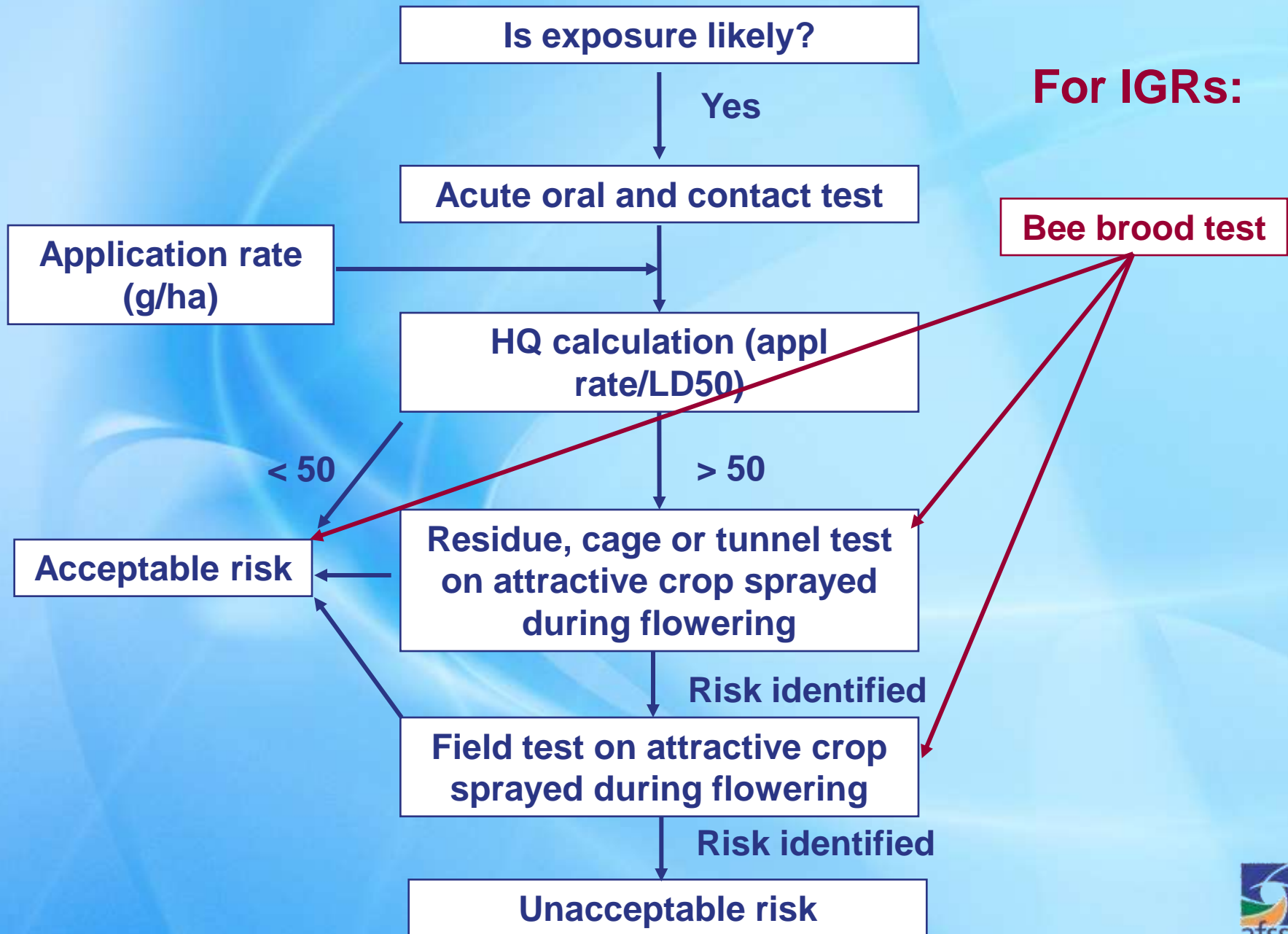
in accordance with protection aims

## •Scale:

- Treated plot
- Colony

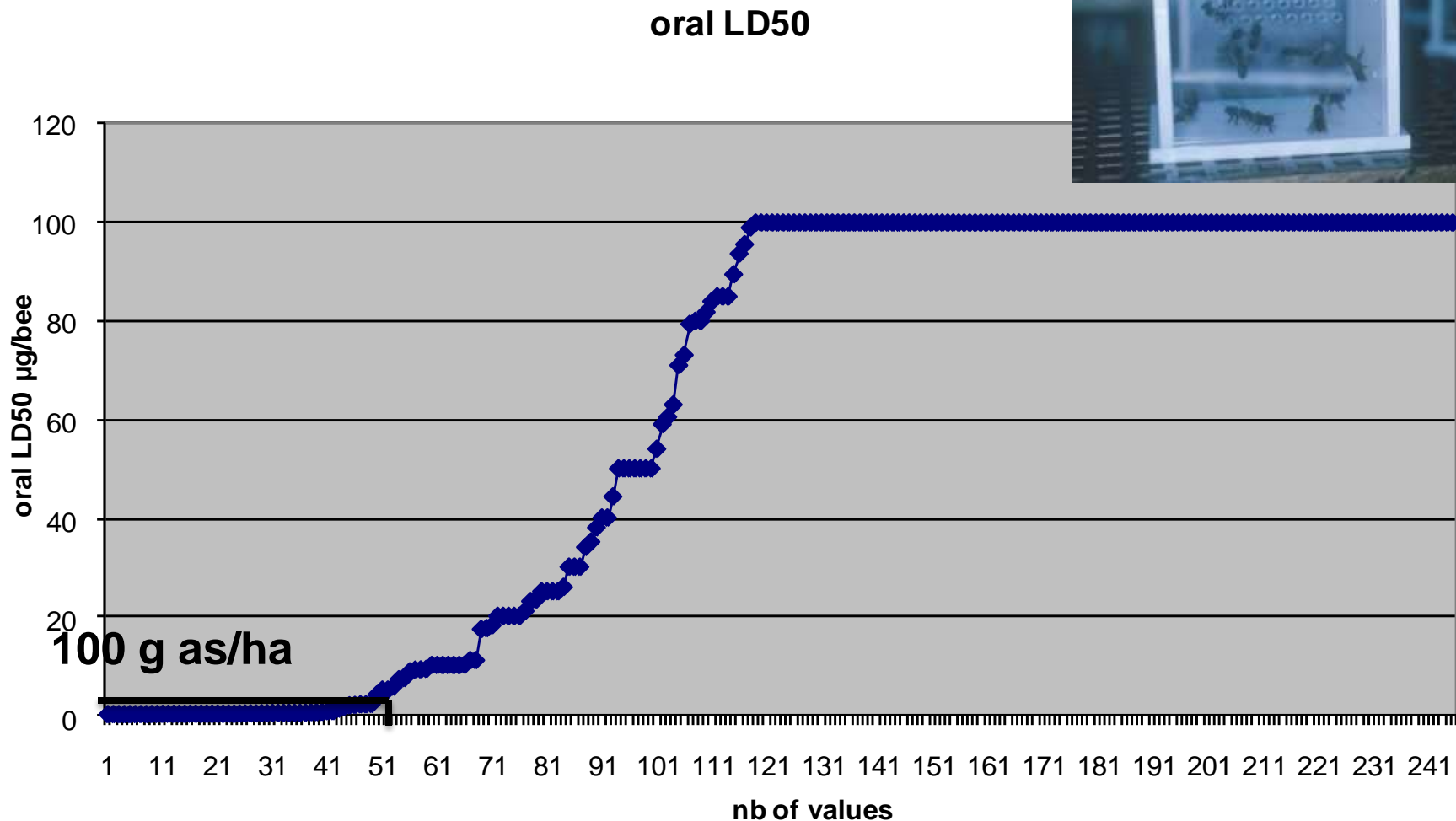
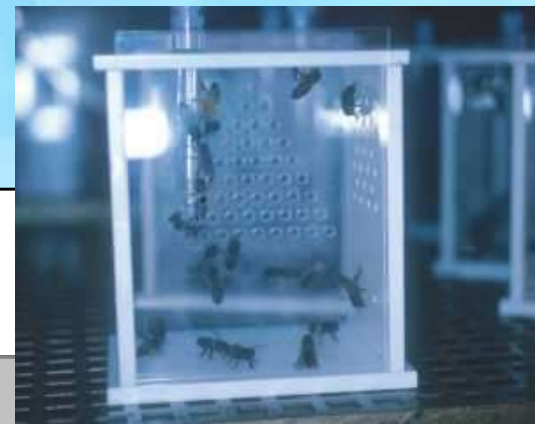
in accordance with protection aims







# Acute test: oral – distribution of LD50, all modes of action



# Update the risk assessment?

- **Testing protocols:**
  - effects on larvae
  - semi-field testing
  - field testing
- **Risk assessment, to account for :**
  - new exposure route
  - unexpected exposure route

# Testing protocols:

- All cases:

Acute oral and contact toxicity tests (LD50 determination – intrinsic toxicity)

- If HQ > 50:

Test	Guideline	Parameter(s)	Exposure route
Brood test	Oomen <i>et al.</i> (1992)	Larval development over 21 days +, lethal effects on adults and larvae	1 L spiked syrup/colony/24 hour
Residue test	-	LT 50	Aged residues on foliage, 24 hours
Cage/tunnel	EPPO PP1/170 (3)	Survival Behaviour of foragers	Treated crop, 7 days
Field	EPPO PP1/170 (3)	Survival Behaviour of foragers Colony development	Treated crop, 28 days to 3 months

# Semi-field testing

- Size (dependent on crop attractiveness, trial objectives and size of test colony)
- Crop (standard or higher tier)
- Size of the colony (dependent on aims of the study)
- Pre-treatment assessments (sufficient to demonstrate a stable background mortality)
- Post-treatment assessments (adapt duration and test design)
- Preferably daily but at least on days 0,1,2,4 and 7 (with e.g. OECD Guidance Doc. 75)
- Test treatments (control, toxic standard)
- Replication - normally 3 replicates per treatment group (may be reduced if a high number of treatment groups are tested)
- Results (validity)



