Practical examples on active substance risk assessment: Insecticides

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Practical examples

Aim to illustrate the most important items of the guidance provided in the new AGD

Focus of this presentation on:

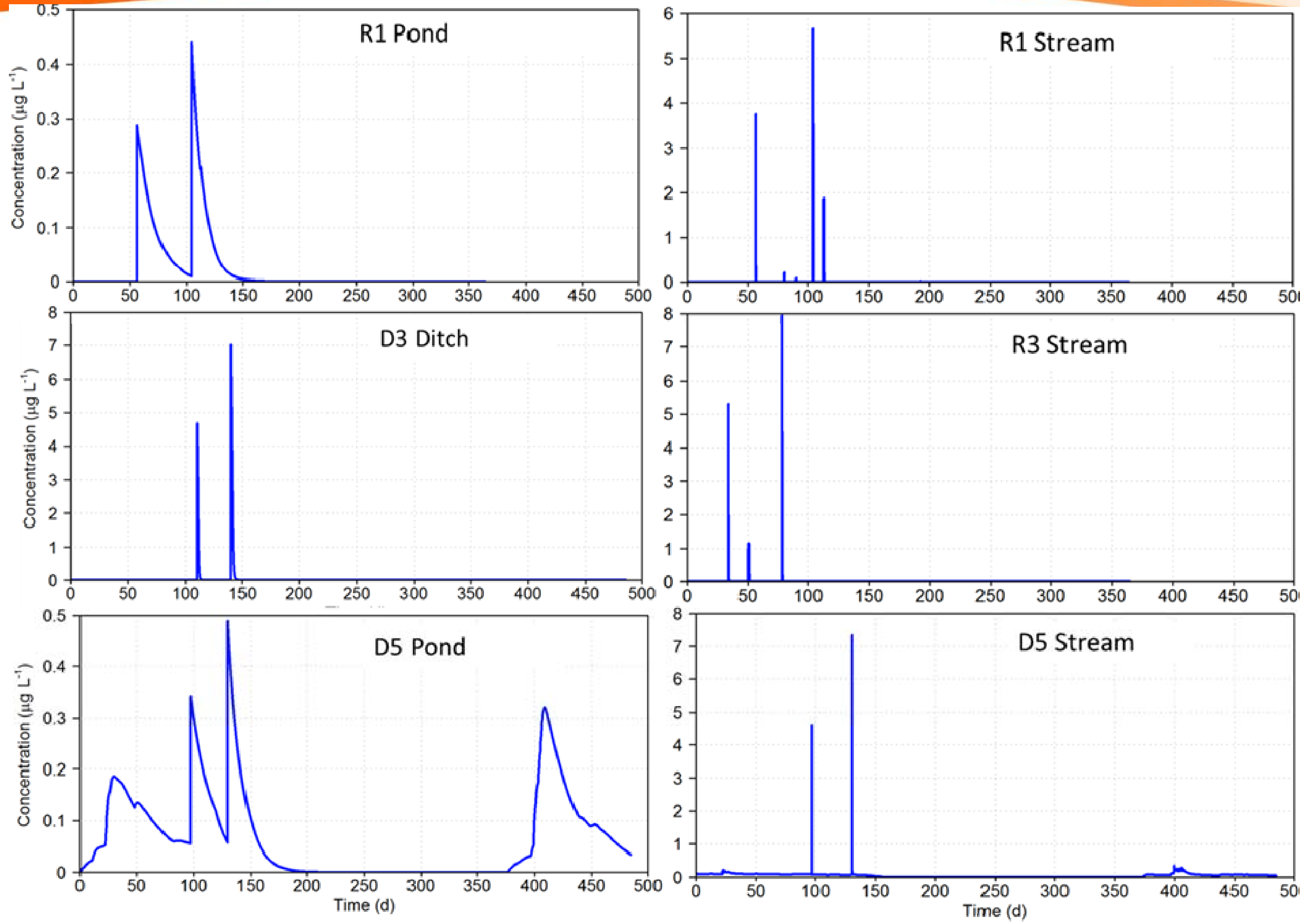
- Insecticides
- Tiered approach in effect assessment

Practical examples

Insecticide I_N case study (Appendix H.3)

- Neonicotinoid
- Use in apples
- 2 applications (30 d interval)
- 0.07 kg/ha (first application)
- 0.105 kg/ha (second application)
- FOCUS Step 3 calculations
- FOCUS Step 4 calculations (90% drift reducing nozzles)

Typical exposure profiles for I_N (FOCUS sw)



Step 3 $PEC_{sw;max}$: 0.441–7.940 µg/L ; Step 4 $PEC_{sw;max}$: 0.044 –1.299 µg/L

Tier 1 effect assessment

	Acute (µg/L)	Chronic (µg/L)
Daphnia magna	37397 (48 h EC_{50})	2548 (21 d NOEC)
Chironomus tentans/riparius	5.5 (96 h EC_{50})	1.14 (28 d EC_{10})
Americamysis bahia	38.2 (96 h LC_{50})	-
Oncorhynchus mykiss	211000 (96 h LC_{50})	1200 (98 d NOEC)
Scenedesmus subspicatus	-	>10000 (72h E_rC_{50})

- AF of 100 to the lowest acute toxicity value (5.5 µg/L)

  Tier 1 $RAC_{sw;ac}$ = 0.055 µg/L (lower than critical Step 3 and 4 $PEC_{sw;max}$ values)
- AF of 10 to the lowest chronic toxicity value (1.14 µg/L).

