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Pesticide risk assessment for bees in the European Union

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EU regulatory system for pesticides

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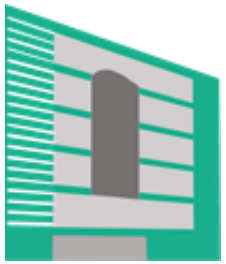
Risk assessment **Risk management**

Actors



EFSA

EU Commission

Regulations

Regulation No 1107/2009 → Authorisation of active substances and PPP (Plant Protection Products)

Regulation (EC) No 396/2005 → Regulation on maximum residue levels in food (MRL)

Directive 2009/128/EC → Sustainable use directive

Directive 2008/105/EC | Directive 2013/39/EU → Environmental Quality Standard (water env.)

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Approval of active substances (Regulation 1107/2009)

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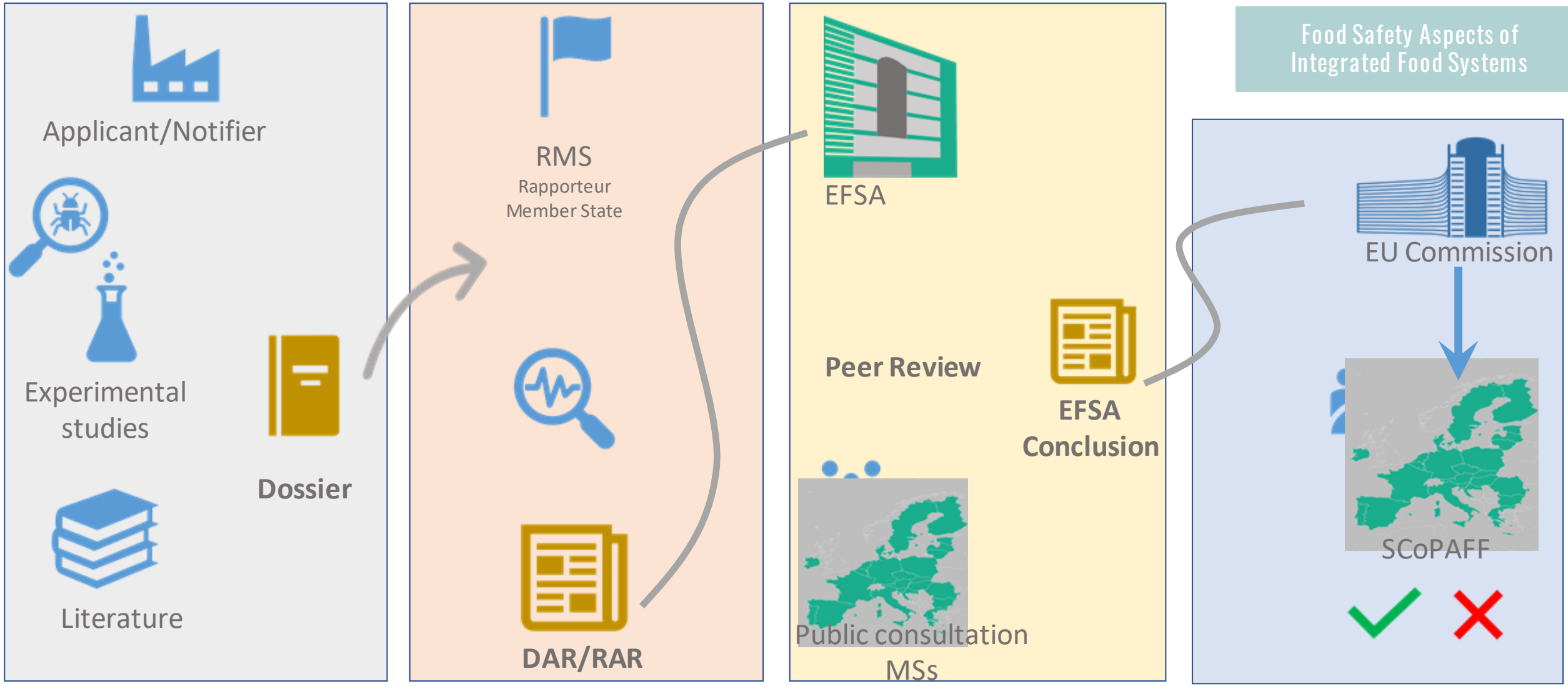