# Field testing

- Many semi-field testing points also apply to field testing
- Colonies (number and size)
- Plots/ fields (size and replication)
- Test treatment (toxic standard)
- Application (single/multiple application)
- Assessments
- Timing of assessments
- Results validity, statistics
- Acceptable/unacceptable effect



# Effects on larvae and brood

Method of Aupinel et al. (2005): laboratory test on larvae individually exposed



Oomen et al. (1992): feeding spiked solution at dose rate



Aupinel et al., 2005. Bulletin of Insectology 58 (2): 107-111, 2005  
Oomen P.A et al. (1992). Bulletin OEPP 22, pp.613-616

# Effects on larvae and brood

**OECD Guidance document 75 (Schur et al., 2003):**

- **reliable tunnel method**
- **exposure via crop**
- **more realistic than laboratory**
- **evaluation of small colonies (nurse bees)**
- **detailed brood evaluation possible**
- **validated for spray products (i.e. adaption for systemic compounds possible)**

# Exposure

## Situations where an exposure is expected or can not be excluded

- **Sprayed treatment:**
  - spray during flowering
  - spray drift on off-crop vegetation, flowering
  - spray before flowering with a systemic compound, reaching flowers, and nectar and pollen
- **Soil/seed treatment:**
  - systemic compound reaching flowers, and nectar and pollen
  - dusts emitted at sowing, redeposited on off-crop vegetation, flowering
- **Rotational crops:**
  - soil persistent systemic compound from a previous crop treatment, reaching flowers, and nectar and pollen
- **All: guttation droplets**



# Case of soil/seed treatments

- mentioned in Dir 91/414/EC but little guidance on how to evaluate the risks
- exposure to dusts
- issue of rotational crop
- systemic properties and guttation droplets



# ICPBR working group on systemic compounds used through soil/seed treatments

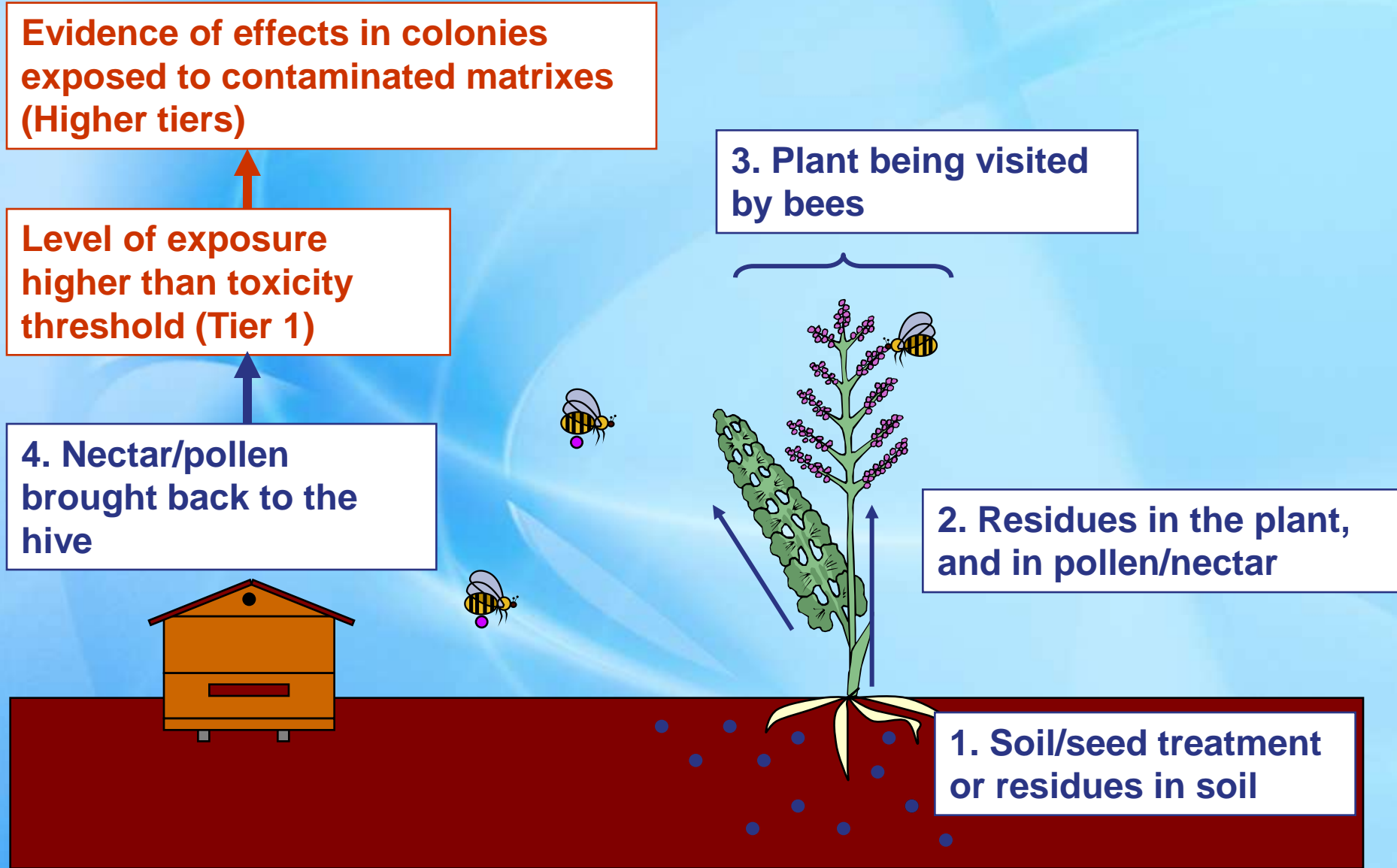
**Who :** Anne Alix (AFSSA – DiVE), Sophie Duchard (AFSSA – DiVE), Marie-Pierre Chauzat (AFSSA), Helen Thompson (CSL), Mark Miles (Dow Agrosciences), Christian Maus (Bayer CropScience), Ed Pilling (Syngenta), Gavin Lewis (JSC International), Klaus Wallner (University Hohenheim)

