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Proposals for registration criteria (safety factors) and risk classification criteria

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Proposal Registration Criteria (safety factors) and criteria for risk classification Ethiopia for each protection goal

- Registration criteria based on the EU (safety factors)
- Criteria for risk classification based on an estimation of low risk, possible risk and high risk
- Protection goals as selected for Ethiopia:
  - surface water as source of drinking water
  - groundwater as source of drinking water
  - aquatic ecosystem
  - birds
  - bees
  - non-target arthropods
  - earthworms
  - non-target terrestrial plants

Registration criteria and criteria for risk classification

For each protection goal proposals for:

- Exposure
- Toxicity
- Registration criteria (safety factors; based on the EU)
- Criteria for risk classification (ETR approach):

ETR < 1/safety factor	→ low risk
1/safety factor ≤ ETR ≤ X	→ possible risk
ETR > X	→ high risk

Registration criteria and criteria for risk classification

- Low risk: acceptable and registration possible
- Possible risk: uncertainty about risk
  - take into account assessments of other countries (e.g. EU (EFSA conclusions)
  - if risk reduction measures are possible, they should be applied

- High risk: not acceptable, unless sufficient risk reduction measures can be applied

Criteria for risk classification

Where are choices for factor X (risk classification) based on?

- Depends on type of organism:
  - vertebrates (fish, birds) have a higher protection level than non-vertebrates (dead birds and fish are not desired)
  - organisms which can reproduce fast have a higher ability of recovery after suffering from effects
- Depends also on how conservative the first tier assessment is (e.g. safety factor of 100 for aquatic invertebrates is quite strict; exposure calculation may be conservative)

Criteria for risk classification

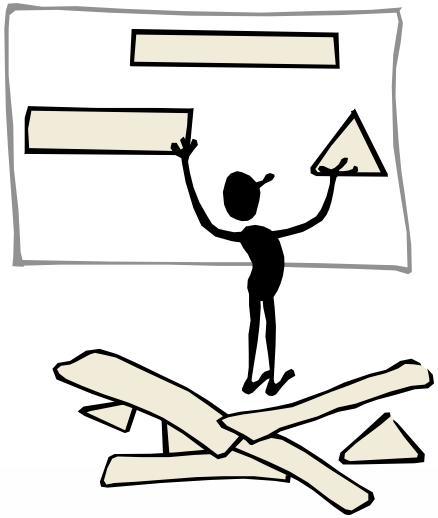
- The economic consequences are also taken into account (which % of pesticides will have a high risk and maybe have to be banned)
  - a rough estimate has been made based on experience, but this is a topic for further research
- Some choices for factor X are not so easy to underpin, but are more a gut feeling

- It could be that some choices must be adjusted, based on further analysis and experiences in practice

Registration criteria and criteria for risk classification

- Only **proposals** are presented here!

- The proposals should be discussed here at the workshop and **you** must make the final choices for registration criteria and risk classification criteria!!!!!



Surface water as source of drinking water

Proposal

- Where? At drinking water abstract points
- How strict? Based on human toxicity values (ADI-approach)
- Exposure: PECsw at drinking water abstract points (PECsw-dw): see surface water models Alterra
- Toxicity: Drinking Water Standard (DWS): based on ADI (Acceptable Daily Intake)

$$DWS = \frac{ADI * bw * P}{ConsWater}$$

ADI = Acceptable Daily Intake (mg/kg * d)
(safety factor of 100 included)
bw = body weight (60 kg for adults)
P = fraction of the ADI allocated to drinking water (DF = 0.1)
ConsWater = daily drinking water consumption (DF = 2 L for adults, L/d)

Surface water as source of drinking water

Risk assessment:

$$ETR_{sw\text{-}dw} = \frac{PEC_{sw\text{-}dw}}{DWS \times 1000}$$

(1000 = factor to correct from ug/L to mg/L)