Risk, Hazard, Exposure

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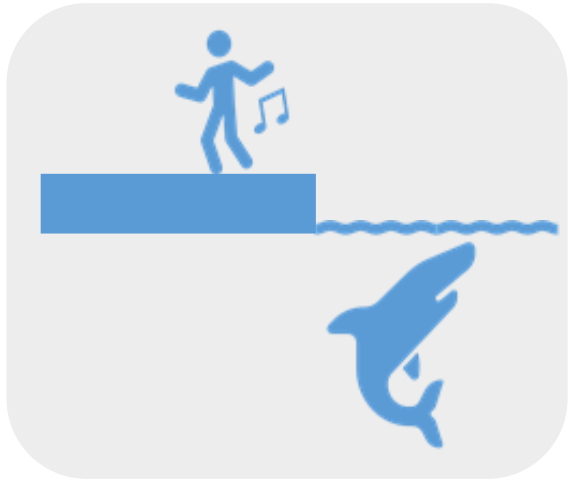
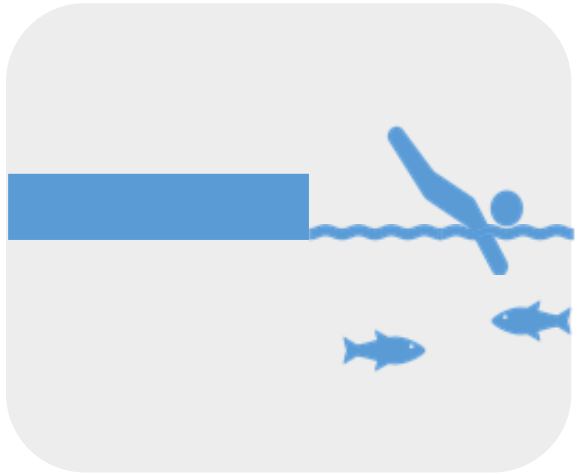
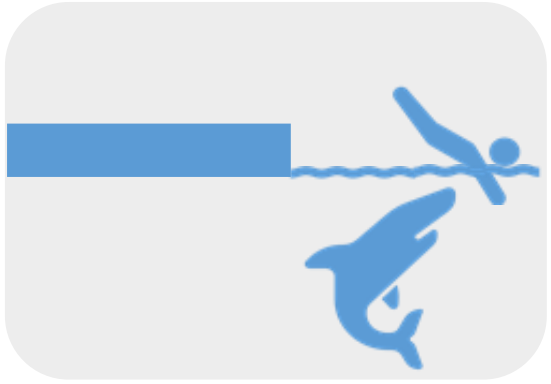


High hazard, no exposure = **low risk**



Low hazard, exposure = **low risk**



High hazard, exposure = **high risk**

A hazard is something that has the potential to harm

Risk is the likelihood of a hazard causing harm

Risk is always determined by both **hazard** and **exposure**

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Risk assessment in ecotoxicology

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"Dosis sola facit, ut venenum non fit."

"Everything is a poison, nothing is a poison. It is the dose that makes the poison"

Risk is assessed by comparing the **hazard** and the **exposure** that is likely to occur in the environment

Hazard is expressed as a function of the exposure (increasing exposure determines increasing harm) =>Dose-response relationship

Exposure the predicted environmental concentration/quantity

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Risk assessment of pesticides for bees: the evolution