**Aim:** complete the current risk assessment scheme (EPPO) based on available data, for the assessment of risks from an exposure to systemic soil/seed treatments.

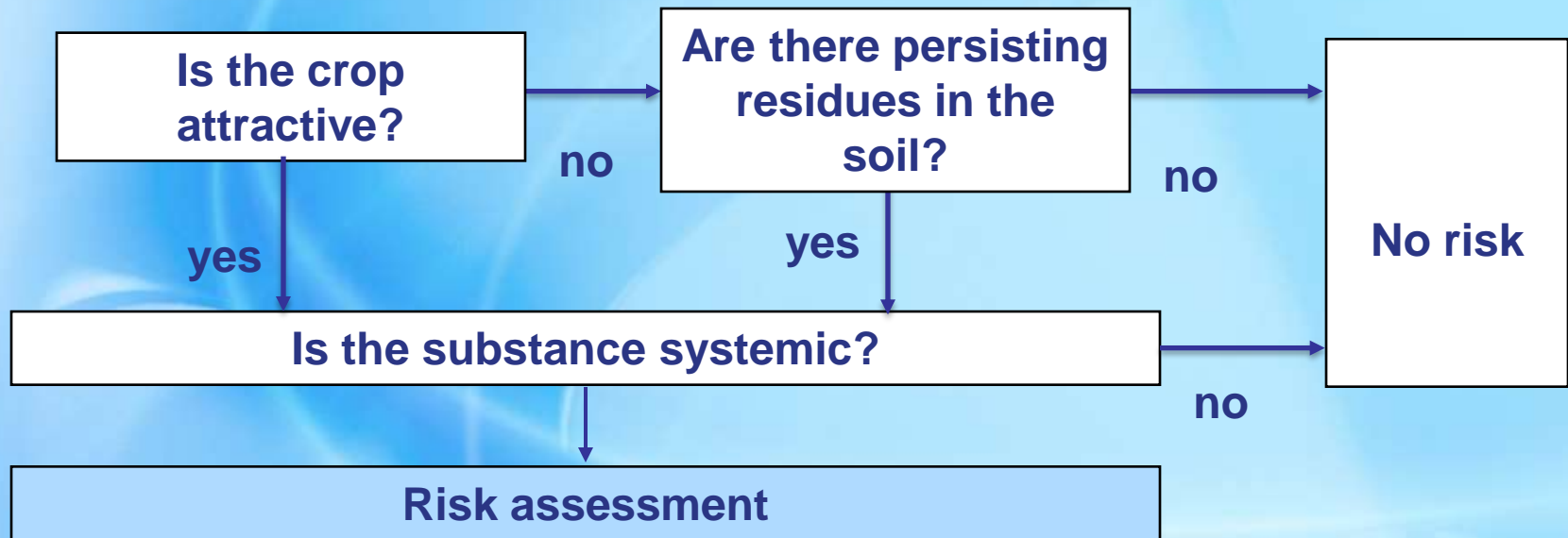
**Three meetings:** May 2006, January 2007 and November 2007.