  Tier 1 $RAC_{sw;ch}$ = 0.114 µg/L (lower than critical Step 3 and 4 $PEC_{sw;max}$ values)

Tier 2A acute effect assessment

Crustacea	48–96 h $L(E)_{50}$ (µg a.s./L)	Insecta	48–96 h $L(E)_{50}$ (µg a.s./L)
Daphnia magna	37 397	*Chaoborus flavicans*	284
Gammarus fossarum	1 335	*Plea minutissima*	50.6
Chydorus ovalis	832	*Aedes communis*	44
Palaemonetes paludosus	417.1	*Sialis lutaria*	35.9
Artemia salina	329.2	*Notonecta glauca*	18.2
Hyalella azteca	119	*Corixa striata*	10.8
Asellus aquaticus	75.7	*Cloeon dipterum*	8.49
Americamysis bahia	38.2	*Simulium costatum*	8.1
Gammarus roeseli	18.3	*Chironomus tentans*	5.5
Gammarus pulex	10	*Cheumatopsyge lepida*	4.98
Cypridopsis vidua	5.2	*Rhaptobaetopus tenellus*	4.2
Ceriodaphnia dubia	3	*Limnephilus elegans*	1.79
Cypretta nigra	2.07	*Baetis rhodani*	1.77
Ilyocryptus brevidentatus	1	*Nemoura cineria*	1.02
		Caenis robusta	0.65
Geomean	61.70 µg/L	Geomean	8.41 µg/L

Geomean approach: Applying an AF of 100 to geomean EC_{50} of insects results in a Geom-$RAC_{sw;ac}$ of 0.084 µg/L

Tier 2A chronic effect assessment

Crustacea	Chronic EC_{10}/NOEC(µg/L)	Insecta	Chronic EC_{10}/NOEC (µg/L)
Daphnia magna	2 548 (21 d repro)	*Chironomus tentans*	2.09 (28 d emerg.)
Gammarus pulex	7.7 (28 d mort.)	*Chronomus riparius*	1.14 (28 d emerg.)
Hyalella azteca	2.95 (28 d mort.)	*Chaoborus flavicans*	1.99 (28 d mort.)
Neocaridina dentic.	1.71 (28 d mort.)	*Silalis lutaria*	2.03 (28 d mort.)
Asellus aquaticus	1.0 (28 d mort.)	*Plea minutissima*	1.28 (28 d mort.)
		Baetis rhodani	0.033 (28 d mort.)
		Caenis robusta	0.024 (28 d mort.)
Geomean	2.496 µg/L	Geomean	0.516 µg/L

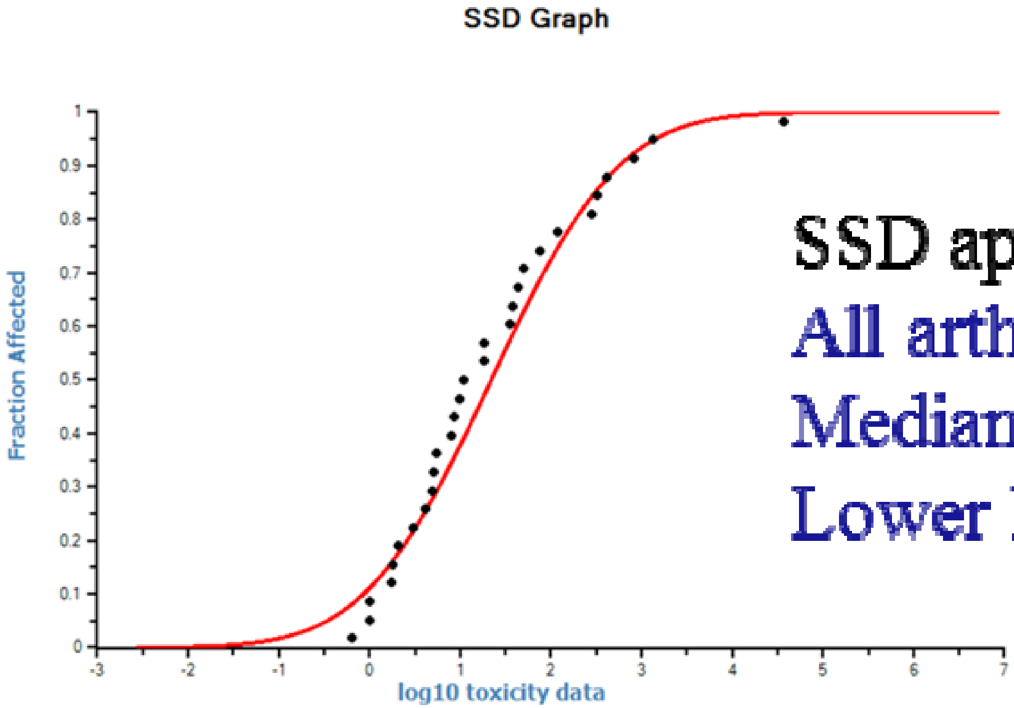
Geomean approach: Applying an AF of 10 to geomean EC_{10}/NOEC of insects.

