

## APPENDIX A

## TIER 1 TABLES FOR BIRDS AND MAMMALS

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## **BIRD TIER 1 TABLES**

ц	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
1	Bare soils	BBCH < 10	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.7
2	Bare soils	BBCH < 10	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
3	Bare soils	BBCH < 10	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
4	Bare soils	BBCH < 10	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.35	50% seeds, 50% ground arthropods	Combination (ground invertebrates without interception)	1	23.9	50.4	8.2	17.4
5	Bare soils	BBCH < 10	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.9	10.9
6	Bulbs and onion like crops	BBCH 10 - 39	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.7
7	Bulbs and onion like crops	$BBCH \ge 40$	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	0.6	40.2	87	6.9	14.8
8	Bulbs and onion like crops	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
9	Bulbs and onion like crops	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
10	Bulbs and onion like crops	BBCH 10 - 39	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8
11	Bulbs and onion like crops	BBCH≥40	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.6	28.7	70.3	38.9	95.3



ц	Crop	Scenario	Generic focal species	<b>Representative</b> species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
12	Bulbs and onion like crops	BBCH 10 - 39	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
13	Bulbs and onion like crops	BBCH≥40	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.6	40.2	87	5.6	12.1
14	Bulbs and onion like crops	BBCH 10 - 39	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
16	Bulbs and onion like crops	BBCH≥40	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.6	21.0	46.2	6.5	14.4
17	Bulbs and onion like crops	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8
18	Bulbs and onion like crops	BBCH≥20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.7	25.2
19	Bush and cane fruit	Fruit stage BBCH 71-79 currants	Frugivorous bird "blackcap"	Blackcap (Sylvia atricapilla)	Frugivorous	Fruit	15.5	2.77	100% fruit	Berries	1	8.3	16.7	23.0	46.3
20	Bush and cane fruit	Whole season BBCH 00-79 Currants	Small insectivorous bird "warbler"	Willow warbler (Phylloscopus trochilus)	Insectivorous	Foliar	9.5	0.96	100% foliar insects	Foliar insects	1	21	54.1	20.3	52.2
21	Cereals	Late post- emergence (May-June) BBCH 71-89	Small insectivorus bird "passerine"	Fan tailed warbler	Insectivorous	Foliar	7	1.06	100% foliar insects	Foliar insects	1	21	54.1	22.4	57.6
22	Cereals	Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose"	Pink-foot goose (Anser brachyrhynchus)	Herbivorous	Ground	2645	0.30	100% cereal shoots	Grass + cereals	1	54.2	102. 3	16.2	30.5
23	Cereals	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3



и	Crop	Scenario	Generic focal species	<b>Representative</b> species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
24	Cereals	$BBCH \ge 20$	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
25	Cereals	BBCH 10 - 29	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% non-grass herbs	Non-grass herbs	1	28.7	70.3	64.8	158.8
26	Cereals	BBCH 30 -39	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% non-grass herbs	Non-grass herbs	0.5	28.7	70.3	32.4	79.4
27	Cereals	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% non-grass herbs	Non-grass herbs	0.3	28.7	70.3	19.4	47.6
28	Cereals	BBCH 10 - 29	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
29	Cereals	BBCH 30 -39	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.5	40.2	87	4.7	10.1
30	Cereals	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.3	40.2	87	2.8	6.1
31	Cereals	BBCH 10 - 29	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates with interception)	1	21.0	46.2	10.9	24.0
33	Cereals	BBCH 30 -39	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates with interception)	0.5	21.0	46.2	5.4	12.0
34	Cereals	BBCH≥40	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates with interception)	0.3	21.0	46.2	3.3	7.2
35	Cereals	Late season- Seed heads	Small granivorous/insect ivorous bird "bunting"	Yellowhammer (Emberiza citronella)	granivorous	Ground	23	0.31	100% cereal seeds	Grains/ear	1	15	13	4.7	4.0
36	Cotton	BBCH 10 - 19	Medium insectivorous bird "pranticole"	Collared Pratincoles Glareola pratincola	Insectivorous	Ground	75	0.31	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	2.3	4.2