**Output:** guidance document EPPO (chapter 10) amended on the issue of soil/seed treatment

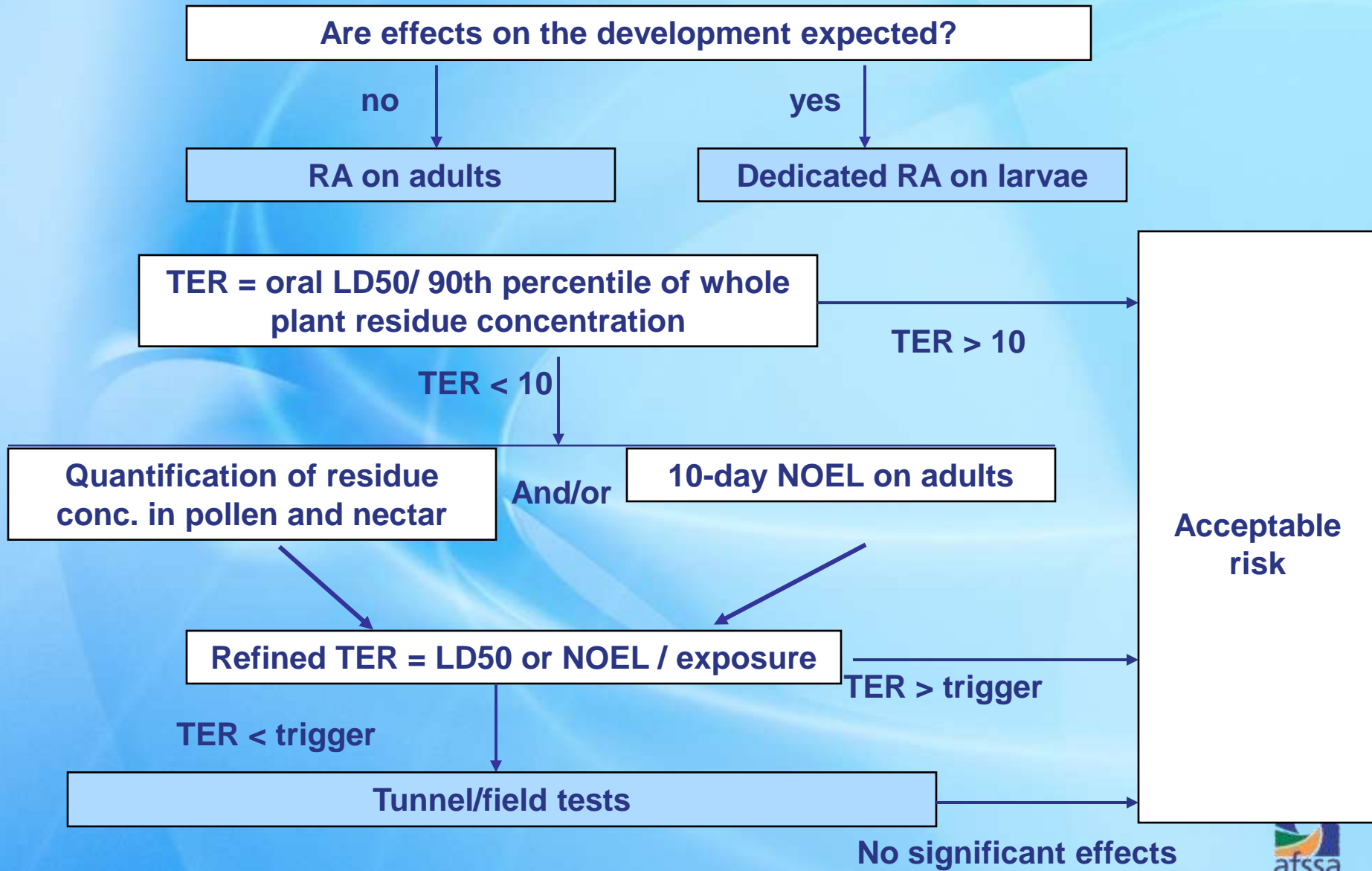
# Reasoning: conditions for a **risk** to bees



# Risk assessment



# Risk assessment



# Methodology

**Review of available data on:**

- Attractive plants**
- Residues in plants from soil/seed treatments**
- Predictability of systemic properties**
- Predictability of concentrations in nectar/pollen**
- Degradation of residues in hive matrices**
  
- Relative sensitivity of larvae compared to adults**

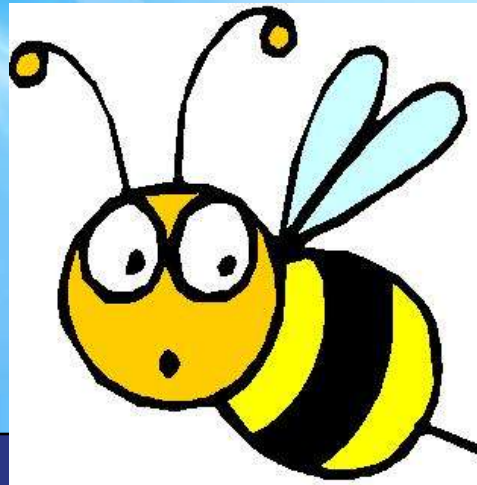
**In scientific journals, and from discussion with experts from other fields**

# Updated documents to come

- **EPPO chapter 10 (2010)**
- **Guidance document on terrestrial ecotoxicity and risk assessment (EFSA Panel)**

# Conclusions for the bees

- test guidelines are available, need for standardization
- need to distinguish the criteria that are relevant for pre-registration from the criteria that are relevant for post-registration investigations
  - on a regulatory point of view
  - on a practical point of view
  - should the risk assessment for pesticide have to cover other weakness?