Geomean/10 (=0.0516 µg/L) is higher than the lowest chronic toxicity value (0.024 µg/L for *Caenis robusta*)

Geom-$RAC_{sw;ch}$ ≤ 0.024 µg/L

Tier 2B effect assessment

Appropriate fit of the SSD curve was obtained with acute toxicity data only



SSD approach
All arthropods
Median HC5 = 0.326 µg/L
Lower limit HC5 = 0.077 µg/L

- AF of 3 – 6 has to be applied to median HC5

Tier 2B acute effect assessment

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1. The quality of the acute toxicity data used to construct the SSD (e.g. EPT taxa)
2. The lower limit value of the HC5
3. Tier 1 and Tier 2A RACs
4. Position of toxicity data in lower tail of SSD
5. Steepness of the SSD curve
6. Read across information
7. Information on chronic effects

AF of 4.5 is selected

$\text{SSD-RAC}_{sw;ac} = 0.072\ \mu g/L$

Tier 3 effect assessment

- Experimental stream mesocosm (recirculating)
- Single application of insecticide I_N (nominal 0.1 – 600 µg/L)
- Dissipation DT50 = 15 days (realistic to worst case exposure relative to field; except for D5 pond scenario)
- More than 8 taxa of potentially sensitive group with an appropriate MDD present in test system (12 insects; 1 macro-crustacean)
- See summary Table H.17 on page 257

Tier 3 effect assessment

Overall summary of Effect class responses experimental stream study

Concentration	Treatment level (µg/L)					
Nominal	0.1	0.6	3.2	20	100	600
7-d TWA	0.08	0.43	2.31	14.4	80	430
21-dTWA	0.04	0.23	1.67	7.6	40	230
Effect class (most sensitive taxon)	**1**	**5A**	**5A**	**5A**	**5A**	**5A**
Effect class (most sensitive community level endpoint)	**1**	**5A**	**5B**	**5B**	**5B**	**5B**

Ecological threshold option (Effect class 1 concentration and AF of 2); *Ecological Recovery option* (not possible)

Acute: ETO-RAC$_{sw;ac}$ = 0.05 µg/L

Chronic: ETO-RAC$_{sw;ch}$ = 0.05 µg/L (except D5 Pond)

ETO-RAC$_{sw;ch}$ = 0.02 µg/L for D5 Pond (Effect class 1 concentration on basis of 21 d TWA conc.)