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37	Cotton	BBCH≥20	Medium insectivorous bird "pranticole"	Collared Pratincoles Glareola pratincola	Insectivorous	Ground	75	0.31	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	1.1	3.0
38	Cotton	BBCH 10 - 19	Single diet for T1	House sparrow (Passer domesticus)	Insectivorous	Ground	27.7	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.4
39	Cotton	BBCH≥20	Single diet for T1	House sparrow (Passer domesticus)	Insectivorous	Ground	27.7	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
40	Cotton	BBCH 10 - 49	Single diet for T1	House sparrow (Passer domesticus)	Herbivorous	Ground	27.7	2.28	100% non-grass herbs	Non-grass herbs	1	28.7	70.3	65.4	160.3
41	Cotton	BBCH≥50	Single diet for T1	House sparrow (Passer domesticus)	Herbivorous	Ground	27.7	2.28	100% non-grass herbs	Non-grass herbs	0.25	28.7	70.3	16.4	40.1
42	Cotton	BBCH 10 - 49	Single diet for T1	House sparrow (Passer domesticus)	Granivorous	Ground	27.7	0.23	100% seeds	Small seeds	1	40.2	87	9.4	20.4
43	Cotton	BBCH≥50	Single diet for T1	House sparrow (Passer domesticus)	Granivorous	Ground	27.7	0.23	100% seeds	Small seeds	0.25	40.2	87	2.4	5.1
44	Cotton	BBCH 10 - 49	Small omnivorous bird "sparrow"	House sparrow (Passer domesticus)	Omnivorous	Ground	27.7	0.38	Weed seeds 50% weed plant matter 25%, animal matter 25%	Combination (invertebrates without interception)	1	29.2	46.2	11.2	17.7
46	Cotton	BBCH≥50	Small omnivorous bird "sparrow"	House sparrow (Passer domesticus)	Omnivorous	Ground	27.7	0.38	Weed seeds 50% weed plant matter 25%, animal matter 25%	Combination (invertebrates without interception)	0.25	29.2	46.2	2.8	4.4
47	Fruiting vegetables	Fruit stage BBCH 71-89	Frugivorous bird "crow	Crow (Corvus brachyrhynchos)	Frugivorous	Fruit	448	0.93	100% fruit	Gourds	1	34.3	61.5	32.0	57.4
48	Fruiting vegetables	BBCH 10 - 49	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.7
49	Fruiting vegetables	$BBCH \ge 50$	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	0.3	40.2	87	3.4	7.4

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50	Fruiting vegetables	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
51	Fruiting vegetables	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
52	Fruiting vegetables	BBCH 10 - 49	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% non-grass herbs	Non-grass herbs	1	28.7	70.3	64.8	158.8
53	Fruiting vegetables	$BBCH \ge 50$	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% non-grass herbs	Non-grass herbs	0.3	28.7	70.3	19.4	47.6
54	Fruiting vegetables	BBCH 10 - 49	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
55	Fruiting vegetables	$BBCH \ge 50$	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.3	40.2	87	2.8	6.1
56	Fruiting vegetables	BBCH 10 - 49	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
58	Fruiting vegetables	BBCH≥50	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.3	21.0	46.2	3.3	7.2
59	Fruiting vegetables	Fruit stage BBCH 71-89	Frugivorous bird "Starling"	Starling (Sturnus vulgaris)	Frugivorous	Fruit	82.3	1.62	100% fruit	Tomato	1	12.8	30.6	20.7	49.4
60	Fruiting vegetables	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8
61	Fruiting vegetables	BBCH≥20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.7	25.2
62	Grassland	New sown grass seeds	Small granivorous bird "Sparrow"	House sparrow (Passer domesticus)	Granivorous	Ground	27.7	0.23	100% grass seeds	Small seeds	1	40.2	87	9.4	20.4
63	Grassland	Late season (seed heads)	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.7