### 3. Evaluating risks to other Non Target Arthropods



## Directive 91/414/EC (Annex VI point C 2.5.2.4: Specific principles for decision-making)

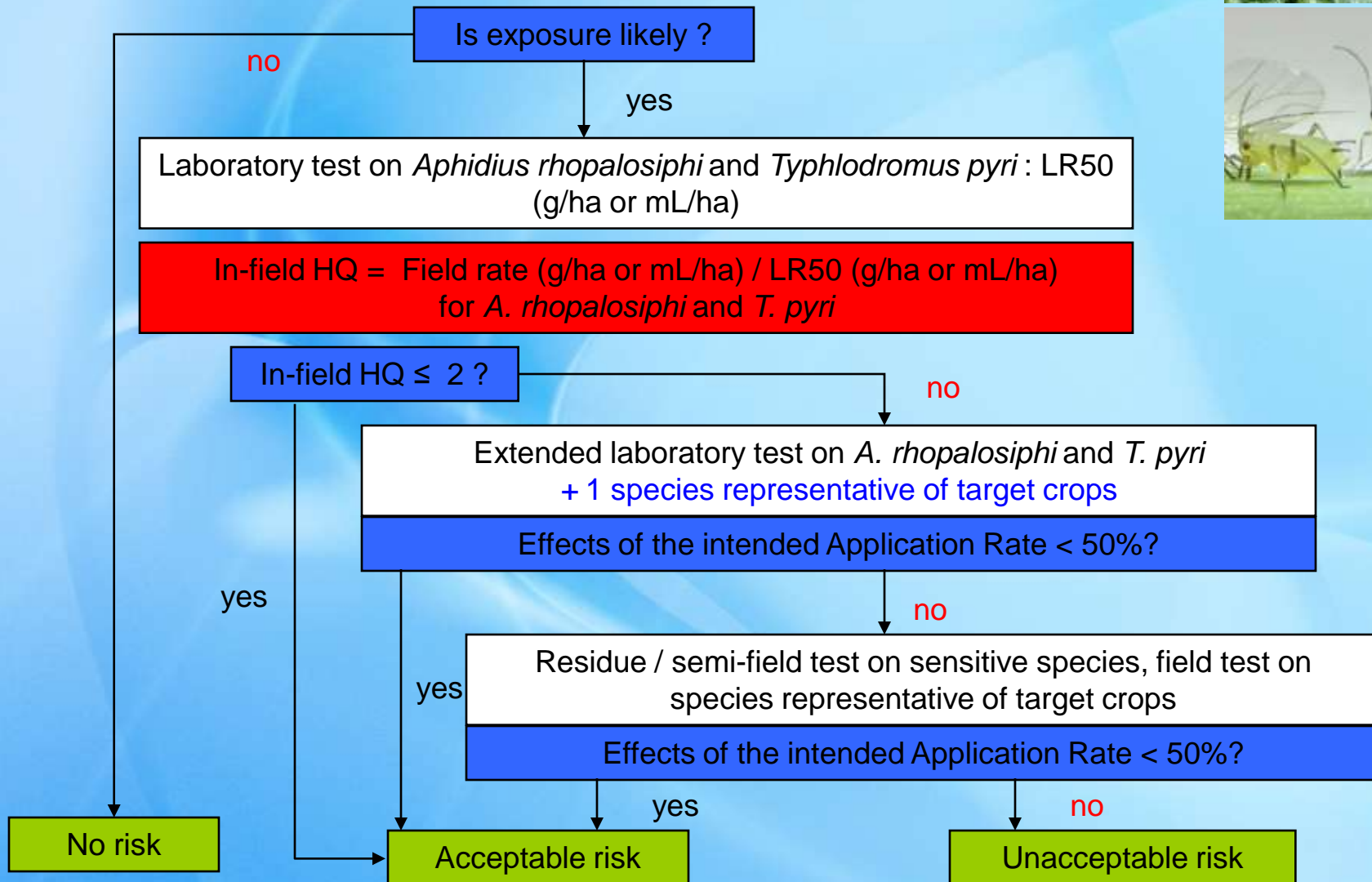
*“Where there is a possibility of beneficial arthropods other than honeybees being exposed, no authorization shall be granted if more than 30 % of the test organisms are affected in lethal or sublethal laboratory tests conducted at the maximum proposed application rate, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on those organisms after use of the plant protection product according to the proposed conditions of use. Any claims for selectivity and proposals for use in integrated pest management systems shall be substantiated by appropriate data.”*