I_N: Summary effect assessment

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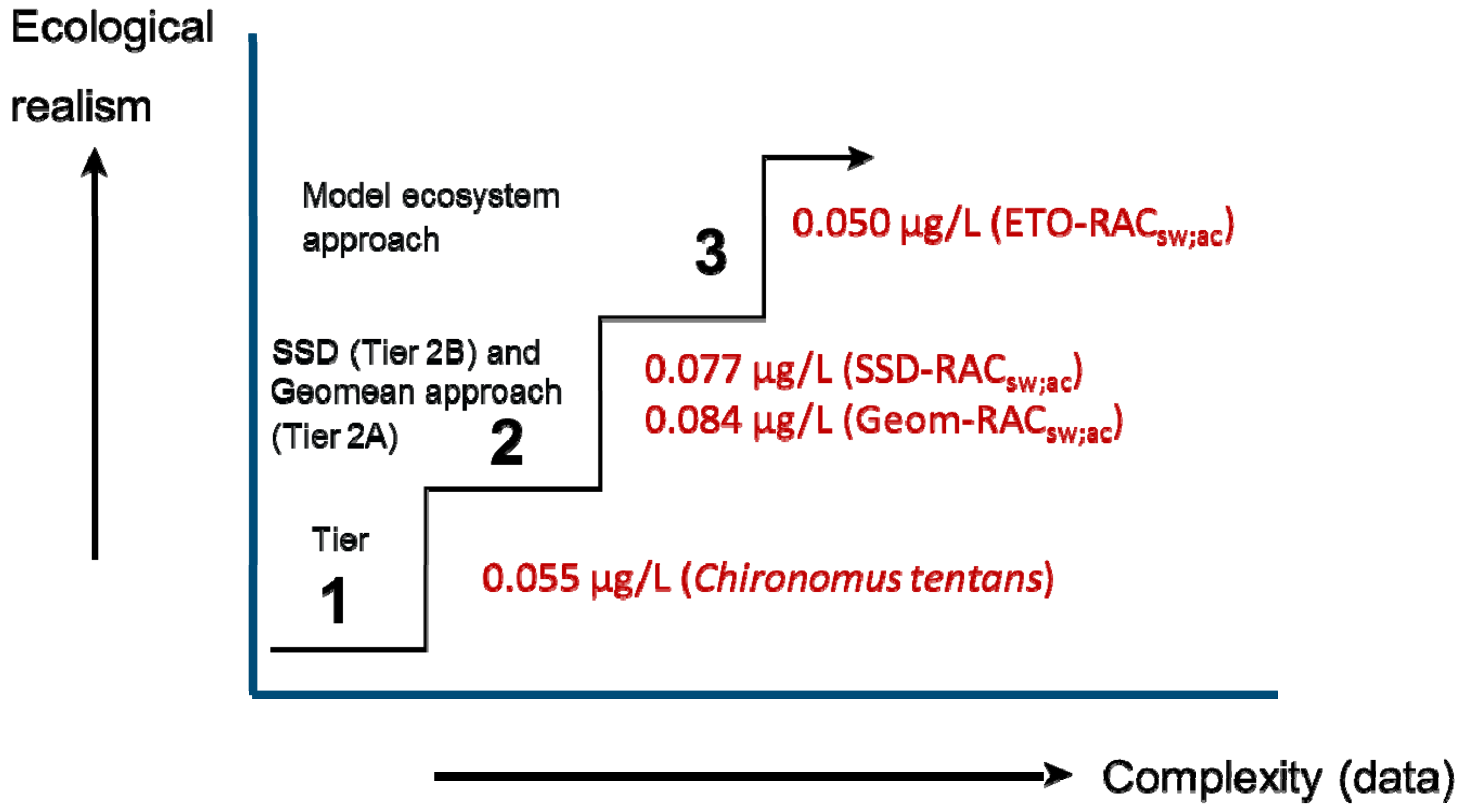

Differences between tiers are very small

I_N: Summary risk assessment

Scenario	$PEC_{sw;max}$ of insecticide I_N (µg/L) Step 3	Step 4 90 % drift reduction
D3 Ditch	7.020	0.703
D4 Pond	0.487	0.487
D4 Stream	7.180	0.793
D5 Pond	0.471	0.311
D5 Stream	7.601	0.803
R1 Pond	0.441	**0.044**
R1 Stream	5.664	1.299
R2 Stream	7.469	0.747
R3 Stream	7.940	0.911
R4 Stream	5.663	1.190

Linking the ETO-$RAC_{sw;ac}$ (0.05 µg/L) to the $PEC_{sw;max}$ indicates that acute risks are acceptable in R1 Pond scenario only.

Pyrethroid insecticide I_P

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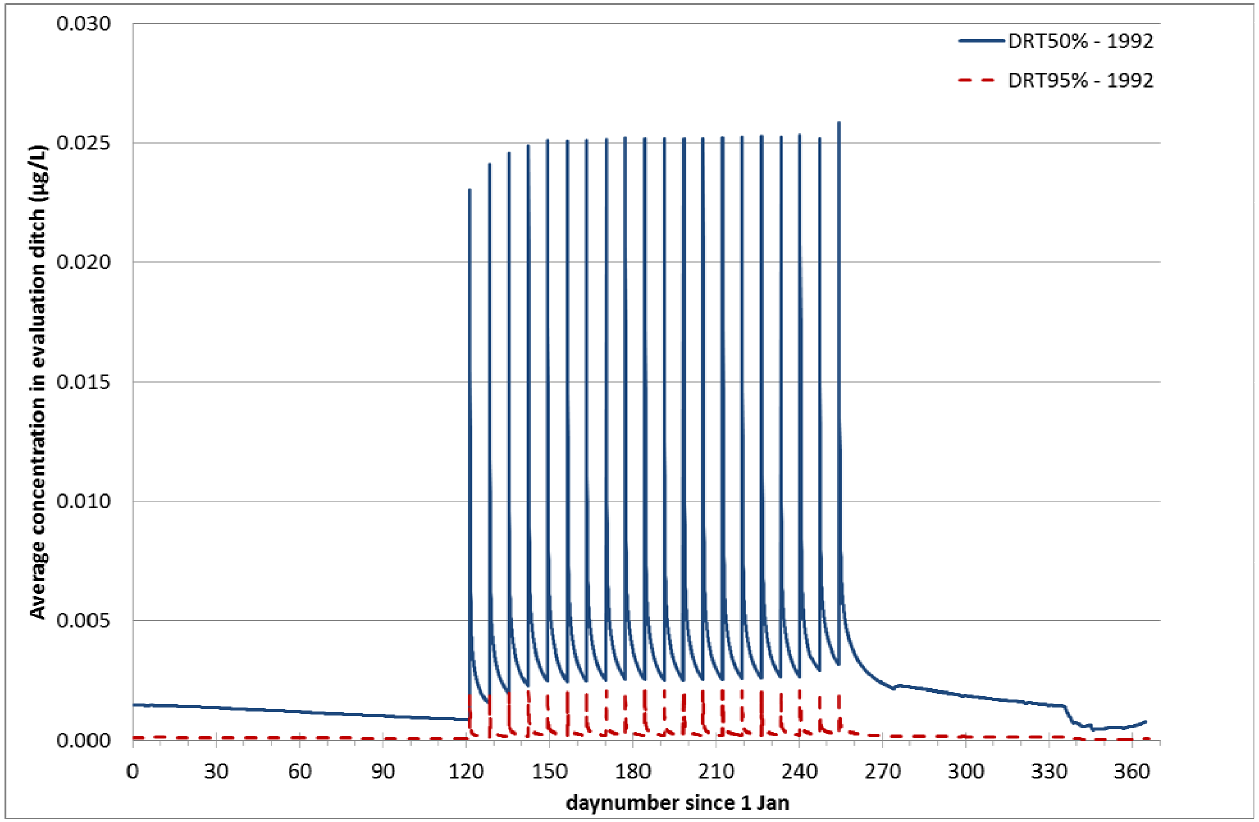
National exposure scenario for NL (use in lilies)