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64	Grassland	Growing shoots	Large herbivorous bird "goose"	Pink-foot goose (Anser brachyrhynchus)	Herbivorous	Ground	2645	0.30	100% grass leaves	Grass + cereals	1	54.2	102. 3	16.2	30.5
65	Grassland	Growing shoots	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8
66	Нор	BBCH 10 - 19	Small insectivorous bird "finch"	Chaffinch (Fringilla coelebs)	Insectivorous in relevant period	Foliar/ ground	21	0.75	50% ground arthropods 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.1	23.8
67	Нор	BBCH≥20	Small insectivorous bird "finch"	Chaffinch (Fringilla coelebs)	Insectivorous in relevant period	Foliar/ ground	21	0.75	50% ground arthropods 50% foliar arthropods	Combination (ground arthropods without interception)	1	14.3	34.0	10.6	25.3
68	Нор	BBCH 10 - 19	Small granivorous bird "finch"	Goldfinch (Carduelis carduelis)	Granivorous	Ground	15.6	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.6
69	Нор	BBCH 20 - 39	Small granivorous bird "finch"	Goldfinch (Carduelis carduelis)	Granivorous	Ground	15.6	0.28	100% weed seeds	Small seeds	0.5	40.2	87	5.7	12.3
70	Нор	BBCH≥40	Small granivorous bird "finch"	Goldfinch (Carduelis carduelis)	Granivorous	Ground	15.6	0.28	100% weed seeds	Small seeds	0.3	40.2	87	3.4	7.4
71	Leafy vegetables	BBCH 10 - 49	Small granivorous bird "finch"	Serin (Serinus serinus)	Granivorous	Ground	11.2	0.31	100% seeds	Small seeds	1	40.2	87	12.6	27.4
72	Leafy vegetables	$BBCH \ge 50$	Small granivorous bird "finch"	Serin (Serinus serinus)	Granivorous	Ground	11.2	0.31	100% seeds	Small seeds	0.3	40.2	87	3.8	8.2
73	Leafy vegetables	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
74	Leafy vegetables	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
75	Leafy vegetables	BBCH 10 - 49	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8



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76	Leafy vegetables	$BBCH \ge 50$	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.3	28.7	70.3	19.4	47.6
77	Leafy vegetables	BBCH 10 - 49	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
78	Leafy vegetables	$BBCH \ge 50$	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.3	40.2	87	2.8	6.1
79	Leafy vegetables	BBCH 10 - 49	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
81	Leafy vegetables	BBCH≥50	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.3	21.0	46.2	3.3	7.2
82	Leafy vegetables	Leaf development BBCH 10-19	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Herbivorous	Ground	490	1.29	100% leaves	Non-grass herbs	1	28.7	70.3	37.0	90.6
83	Leafy vegetables	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8
84	Leafy vegetables	BBCH≥20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.7	25.2
85	Legume forage	BBCH 10 - 49	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.7
86	Legume forage	$BBCH \ge 50$	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	0.3	40.2	87	3.4	7.4
87	Legume forage	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
88	Legume forage	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
89	Legume forage	BBCH 10 - 49	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8

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90	Legume forage	BBCH≥50	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.3	28.7	70.3	19.4	47.6
91	Legume forage	BBCH 10 - 49	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
92	Legume forage	BBCH≥50	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.3	40.2	87	2.8	6.1
93	Legume forage	BBCH 10 - 49	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
95	Legume forage	BBCH≥50	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.3	21.0	46.2	3.3	7.2
96	Legume forage	Leaf development BBCH 21-49	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Herbivorous	Ground	490	0.79	100% crop	Non-grass herbs	1	28.7	70.3	22.7	55.6
97	Legume forage	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8
98	Legume forage	BBCH≥20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.7	25.2
99	Maize	BBCH 10 - 29	Medium granivorous bird "gamebird"	Partridge (Perdix perdix)	Granivorous	Ground	390	0.08	100% seed	Small seeds	1	40.2	87	3.0	6.6
100	Maize	BBCH 30 - 39	Medium granivorous bird "gamebird"	Partridge (Perdix perdix)	Granivorous	Ground	390	0.08	100% seed	Small seeds	0.5	40.2	87	1.5	3.3
101	Maize	BBCH≥40	Medium granivorous bird "gamebird"	Partridge (Perdix perdix)	Granivorous	Ground	390	0.08	100% seed	Small seeds	0.25	40.2	87	0.8	1.6