$ETR_{sw\text{-}dw} < 1$	→ low risk
$1 \leq ETR_{sw\text{-}dw} \leq 10$	→ possible risk
$ETR_{sw\text{-}dw} > 10$	→ high risk

- Because a high safety factor is used to derive the ADI (factor 100) an exceedance factor of 10 is still considered relatively safe)

Groundwater as source of drinking water

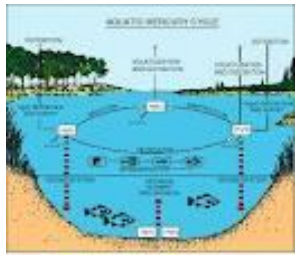
Proposal

- Where: at 10 m depth
- Exposure: see groundwater exposure models Alterra
- Toxicity: see surface water as source of drinking water

$$\text{ETR gw-dw} = \frac{\text{PECgw-dw}}{\text{DWS} \times 1000}$$

ETRsw-dw < 1	→ low risk
1 ≤ ETRsw-dw ≤ 10	→ possible risk
ETRsw-dw > 10	→ high risk

Aquatic ecosystem



What? Populations of aquatic species

Where? (temporary) lakes, streams, rivers, storage reservoirs

How strict? Sustainability of aquatic ecosystems should be ensured.
Therefore, survival and reproduction of the most sensitive aquatic species should not, or only briefly, be affected

- Exposure: PECsw (see surface water models Alterra)
  - PECmax for acute risk assessment
  - PECmax or PECtwa for chronic risk assessment

- Toxicity:
  - acute LC50 (fish) and EC50 (algae, invertebrates, macrophytes)
  - chronic NOEC (fish and invertebrates)

Aquatic ecosystem

Safety factors used in the EU:

- acute LC50 fish: 100
- acute EC50 invertebrates: 100
- EC50 algae and macrophytes: 10
- chronic NOEC fish: 10
- chronic NOEC invertebrates: 10

Risk assessment

1. Fish (vertebrates: higher protection level)

- Acute
  ETRfish-ac < 0.01 → Low risk
  0.01 ≤ ETRfish-ac ≤ 0.1 → Possible risk
  ETRfish-ac > 0.1 → High risk

Aquatic ecosystem

- Chronic fish

2 options:
a) Use of PECmax

ETRfish-chr < 0.1	→ Low risk
0.1 ≤ ETRfish-chr ≤ 1	→ Possible risk
ETRfish-chr > 1	→ High risk

b) Use of PECtwa

ETRfish-chr < 0.1	→ Low risk
0.1 ≤ ETRfish-chr ≤ 0.5	→ Possible risk
ETRfish-chr > 0.5	→ High risk

Aquatic ecosystem

2. Invertebrates

- Acute
  ETRinv-ac < 0.01 →Low risk
  0.01 ≤ ETRinv-ac ≤ 1 →Possible risk
  ETRinv-ac > 1 → High risk

- Chronic
  2 options:
  a) Use of PECmax
  ETRinv-chr < 0.1 →Low risk
  0.1 ≤ ETRinv-chr ≤ 10 →Possible risk
  ETRinv-chr > 10 → High risk

Aquatic ecosystem

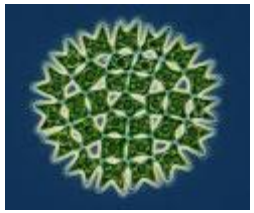
b) Use of PECtwa

ETRinv-chr < 0.1	→Low risk
$0.1 \leq$ ETRinv-chr ≤ 1	→Possible risk
ETRinv-chr > 1	→ High risk

3. **Algae**

- no distinction between acute and chronic; use of PECmax

ETRalg < 0.1	→Low risk
$0.1 \leq$ ETRalg ≤ 10	→Possible risk
ETRalg > 10	→ High risk



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Aquatic ecosystem

4. **Macrophytes (Aquatic plants)**

- no distinction between acute and chronic; use of PECmax

ETRmac < 0.1	→Low risk
0.1 ≤ ETRmac ≤ 1	→Possible risk
ETRmac > 1	→ High risk

Bees

Protection:

- What? Beehives of honeybees
- Where? Everywhere
- How strict? No long-term effects on beehives of honeybees

- Note that only honey bees are assessed, no wild bees. Assumption is that the assessment of honeybees will also cover the wild bees.