50% drift reduction: PEC_{max}= 25.9 ng/L; $PEC_{7d\text{-}twa}$= 4.9 ng/L

95% drift reduction: PEC_{max}= 2.1 ng/L; $PEC_{7d\text{-}twa}$= 0.4 ng/L

Tier 1: Pyrethroid I_P

	Acute (ng/L)	Chronic (ng/L)
Daphnia magna	140 (48 h EC_{50})	2.0 (21 d NOEC)
Chironomus riparius	136 (96 h LC_{50})	45 (28 d EC_{10})
Americamysis bahia	2.3 (96 h LC_{50})	-
Oncorhynchus mykiss	180 (96 h LC_{50})	60 (21 d NOEC)
Scenedesmus subspicatus	-	> 90000 (72 h E_rC_{50})

- AF of 100 to the lowest acute toxicity value (2.3 ng/L)

  Tier 1 $RAC_{sw;ac}$ = 0.023 ng/L
- AF of 10 to the lowest chronic toxicity value (2.0 ng/L).

  Tier 1 $RAC_{sw;ch}$ = 0.20 ng/L

Tier 2A: Geomean acute

Crustacea	Acute EC_{50}/LC_{50} (ng/L)	Insecta	Acute EC_{50}/LC_{50} (ng/L)
Americamysis bahia	2.3	*Chaoborus flavicans*	4.8
Daphnia magna	140	*Cloeon dipterum*	19.2
Asellus aquaticus	124.8	*Chironomus riparius*	136
Geomean	34.3 ng/L	Geomean	23.2 ng/L

Geomean approach: Applying an AF of 100 to geomean EC_{50} of insects results in a Geom-$RAC_{sw;ac}$ of 0.232 ng/L

Tier 2A: Geomean chronic

Crustacea	Chronic NOEC/EC_{10} (ng/L)	Insecta	Chronic NOEC/EC_{10} (ng/L)
Daphnia magna	2.0	*Chironomus riparius*	45.0
Gammarus pulex	1.9		
Asellus aquaticus	8.1		
Geomean	3.13 ng/L	Geomean	45.0 ng/L

Geomean approach: Applying an AF of 10 to geomean EC_{10}/NOEC of crustaceans results in a Geom-$RAC_{sw;ac}$ of 0.313 ng/L

Tier 3 effect assessment

- Mesocosm experiment 1 (North America)
  - Experimental pond study (6 weekly applications)
  - Dissipation DT50 = 1.2 d (realistic to worst case relative to field)
  - 7 taxa of sensitive group with an appropriate MDD (4 insects; 1 macro-crustacean; 2 micro-crustaceans)
- Microcosm experiment 2 (NL)
  - Enclosures in experimental ditch (4 weekly appl.)
  - Dissipation DT50 = 1.0 d (realistic relative to field)
  - 6 other taxa of sensitive group with an appropriate MDD present (2 insects; 3 micro-crustaceans; 1 macro-crustacean)

Tier 3 effect assessment

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Most sensitive taxon in study 1: *Caenis* spec

(Ephemeroptera; bi-/univoltine life-cycle)

Abundance

day	Controls	5 ng/L	10 ng/L	25 ng/L	50 ng/L	100 ng/L	Williams	MDD%
-5	9.3	9.3	8.6	13.9	8.6	10.3	- NOEC>=100 ng/L	40.8
3	12.0	13.0	9.6	15.6	8.9	1.6	* NOEC=50 ng/L (decr.)	42.5
9	11.6	10.6	6.0	4.9	2.6	0.0	* NOEC=5 ng/L (decr.)	50.4
23	9.0	14.3	14.3	7.6	3.6	0.3	* NOEC=10 ng/L (decr.)	41.3
37	12.0	9.6	11.9	12.9	4.3	0.0	* NOEC=25 ng/L (decr.)	58.4
51	11.6	12.0	8.6	13.6	5.3	0.0	* NOEC=25 ng/L (decr.)	47.5
65	12.3	8.0	12.9	13.3	6.9	0.0	* NOEC=25 ng/L (decr.)	63.2
79	8.6	10.6	13.9	16.6	4.0	0.0	* NOEC=25 ng/L (decr.)	72.8
Effect class		**1**	**2**	**3A**	**5B**	**5B**		