# Criteria of effects according to Annexes II and III

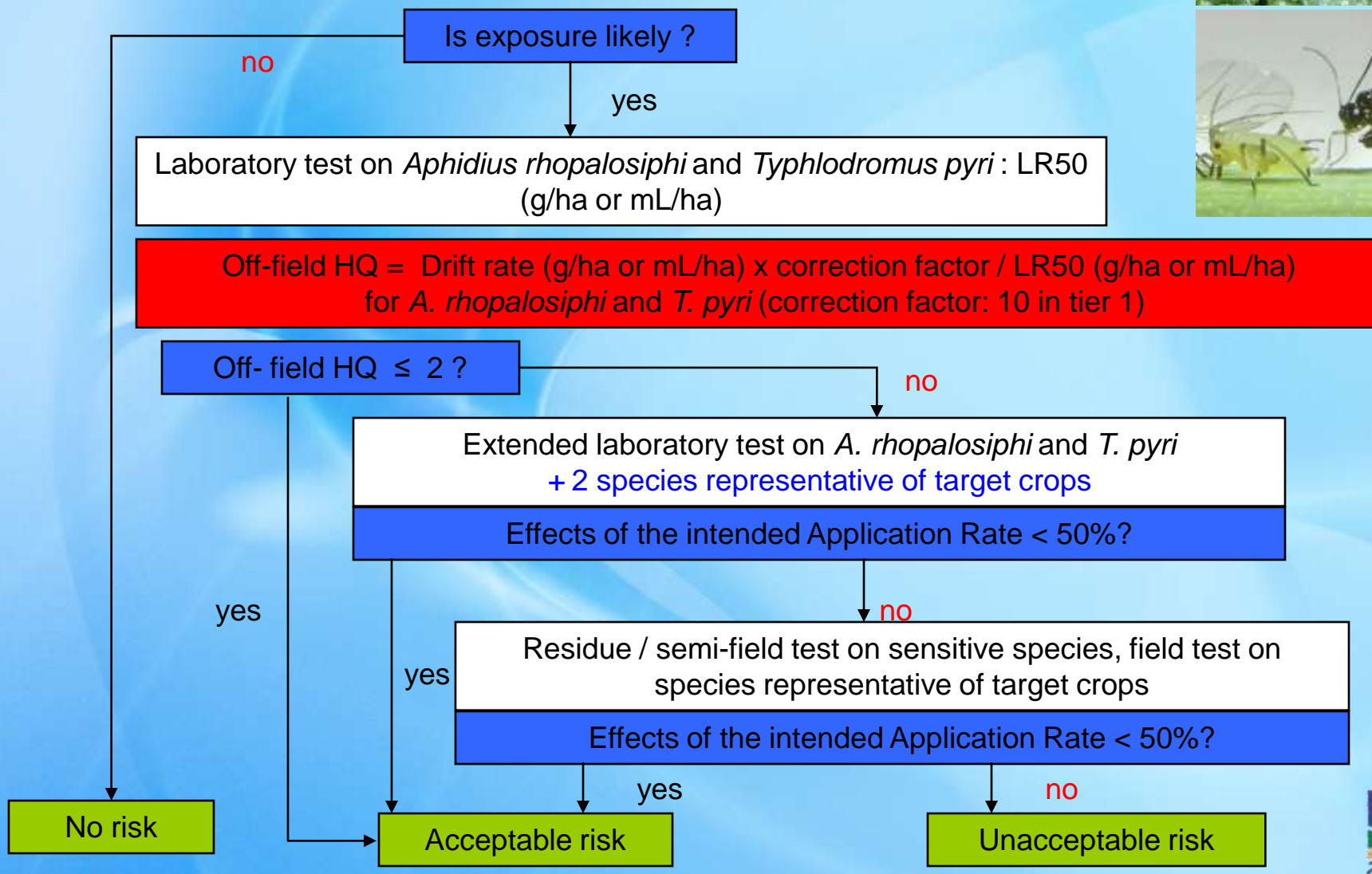
- according to Annex VI:
  - 30% effects
  - no in-field vs off-field difference
  - no mention of recovery
- according to Escort 2:
  - 50% effect
  - in-field and off-field are considered separately
  - recovery over one year or season acceptable