- From literature it is likely that the western honeybee is reasonably representative for the African honeybee, but this comparison is only based on one compound.

- For the time being only sprays are taken into account.

Bees

Exposure:
- in-crop: single dose rate (g as/ha)
- off-crop: single dose rate (g as/ha) * drift factor

Toxicity: LD50 (µg/bee)

Safety factor: same as in the EU: 50

Risk assessment:

ETRbee < 50	→ Low risk
50 ≤ ETRbee ≤ 400	→ Possible risk
ETR > 400	→ High risk

Bees

- Validation of registration criteria: empirical
  - assessment of observed bee kills/colony effects for various pesticides and different application rates
  - two studies with UK data (Mineau et al., 2008)

- No field incidents at ETR < 50
- About 50% probability of hive mortality at ETR > 400

- No compliance with the criteria almost always leads to risk management, not refusal of registration.

Non-target arthropods

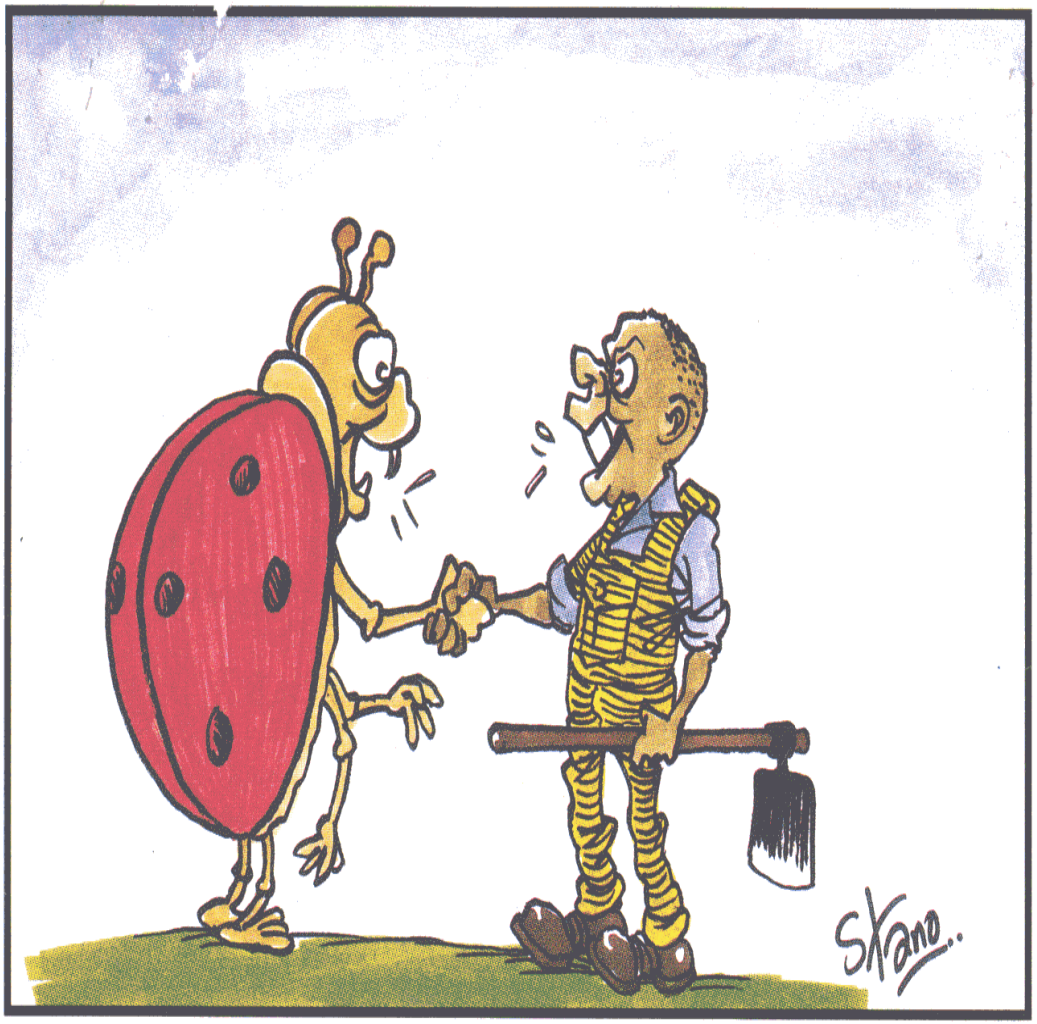
Very important in relation to Integrated Pest Management (IPM)