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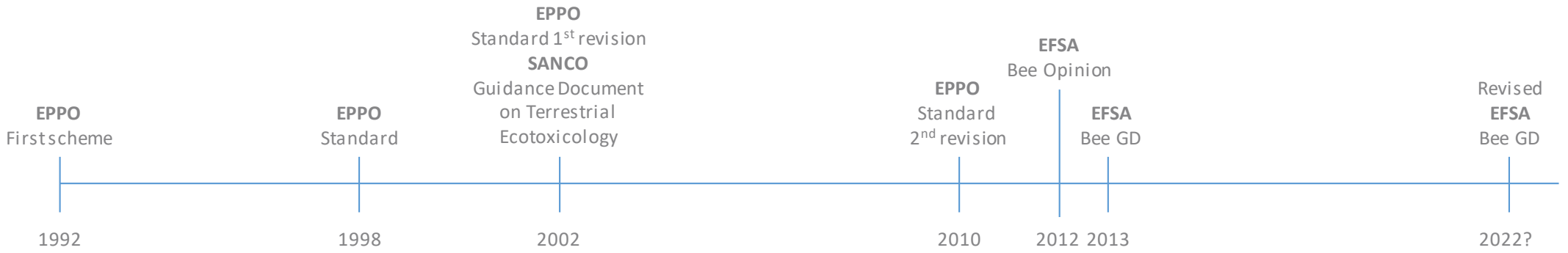
Risk assessment frameworks



- The regulation accelerated after 2008 → concerns on bee decline due to the use of neonicotinoids
- EFSA Bee GD (2013) never accepted by MSs
- Used only for some specific evaluations (e.g. Neonicotinoids, 2018)
- A revision of the EFSA Bee GD is currently ongoing

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EFSA bee guidance: three bee groups

Honey bee

- One species only in Europe (*Apis mellifera*)
- Large perennial colonies
- One egg-laying queen
- Mostly managed
- Highly structured social system
- Nests contains large reserves of food

Bumble bee

- 68 species in Europe belonging to the same genus (*Bombus*)
- Small annual colonies
- One egg-laying queen that overwinters
- Mostly wild
- Eusocial, but with limited structure
- Limited food storage in the nest

Solitary bee

- ~ 1900 species in Europe
- Taxonomically diverse group
- Not eusocial (no colonies)
- All females lay (a limited number of) eggs
- Mostly wild
- Provision nests only once

The principles of the tiered assessment

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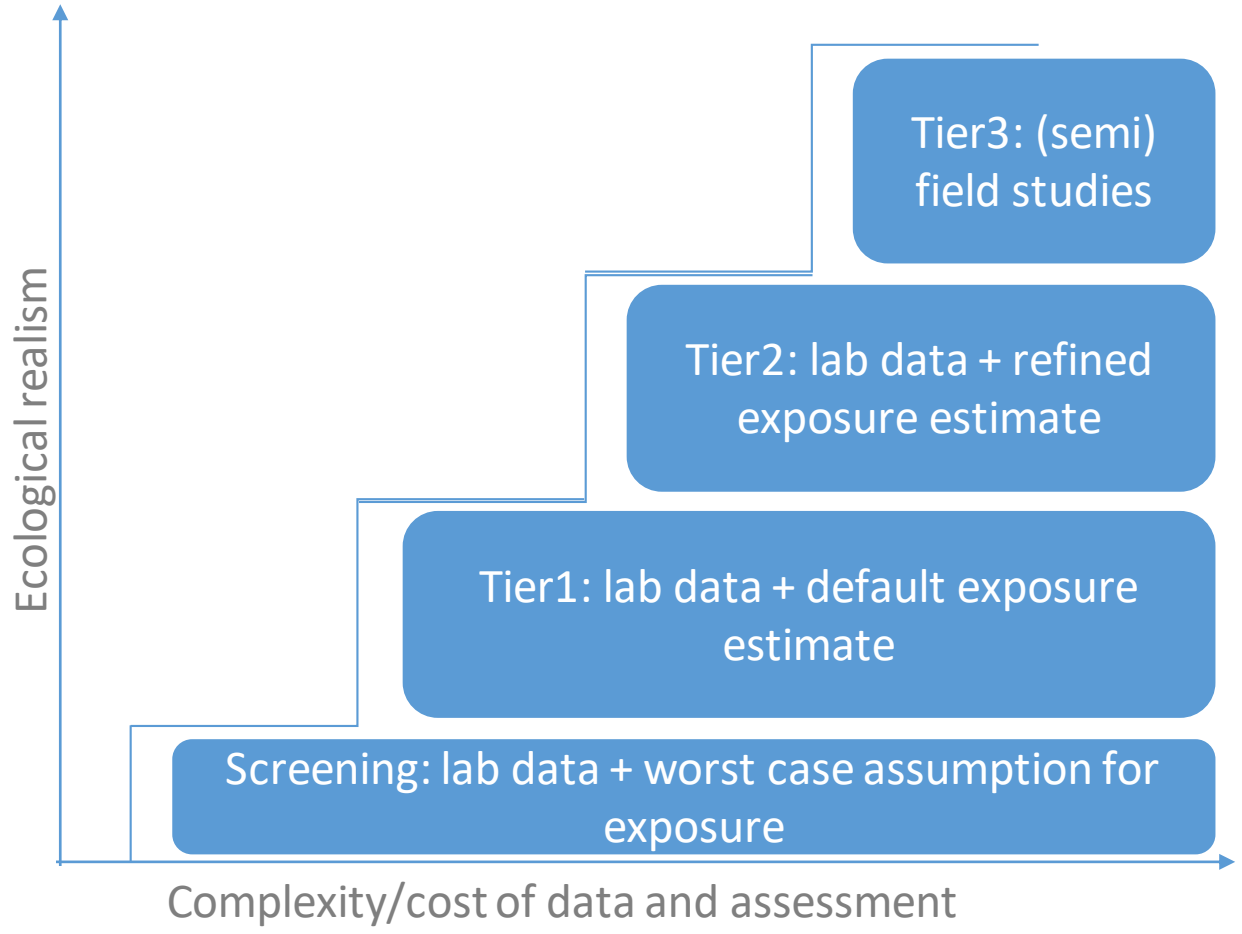