In the 10 and 25 ng/L treatments the MDD remains sufficiently low in the period after the significant effect so that recovery can be demonstrated

Tier 3 effect assessment

Most sensitive taxon in study 2: *Gammarus pulex*

(Amphipoda; bivoltine; no re-colonization in test system)

Abundance

day	Controls	5 ng/L	10 ng/L	25 ng/L	50 ng/L	100 ng/L	Williams	MDD%
-5	35.6	22.1	22.1	17.3	28.5	22.3	- NOEC>=100 ng/L	45.2
7	19.1	14.8	16.6	20.5	35.3	1.8	* NOEC=50 ng/L (decr.)	48.9
14	25.2	26.7	17.2	17.9	14.2	0.0	* NOEC=5 ng/L (decr.)	59.8
21	26.3	21.9	31.5	25.2	18.7	0.0	* NOEC=10 ng/L (decr.)	61.9
28	19.6	17.4	34.9	20.3	15.7	0.0	* NOEC=25 ng/L (decr.)	62.6
35	18.2	18.7	23.7	23.5	21.0	0.0	* NOEC=50 ng/L (decr.)	52.8
49	19.5	20.8	30.0	19.9	20.3	0.0	* NOEC=50 ng/L (decr.)	78.8

Effect class	5 ng/L	10 ng/L	25 ng/L	50 ng/L	100 ng/L
	1	2	3A	3A	5B

In the 10, 25 and 50 ng/L treatments the MDD remains sufficiently low in the period after the significant effect so that recovery can be demonstrated

Tier 3 effect assessment

Overall summary of Effect class responses in two micro-/mesocosm studies

	Peak exposure concentration of I_P in ng/L				
	Effect class 1	Effect class 2	Effect class 3A	Effect class 4	Effect class 5B
Study 1	**5.0**	**10**	**25**		**50**
Study 2	**5.0**	**10**	**25 - 50**		**100**

- Ecological Threshold Option
  - Effect class 1; AF of 2 (ETO-RAC_{sw} = 5.0/2= 2.5 ng/L)
  - Effect class 2; AF of 2-3 (ETO-RAC_{sw} = 10/3= 3.3 ng/L)
- Ecological Recovery Option
  - Effect class 3A; AF of 3-4 (provisional ERO-RAC_{sw} = 25/4= 6.3 ng/L ; number applications less than in field)

Is ERO-RAC protective for fish?

In micro-/mesocosm test systems fish was not present.

Is the Tier 3 ERO-RAC of 2.5 ng/L also protective for fish?

	Acute (ng/L)	Chronic (ng/L)
Daphnia magna	140 (48 h EC_{50})	2.0 (21 d NOEC)
Chironomus riparius	136 (96 h LC_{50})	45 (28 d EC_{10})
Americamysis bahia	2.3 (96 h LC_{50})	-
Oncorhynchus mykiss	180 (96 h LC_{50})	60 (21 d NOEC)
Scenedesmus subspicatus	-	> 90000 (72 h E_rC_{50})

Perhaps not: Tier 1 $RAC_{sw;ac}$ for fish = 180/100= 1.80 ng/L, although Tier 1 $RAC_{sw;ch}$ for fish = 60/10= 6.0 ng/L

Laboratory LC_{50} data for additional fish species were obtained as a higher tier approach

Is ERO-RAC protective for fish?