Protection:
- What? Populations of non-target arthropods
- Where? In-crop as well as off-crop
- How strict? No long-term effects on populations of non-target arthropods

Exposure
- PEC (in-field): single dose rate (g as/ha) * MAF
- PEC (off-field): single dose rate (g as/ha) * MAF * drift factor

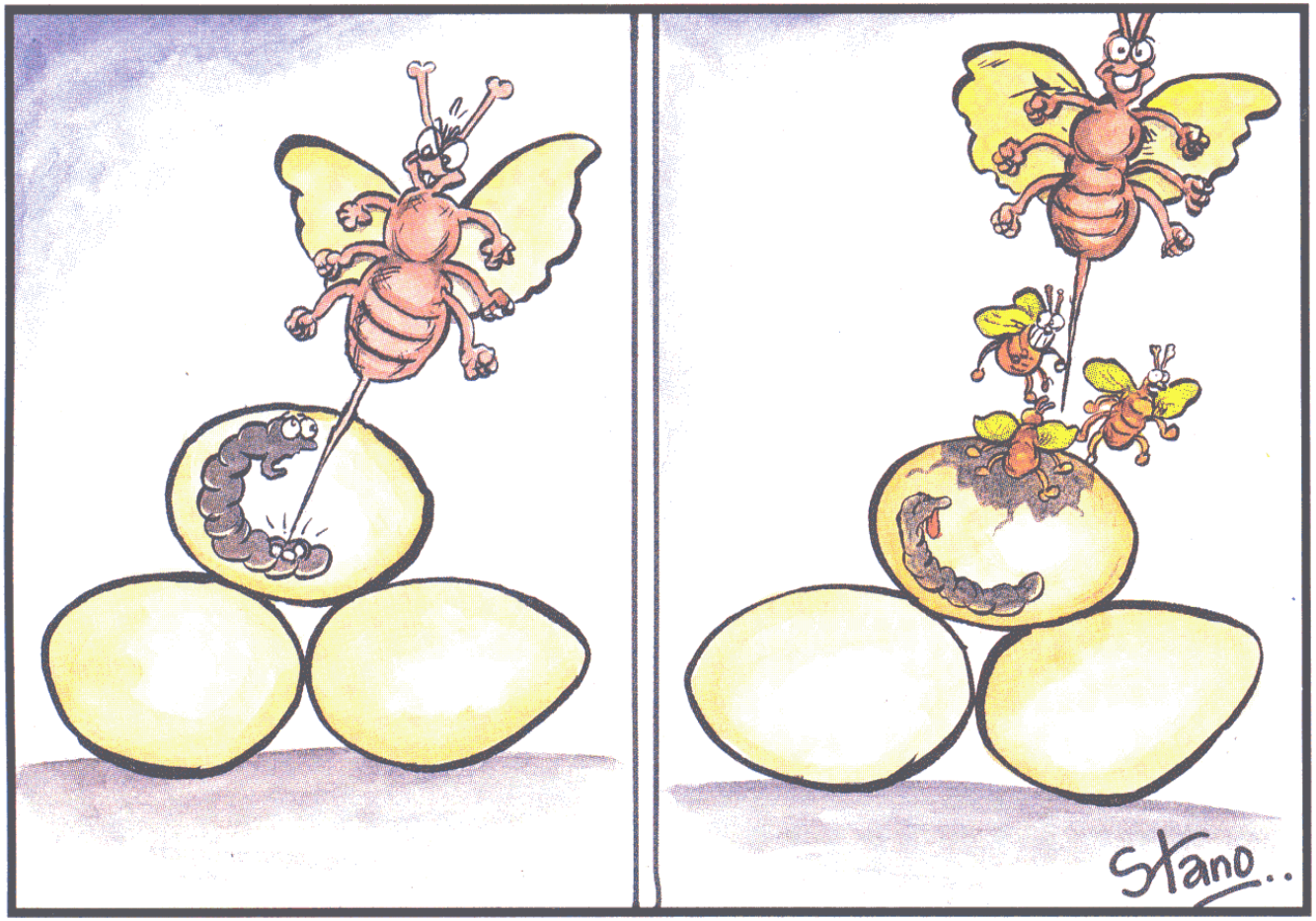
MAF: depends on the number of applications