Every assessment starts from the bottom and only moves to the next step if a potential for high risk is identified.

Main principle: the more likely that a certain use of a substance is safe, the less data and assessments are required.

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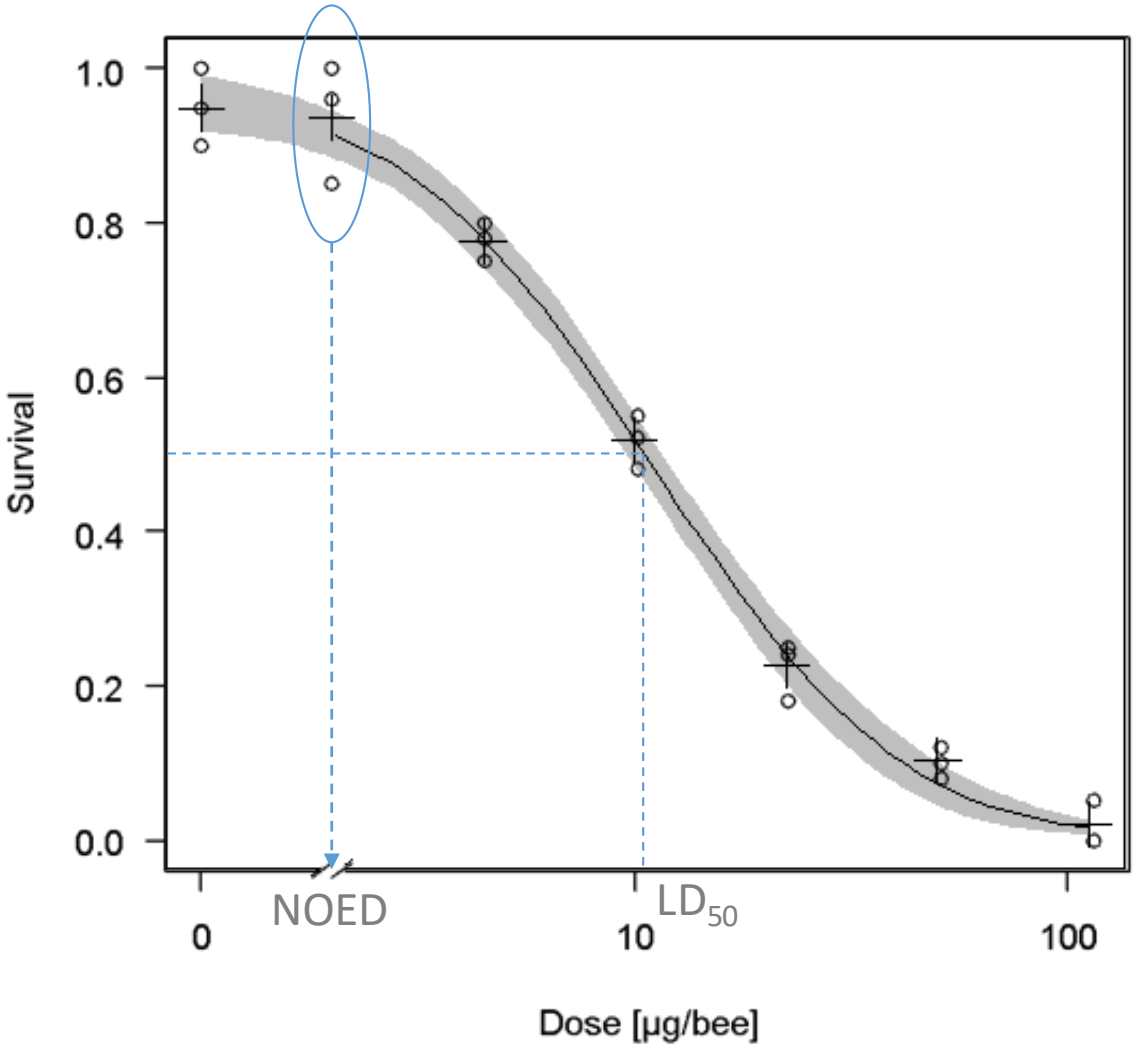
Hazard characterisation: lab studies