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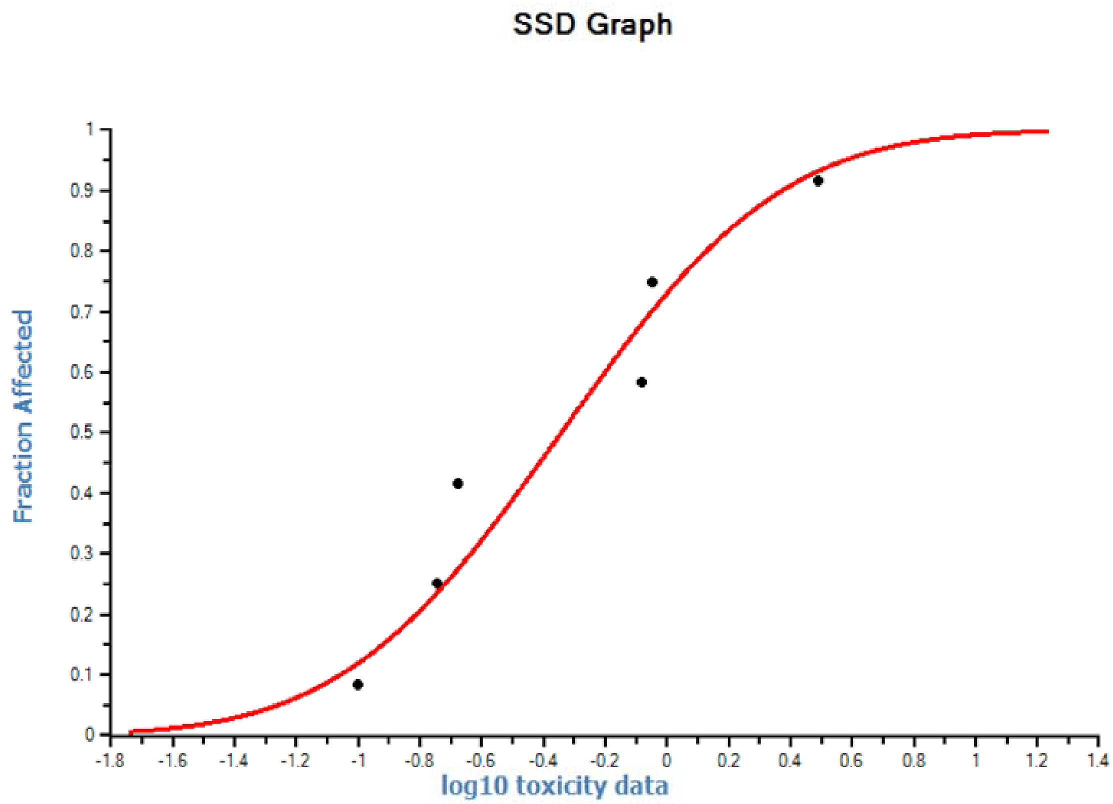

Median acute HC_5 = 47.84 ng/L (LL HC_5 = 3.87 ng/L)