Non-target arthropods



Some insects like the ladybird are farmers' friends because they kill pests

Non-target arthropods



Farmers' friends can kill a pest by laying eggs in it

Wadudu marafiki wanaweza kuua kisumbufu kwa kutega mayai ndani

Non-target arthropods

Toxicity:

- glass-plate tests (lab tests) with *Aphidius rhopalosiphi* and *Typhlodromus pyri*: LR50 (g as/ha)
- Safety factor in the EU: 2 (based on empirical data)
- In a lot of cases extended laboratory tests are available (tests on natural substrate): LR50 (g as/ha)
- Safety factor in the EU: 1 (based on the criterion that less than 50% effect is acceptable)

Non-target arthropods

Risk assessment:

a) In-crop

ETRnta-glass < 2	→ low risk
2 ≤ ETRnta-glass ≤ 100	→ possible risk
ETRnta-glass > 100	→ high risk

ETRnta-ext < 1	→ Low risk
1 ≤ ETRnta-ext ≤ 50	→possible risk
ETRnta-ext > 50	→ high risk

Non-target arthropods

b) Off-crop

- Protection level off-crop is more strict, because severe in-crop effects should be compensated by recolonisation of organisms from the off-crop area

ETRnta-glass < 2 →Low risk
2 ≤ ETRnta-glass ≤ 20 → possible risk
ETRnta-glass > 20 → high risk

ETRnta-ext < 1 → Low risk
1 ≤ ETRnta-ext ≤ 10 →possible risk
ETRnta-ext > 10 → high risk

Earthworms

Protection:

What? Populations of earthworms

Where? In-field

How strict? No long-term effect on populations of earthworms

Exposure: The concentration for the within field soil compartment is calculated from the dose of the pesticide divided by the amount of soil (kg) in the upper part of the soil (default depth of upper part of the soil = 0.05 m)

Earthworms

Exposure

C_{soil} = 0.1 * M / DEPTH

C_{soil} = concentration in the upper part of the soil (mg pesticide / m^3 soil)

0.1 = correction factor to convert from g/ha to mg/m^3

M = individual dose applied (g as/ha)

DEPTH = depth of the field (default value = 0.05 m)

Earthworms

$PEC_{soil} = C_{soil} / (\rho_b * 1000)$

PEC_{soil} = concentration in the upper part of the soil from one application (in mg pesticide /kg soil)
C_{soil} = concentration in the upper part of the soil (in mg pesticide /m^3 soil
ρ_b = dry bulk density of the soil (default value = 1.0 kg /dm^3)
1000 = factor to convert from kg /dm^3 to kg /m^3