- Acute oral toxicity test for honey bees (OECD 213)
- Acute contact toxicity test for honey bees (OECD 214)
- Chronic oral toxicity test for honey bees (OECD 245)
- Honey Bee Larval Toxicity Test following Repeated Exposure (OECD GD 239)

- Acute oral toxicity test for bumble bees (OECD 247) – *B.terrestris*
- Acute contact toxicity test for bumble bees (OECD 246) – *B.terrestris*

- Young bees are collected and kept in cages; larvae are kept in grafting cells
- 3 batches of 10 bees per tested concentration
- At least 5 concentration levels
- Bees are fed with contaminated sugar solution (oral) or a drop of the solution containing the substance is applied to the thorax of the bee (contact)
- Validity is linked to the survival of control bees above certain thresholds and to the sensitivity of the system checked with a toxic standard

Hazard characterisation: dose-response



- At the end of the test, the number of bees still alive at every dose group is counted
- The maximum dose showing no significant survival decrease compared to the control is the NOED (No Observed Effect Dose)
- A sigmoidal model is fitted to the survival at each dose
- The dose corresponding to the expected 50% mortality is the LD_{50} (Lethal Dose for 50% of individuals) in the acute tests or the LDD_{50} (Lethal Daily Dose for 50% of individuals) in chronic tests

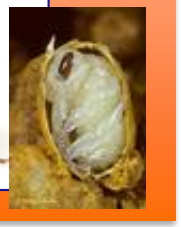
Environmental exposure: Sources of Exposure

Environmental exposure: routes of exposure

Type of exposure	Type of effect	Who is exposed
❑ Contact	❑ Acute	❑ Honey bees ❑ Bumble bees ❑ Solitary bees ❑ Adult ❑ Larvae
❑ Dietary	❑ Acute ❑ Chronic ❑ Sublethal	

Honeybee


Bumble bee

Solitary bee


Exposure estimate: contact

- The exposure model for contact is very simple
- Assumes that the amount of substances that a bee will enter in contact with is only proportional to:
  - The application rate (mass of substance per area)
  - The fraction of the application rate that is deposited on the target surface

$$Exposure = Application\,rate * f_{dep}$$

f_{dep} = 1 in-field and <1 off-field (dust/spray) drift

Exposure estimate: oral (pollen and nectar)