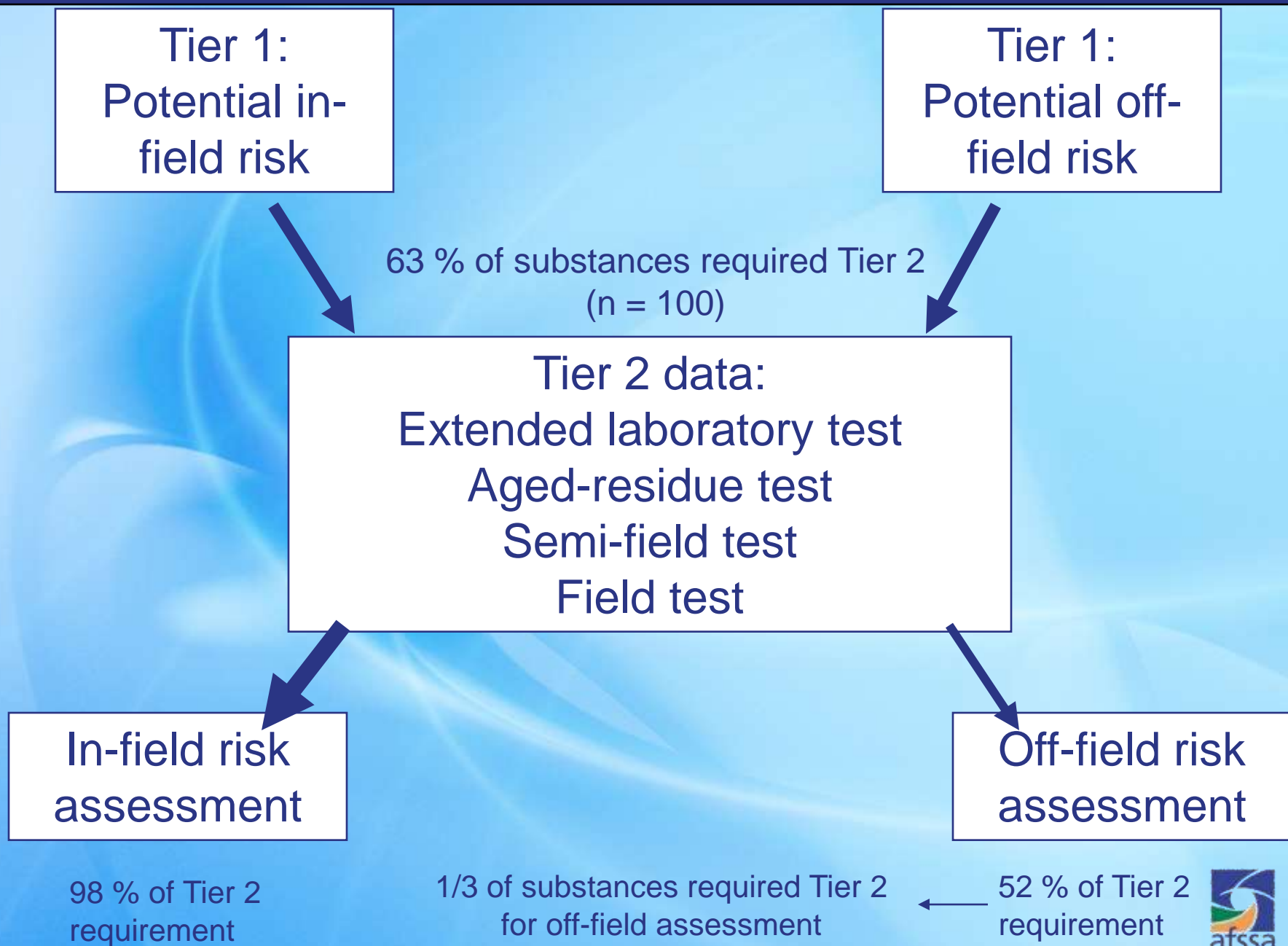
**No consistence with protection aims**

# In-field



# Off-field





**Reasons for not requiring a Tier 2 risk assessment for off-field whereas a Tier 2 risk assessment is required for in-field:**

- $HQ_{\text{off-field}} < 2$  in Tier1**
- no off-field exposure (granules, seed treatment)**

## Update the risk assessment?

- **Protection aims to be further defined**
  - in-field
  - off-field
- **Data set to be adapted to protection aims**
- **Long-term risks and recovery**



# Protection aims

- differs from in-field to off-field:
  - rather beneficial species for in-field
  - all for off-field
- phytophagous species: tests and risk considered in another section (miscellaneous - other organisms potentially at risk)
- habitats are different
- exposure conditions are different



# Data set: relevance of higher tier studies to address in-field and off-field issues

	In-field	Off-field
<b>Extended laboratory tests</b>		
Exposure mode	X	X
Tested species	X	?
<b>Aged residues tests</b>		
Exposure mode	X	X
Tested species	X	?
Tested rates	X	?
<b>Semi-field and field tests</b>		
Exposure mode	X	?
Tested species	X	?
Tested rates	X	X

# Long-term effect and recovery: example

- Tier 1 risk unacceptable in- and off-field:  
    **HQ<sub>in-field</sub> = 508-1250**  
    **HQ<sub>off-field</sub> = 80-197**
- Aged residue tests indicate a residual toxicity at field application rate (250 g a.s./ha) over 21 days (effects < 50% after 21 days)
- Two field studies in orchard performed at 46.5 and 39 g a.s./ha indicate effects > 50%, recovery after *c.a.* 140 days
- Off-field risk assessment based on the field studies, as the tested rate in field studies  $\cong$  27 g a.s./ha (drift rate at 10 m)

## Conclusion:

“effects are observed at the field rate residual toxicity shouldn't last more than 21 days. A recolonisation is expected. The product, applied up to 46.5 g a.s./ha did not have any significant effects on non-target arthropod populations and the in- and off-field risk in orchard is also acceptable, provided that a buffer zone of 10 meters is recommended” .

## In fact:

**Acceptable effects were observed on field populations at a rate corresponding to 10 meters from the treated area after c.a. 140 days**

- is this extrapolable to off-field populations?
- is a recovery period of 140 days acceptable off-field?
- what does it mean for the potential for recovery of in-field populations?
- for in-field populations recovery from off-field area, the residual toxicity over 21 days has to be considered, which is not in accordance with the 140 days needed for a recovery at the off-field rate

# Long-term effects and recovery

- **recovery and recolonisation usually investigated under field conditions**
- **potential for recolonisation may be investigated from residual toxicity studies**
- **recovery from recolonisation implies acceptable effects off-field**

**In-field and off-field are related by the consideration of short-term effects provided recovery and recolonisation occur**

**As a consequence, off-field arthropods should be protected to also ensure an in-field recovery**

# Updated documents to come

- **Escort 3**
- **Guidance document on terrestrial ecotoxicity and risk assessment (EFSA Panel)**

# Conclusions for Non Target Arthropods

- the risks in-field may be assessed based on current data requirements (sensitive laboratory species, guidelines available for semi-field and field tests)
- the risk off-field is currently more problematic as:
  - many extrapolations are needed from in-field to off-field
  - leads the recovery issue
- increasing the number of studies is not necessary, an upgrade of existing test guidelines with off-field specific topics could be sufficient



# Conclusions

- there is a need to amend protection aims for non target arthropods (including bees)
- need to check whether data set are adapted to fulfill the protection aims
  - test guidelines available
  - might need adaptations (other uses, off-field issue...)
- role of modelling in evaluating recovery potential?



# Thank you for your attention