Tier 2B $SSD\text{-}RAC_{sw;ac}$ for fish = 47.84/9 = 5.32 ng/L

Conclusion: Tier 3 ETO-RAC is also protective for fish

I_P: Summary acute effect assessment

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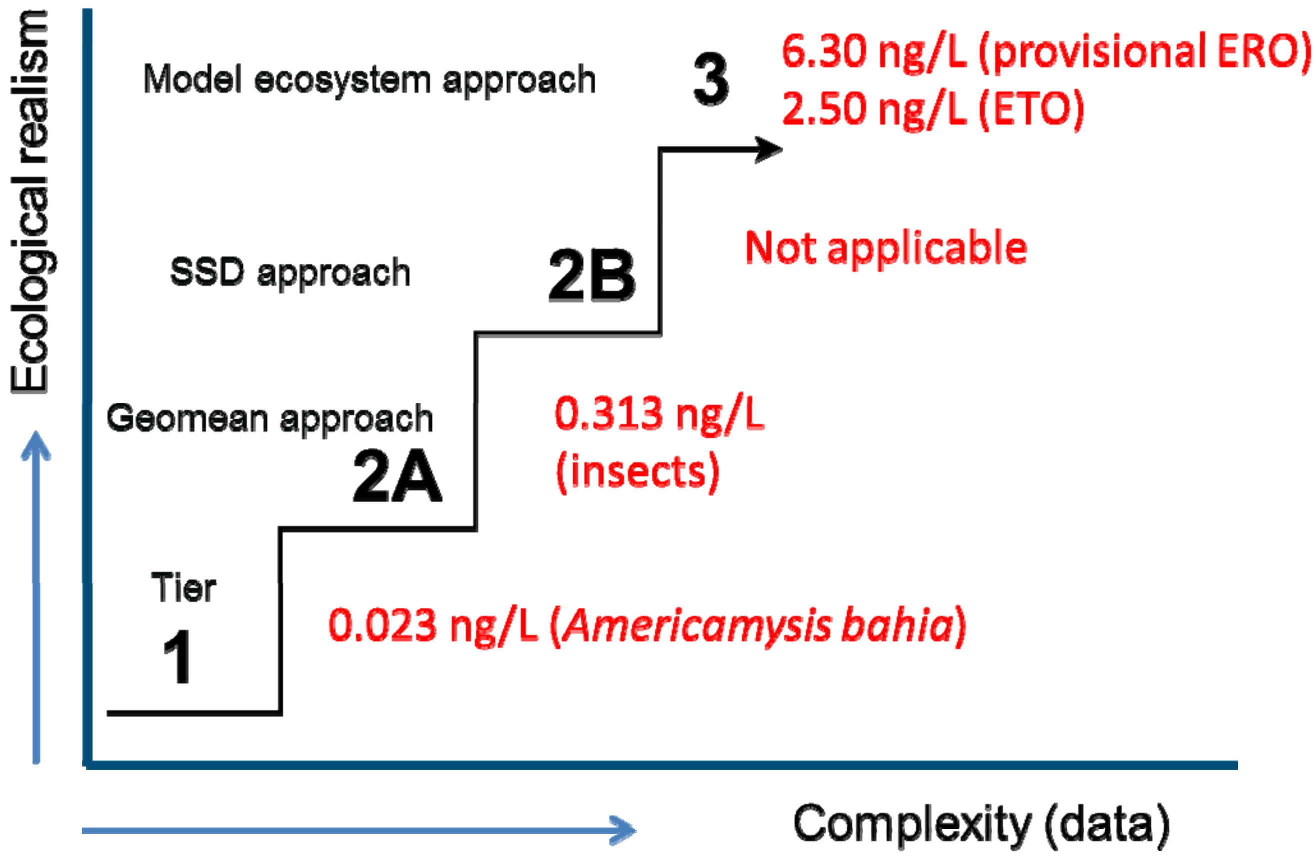
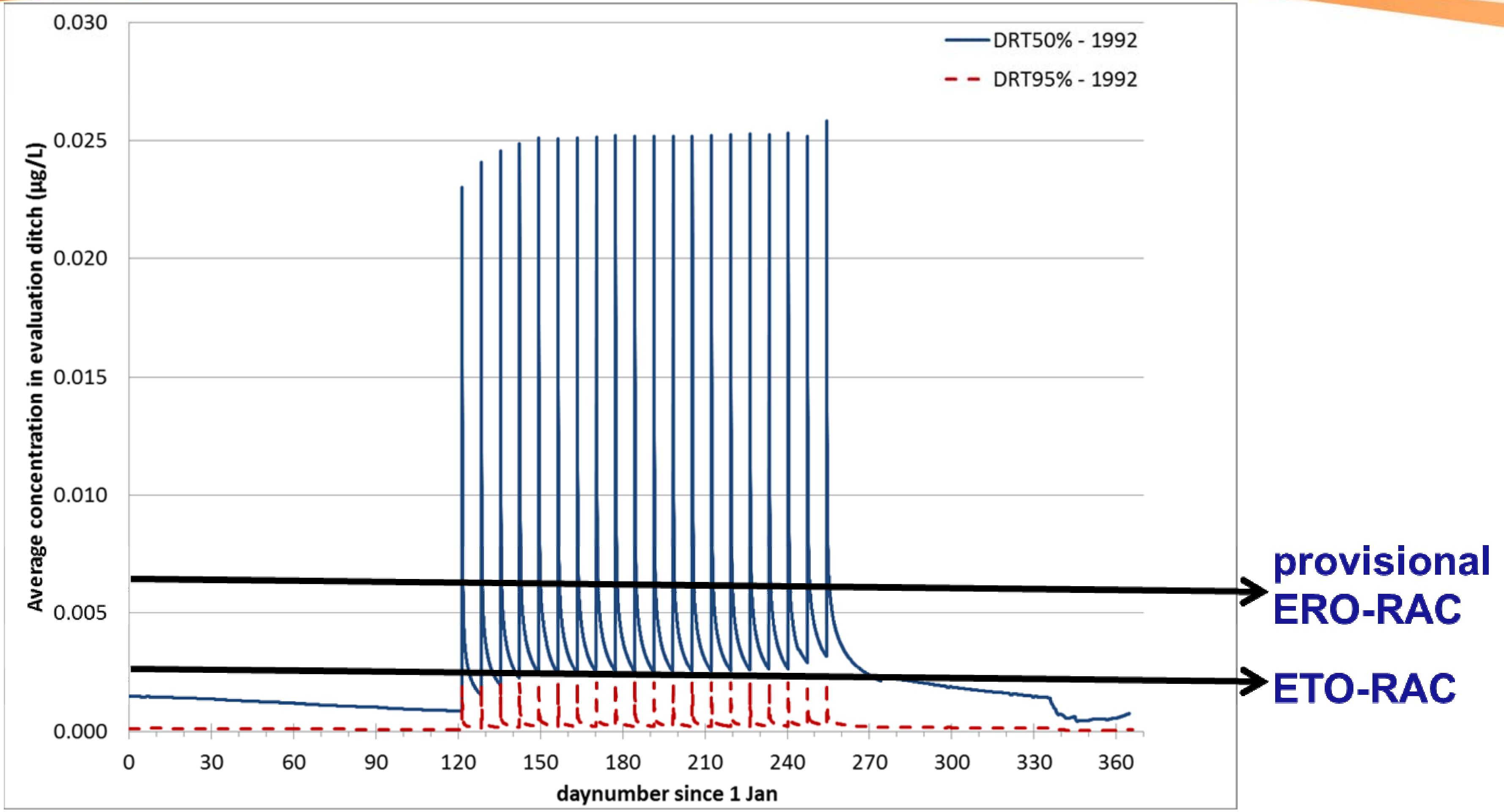


Differences between tiers are relatively large
(probably due to fast field dissipation of insecticide)

Final risk assessment for use of pyrethroid in lilies



Risks are negligible only if 95% drift reducing nozzles are used.

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Thank you !