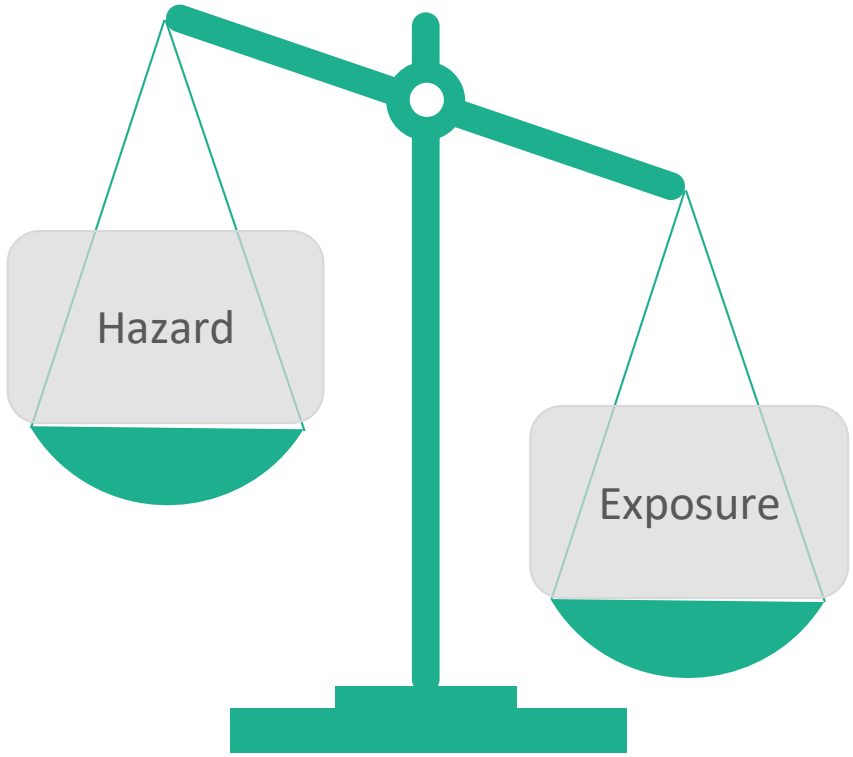
- The exposure model for oral is more complex
- It considers:
  - The application rate (*AR*)
  - An exposure factor (*Ef*, similar to the f_{dep})
  - A Time-Weighted Average factor (*fTWA*, only applicable to chronic exposure), which accounts for the dissipation of the chemical in time
  - The residues on pollen and nectar of the chemical (*RUD* = Residues per Unit Dose)
  - The standard consumption of pollen ($CONS_p$) and sugar ($CONS_s$)
  - The sugar content of nectar (m_s)

$$Exposure = AR * Ef * fTWA * SV$$

$$SV = \frac{RUD_p * CONS_p + RUD_n * \frac{CONS_{sugar}}{m_s}}{1000}$$

Risk characterisation

- The principle of the risk characterisation is always the comparison of the predicted **exposure** in the environment and the **hazard** (i.e. the concentration triggering a certain known effect)
- Such comparison is always performed via a simple ratio, generally called risk quotient
- The risk quotient can be called ETR (Exposure/Toxicity Ratio) or TER (Toxicity/Exposure Ratio). ETR is equivalent to HQ (Hazard Quotient)



The concept of Specific Protection Goal

Regulation 1107 gives a **General protection goal**: *'no unacceptable effects on environment, ecosystems, biodiversity'*

=>Specific Protection Goals (SPGs) based on ecosystem services.

Require the definition of 5 dimensions:

Dimension	Bees (EFSA, 2013)
Ecological entity	colonies for honey bees and bumble bees, population for solitary bees
Attribute	colony strength/population abundance (=number of adult bees)
Spatial scale	edge of the field
Temporal scale	not explicitly defined (=any time)
Magnitude of acceptable effects	<10%

Risk characterisation: trigger values

$$Risk = \frac{Hazard\ (e.g.\ LD_{50})}{Exposure\ (e.g.\ daily\ dose)}$$

Possible interpretation:
If predicted exposure < the hazard (i.e. LD_{50} , LDD_{50}) → the pesticide is likely not killing 50% of the bees in the field

- This interpretation:
  - Does not account for colony/population dynamics
  - It doesn't help addressing whether protection goals have been maintained
- The risk characterisation needs a "reference point" to make explicit whether the specific protection goal is met or not
- This reference point is a set of trigger values, that the risk quotient is compared to
- The trigger values translate standard endpoints (e.g. LD50, LDD50) into effects on colony strength/population abundance, considering the predicted exposure