Toxicity:
- acute LC50
- chronic NOEC

Safety factors used in the EU:
- acute: 10
- chronic: 5

Earthworms

Risk assessment:

a) Acute

ETRearth-ac < 0.1 → Low risk
0.1 ≤ ETRearth-ac ≤ 0.5 → Possible risk
ETRearth-ac > 0.5 → High risk

b) Chronic

ETRearth-chr < 0.2 → Low risk
0.2 ≤ ETRearth-chr ≤ 1 → Possible risk
ETRearth-chr > 1 → High risk

Birds

Vertebrates: higher protection level

- What? Populations of non-target birds
- Where? Treated crop fields or other treated locations, i.e. no consideration of the risk at landscape level
- How strict? No individual mortality or reproduction effects

Use of indicator species for different crops in the EU (mostly small, sensitive birds)

Proposal: to use these indicator species also for the Ethiopian situation

Is this agreed? Or are there special species to be protected?

Birds

Table 1: Relevant indicator species according to crop and crop stage

Crop	Crop stage	Indicator species	Example
Grassland	-	Small herbivorous mammal - 25 g	Vole
		Large herbivorous bird - 3000 g	Goose
Cereals	Early	Small herbivorous mammal - 25 g	Vole
		Large herbivorous bird - 3000 g	Goose
	Late	Insectivorous mammal - 10 g	Shrew
		Insectivorous bird - 10 g	Wren, tit
Leafy crops	Early / late	Medium herbivorous mammal - 3000 g	Hare
		Medium herbivorous bird - 300 g	Partridge, pigeon
Orchard / vine / hops	Early / late	Small herbivorous mammal - 25 g	Vole
		Insectivorous bird - 10 g	Wren, tit
Seed treatment	-	Granivorous mammal - 25 g	Wood mouse
		Granivorous bird - 15 g	Linnet

Birds

Standard exposure scenarios for tier 1

ETE = (FIR / bw) * C * AV * PT * PD (mg/kg bw/d)

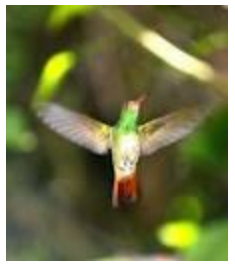
- FIR = Food intake rate of indicator species (g fresh weight per day
- Bw = bodyweight (g)
- C = concentration of compound in fresh diet (mg/kg)
- AV = avoidance factor
- PT = fraction of diet obtained in the treated area
- PD = fraction of food type in diet

Birds

In case of multiple applications or long-term considerations:

$C = C_0 * MAF * f_{twa}$

- C0 = Initial concentration after a single application
- MAF = multiple application factor
- f_{twa} = Time weighted average factor



First tier: AV, PT and PD are 1

MAF = function of number of applications, interval and DT50; in first tier for DT50 on vegetation a default value of 10 days is used

$f_{twa} = (1-e^{-kt})/kt$

k = ln2/DT50

t = averaging time

Birds

Uniform approach of the first step of the risk assessment:

- use of indicator species for the different crops and crop-stage;
- MAF values applied (based on a default DT50 value of 10 days);

- **Acute exposure**
  - residues: 90th percentile of the initial concentration;
  - special MAF-values
- **Long-term exposure**
  - mean residue values
  - twa-value over 21 days (based on a default DT50-value of 10 days) → ftwa = 0.53