ц	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
102	Maize	Leaf development BBCH 10 to 19	Small insectivorous/wor m feeding species "thrush"	Robin (Erithacus rubecula)	Omnivorous	Ground	19.7	0.76	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.7	10.5
103	Maize	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
104	Maize	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
105	Maize	BBCH 10 - 29	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8
106	Maize	BBCH 30 - 39	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.5	28.7	70.3	32.4	79.4
107	Maize	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.25	28.7	70.3	16.2	39.7
108	Maize	BBCH 10 - 29	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
109	Maize	BBCH 30 - 39	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.5	40.2	87	4.7	10.1
110	Maize	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.25	40.2	87	2.3	5.1
111	Maize	BBCH 10 - 29	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
113	Maize	BBCH 30 - 39	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.5	21.0	46.2	5.4	12.0
114	Maize	BBCH≥40	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.25	21.0	46.2	2.7	6.0



п	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
115	Maize	BBCH 10 - 29	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Herbivorous	Ground	490	0.79	100% leaves	Non-grass herbs	1	28.7	70.3	22.7	55.6
116	Maize	BBCH 30 - 39	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Herbivorous	Ground	490	0.79	100% leaves	Non-grass herbs	0.5	28.7	70.3	11.4	27.8
117	Maize	BBCH≥40	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Herbivorous	Ground	490	0.79	100% leaves	Non-grass herbs	0.25	28.7	70.3	5.7	13.9
118	Maize	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8
119	Maize	BBCH ≥ 20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates with interception	0.5	12.3	31.9	4.8	12.6
120	Oilseed rape	late – late (with seeds) (BBCH 30-99)	Small insectivorous bird "dunnock)	Dunnock (Prunella modularis)	Insectivorous	Ground	19.7	0.76	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.7	7.4
121	Oilseed rape	early (shoots) (BBCH 10-19)	Large herbivorous bird "goose"	greylag goose (Anser anser)	Herbivorous	Ground	3108	0.55	100% crop shoots	Non-grass herbs	1	28.7	70.3	15.9	39.0
122	Oilseed rape	late (with seeds) (BBCH 80-99)	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.7
123	Oilseed rape	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
124	Oilseed rape	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
125	Oilseed rape	BBCH 10 - 29	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8
126	Oilseed rape	BBCH 30 - 39	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.3	28.7	70.3	19.4	47.6



п	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
127	Oilseed rape	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.25	28.7	70.3	16.2	39.7
128	Oilseed rape	BBCH 10 - 29	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
129	Oilseed rape	BBCH 30 - 39	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.3	40.2	87	2.8	6.1
130	Oilseed rape	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.25	40.2	87	2.3	5.1
131	Oilseed rape	BBCH 10 - 29	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25 % crop leaves 25 % weed seeds 50 % ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
133	Oilseed rape	BBCH 30 - 39	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25 % crop leaves 25 % weed seeds 50 % ground arthropods	Combination (invertebrates without interception)	0.3	21.0	46.2	3.3	7.2
134	Oilseed rape	BBCH≥40	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25 % crop leaves 25 % weed seeds 50 % ground arthropods	Combination (invertebrates without interception)	0.25	21.0	46.2	2.7	6.0
135	Oilseed rape	BBCH 10 - 19	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Omnivorous	Ground	490	0.79	100% crop shoots	Non-grass herbs	1	28.7	70.3	22.7	55.6
136	Oilseed rape	BBCH 20 - 29	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Omnivorous	Foliar/ ground	490	0.10	50 % crop leaves 50 % weed seeds	Comby to be calculated	1	34.5	39.3	3.5	4.0
137	Oilseed rape	BBCH 30 - 39	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Omnivorous	Foliar/ ground	490	0.10	50 % crop leaves 50 % weed seeds	Comby to be calculated	0.3	34.5	78.7	1.1	2.4
138	Oilseed rape	BBCH≥40	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Omnivorous	Foliar/ ground	490	0.10	50 % crop leaves 50 % weed seeds	Comby to be calculated	0.25	34.5	78.7	0.9	2.0