Risk Quotient < trigger =>low risk
Risk Quotient>trigger => high risk

Risk characterization: a practical example

Use	Value
Oilseed rape (OSR), BBCH 50-70	200 g/ha = 0.2 kg/ha

Endpoint	Value
Acute contact LD50	57 µg a.s./bee
Acute oral LD50	75 µg a.s./bee
Chronic oral LDD50	8 µg a.s./bee/day
Larvae NOED	55 µg a.s./larva/dev. period

Treated field scenario

Contact (acute)

Exposure = AR * fdep = 200

Risk (HQ=ETR) = 200/57 = 3.5

Trigger = 42

HQ<Trigger → **Low risk**

Oral (acute)

Exposure = AR [kg/ha] * Ef * fTWA * SV =

0.2*1*7.6*1 = 1.52

Risk (ETR) = 1.52/75 = 0.02

Trigger= 0.2

ETR<Trigger → **Low risk**

Risk characterization: a practical example

Use	Value
Oilseed rape (OSR), BBCH 50-70	200 g/ha = 0.2 kg/ha

Endpoint	Value
Acute contact LD50	57 µg a.s./bee
Acute oral LD50	75 µg a.s./bee
Chronic oral LDD50	8 µg a.s./bee/day
Larvae NOED	55 µg a.s./larva/dev. period

Treated field scenario

Oral (chronic)

Exposure = AR [kg/ha] * Ef * fTWA * SV =

0.2*1***5.8***0.72** = 0.835

Risk (ETR) = 0.835/8 = 0.104

Trigger= 0.03

ETR>Trigger → **High risk**

Larvae

Exposure = AR [kg/ha] * Ef * fTWA * SV =

0.2*1***4.4***0.85** = 0.748

Risk (ETR) = 0.748/55 = 0.01

Trigger= 0.2

ETR<Trigger → **Low risk**

Tier 2 - Exposure refinement

- If at the tier1 a high risk cannot be excluded, more data are needed
- One possibility is to refine the residues in pollen and nectar following the specific use of the substance
  - Residues can be measured from pollen and nectar sampled directly from the treated plants (worst-case) or let bees sample and then 'steal' samples from them (landscape dilution can occur)
  - If the second method is used, the results are species-specific
  - For avoiding best-case situations, other alternative food sources should be kept minimal (e.g. no bee attractive crop in a 2 km radius)
  - At least 5 independent trials
- Another possibility is to refine the half-life of the substance being investigated

Tier 3: higher tier studies

- Tier 3 (higher tier) studies are characterised by:
  - a high degree of ecological realism
  - a high cost
  - a high complexity in terms of results
- If the exposure is appropriate, they can be immediately use to estimate the risk
- There are three main types of higher tier studies:
  - Semi-field (tunnel) studies
  - Feeder studies
  - Field studies

Tier 3: semi-field studies

Principles

- Bees (hive/nesting units) are released into a tunnel where the only source of food is the treated crop
- The crop is generally treated beforehand
- It is often performed with bee-attractive crops

Disadvantages

- Bees (especially honey bees) are stressed
- Cannot last more than a few days (<10)
- Can only use small hives/nests

Advantages

- It requires a limited area per independent replicate
- Exposure is worst-case (more likely to be in line with the exposure assessment goal)

Tier 3: feeder studies

Principles

- Bees (hive/nesting units) are in proximity of a feeder, generally containing contaminated sugar syrup
- It can be coupled with contaminated pollen pellets
- Sometimes the feeder is within the hive structure
- It is often performed in absence of significant alternative food sources

Disadvantages

- It alters the normal foraging behavior of bees
- Energetic balance is unnatural
- Effects on some sub-lethal effects can be masked

Advantages

- Very good control on exposure levels
- Several doses can be tested (dose-exposure relationship at the colony level)
- Does not need big areas

Tier 3: field studies

Principles

- Bees (several hive/nesting units) are in proximity of a treated field, during the bloom of the crop
- Treatment may happen during bloom or before, according to the intended use
- It is often performed in absence of significant alternative food sources

Disadvantages

- Many potential confounding factors
- Exposure may be substantially less than the goal
- Requires large areas for replication

Advantages

- The highest possible level of realism
- Immediately interpretable as quantification of risk
- Monitoring can last very long time

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