Birds: Acute exposure estimate

Table 4: Standard scenarios for the acute exposure estimate

1	2	3	4	5	6	7
Crop	Crop stage	Indicator species	FIR / bw	Category	RUD (90 %)	MAF
Grassland	-	Small herbivorous mammal	1.15	short grass	142	Table 3
		Large herbivorous bird	0.44	short grass	142	Table 3
Cereals	Early	Small herbivorous mammal	1.15	short grass	142	Table 3
		Large herbivorous bird	0.44	short grass	142	Table 3
	Late	Insectivorous mammal	0.51	insects	14	n.a.
		Insectivorous bird	1.04	insects	14	n.a.
Leafy crops	Early / late	Medium herbivorous mammal	0.25	leafy crops	87	Table 3
		Medium herbivorous bird	0.76	leafy crops	87	Table 3
Orchard / vine / hops	Early / late	Small herbivorous mammal	1.15	short grass* I, F: IF=0.5	H: 142 I, F: 71	Table 3
		Insectivorous bird	1.04	insects	14	n.a.
Seed treatment	-	Granivorous mammal	0.19	seeds	n.a.	n.a.
		Granivorous bird	0.38	seeds	n.a.	n.a.

*) For insecticides (I) and fungicides (F) but not for herbicides (H) an interception factor of 0.5 is assumed

Birds: long-term exposure estimate

Table 7: Standard scenarios for the long-term exposure estimate

1	2	3	4	5	6	7	8
Crop	Crop stage	Indicator species	FIR / bw	Category	RUD (mean)	f_{twa}	MAF
Grassland	-	Small herbivorous mammal	1.15	short grass	76	0.53	Table 5
		Large herbivorous bird	0.44	short grass	76	0.53	Table 5
Cereals	Early	Small herbivorous mammal	1.15	short grass	76	0.53	Table 5
		Large herbivorous bird	0.44	short grass	76	0.53	Table 5
	Late	Insectivorous mammal	0.51	insects	5.1	n.a.	n.a.
		Insectivorous bird	1.04	insects	5.1	n.a.	n.a.
Leafy crops	Early / late	Medium herbivorous mammal	0.25	leafy crops	40	0.53	Table 5
		Medium herbivorous bird	0.76	leafy crops	40	0.53	Table 5
Orchard / vine / hops	Early / late	Small herbivorous mammal	1.15	short grass I, F: IF=0.5	H: 76 I, F: 38	0.53	Table 5
		Insectivorous bird	1.04	insects	5.1	n.a.	n.a.
Seed treatment	-	Granivorous mammal	0.19	seeds	n.a.	n.a.	n.a.
		Granivorous bird	0.38	seeds	n.a.	n.a.	n.a.

*) For insecticides (I) and fungicides (F) but not for herbicides (H) an interception factor of 0.5 is assumed

Birds

Toxicity

- acute: LD50 value from acute study
- Long-term: NOEC from reproduction study

Safety factors: same as in the EU:

- acute: 10
- Long-term: 5

Risk assessment

- Sprays
- Seeds/granules

Birds

- Sprays

  Acute

  ETRac < 0.1 Low risk

  0.1 ≤ ETRac ≤ 0.5 Risk possible

  ETRac > 0.5 High risk

  Long-term

  ETRlt < 0.2 Low risk

  0.2 ≤ ETRlt ≤ 2 Risk possible

  ETRlt > 2 High risk

- Seeds/granules

  - One seed/granule criterion: if consumption of one seed/granule is already enough to exceed the LD50/10, then there is a very high risk

Non-target terrestrial plants

A healthy terrestrial plant ecosystem is very important for all kinds of insects. These insects are important for IPM purposes and are also important as food for birds.

Protection:

What? Populations of non-target terrestrial plants off-field

Where? Along agricultural fields

How strict? No long-term effects on populations of non-target terrestrial plants off-field.

Non-target terrestrial plants

Exposure

- PEC (off-field): single dose rate (g as/ha) * MAF * drift factor

Toxicity

- Lowest ER50 from test with several plant species
- Safety factor in the EU: 5

Risk assessment

ETRntp < 0.2	→ low risk
0.2 ≤ ETRntp ≤ 2	→ possible risk
ETRntp > 2	→ high risk

- Thank you for your attention!!!