и	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
139	Oilseed rape	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.9	10.9
140	Oilseed rape	BBCH 20 - 29	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.8	7.7
141	Orchard	Spring Summer,	Small insectivorous bird "tit"	Bluetit (Parus caeruleus)	Insectivorous	Foliar	13.3	0.86	100% foliar insects	Foliar insects	1	21	54.1	18.2	46.8
142	Orchard	Not crop directed application all season	Small insectivorous/wor m feeding species "thrush"	Robin (Erithacus rubecula)	Omnivorous	Ground	19.7	0.76	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.7	7.4
143	Orchard	Crop directed application BBCH 10 - 19	Small insectivorous/wor m feeding species "thrush"	Robin (Erithacus rubecula)	Omnivorous	Ground	19.7	0.76	100% soil dwelling invertebrates	ground invertebrates with interception	0.8	3.5	9.7	2.1	5.9
144	Orchard	Crop directed application BBCH 20 - 39	Small insectivorous/wor m feeding species "thrush"	Robin (Erithacus rubecula)	Omnivorous	Ground	19.7	0.76	100% soil dwelling invertebrates	ground invertebrates with interception	0.6	3.5	9.7	1.6	4.4
145	Orchard	Crop directed application BBCH ≥ 40	Small insectivorous/wor m feeding species "thrush"	Robin (Erithacus rubecula)	Omnivorous	Ground	19.7	0.76	100% soil dwelling invertebrates	ground invertebrates with interception	0.3	3.5	9.7	0.8	2.2
146	Orchard	Not crop directed application all season	Small granivorous bird "finch"	Serin (Serinus serinus)	Granivorous	Foliar/ ground	11.2	0.31	100% seeds	Small seeds	1	40.2	87	12.6	27.4
147	Orchard	Crop directed application BBCH 10 - 19	Small granivorous bird "finch"	Serin (Serinus serinus)	Granivorous	Foliar/ ground	11.2	0.31	100% seeds	Small seeds	0.8	40.2	87	10.1	21.9
148	Orchard	Crop directed application BBCH 20 - 39	Small granivorous bird "finch"	Serin (Serinus serinus)	Granivorous	Foliar/ ground	11.2	0.31	100% seeds	Small seeds	0.6	40.2	87	7.6	16.4



ц	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
149	Orchard	Crop directed application $BBCH \ge 40$	Small granivorous bird "finch"	Serin (Serinus serinus)	Granivorous	Foliar/ ground	11.2	0.31	100% seeds	Small seeds	0.3	40.2	87	3.8	8.2
150	Ornamental s/nursery	Application to plant	Small insectivorous bird "tit"	Bluetit (Parus caeruleus)	Insectivorous	Foliar	13.3	0.86	100% foliar insects	Foliar insects	1	21	54.1	18.2	46.8
151	Ornamental s/nursery	Application to plant – exposure to underlying ground	Small insectivorous/wor m feeding species "thrush"	Robin (Erithacus rubecula)	Omnivorous	Ground	19.7	0.76	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.7	7.4
152	Potatoes	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
153	Potatoes	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
154	Potatoes	BBCH 10 - 39	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8
155	Potatoes	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.3	28.7	70.3	19.4	47.6
156	Potatoes	BBCH 10 - 39	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
157	Potatoes	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.3	40.2	87	2.8	6.1
158	Potatoes	BBCH 10 - 39	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
160	Potatoes	BBCH≥40	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.3	21.0	46.2	3.3	7.2
161	Potatoes	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8



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162	Potatoes	BBCH≥20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.7	25.2
163	Pulses	BBCH 10 - 49	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.7
164	Pulses	$BBCH \ge 50$	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	0.3	40.2	87	3.4	7.4
165	Pulses	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
166	Pulses	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
167	Pulses	BBCH 10 - 49	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8
168	Pulses	$BBCH \ge 50$	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.3	28.7	70.3	19.4	47.6
169	Pulses	BBCH 10 - 49	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
170	Pulses	$BBCH \ge 50$	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.3	40.2	87	2.8	6.1
171	Pulses	BBCH 10 - 49	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
173	Pulses	BBCH≥50	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.3	21.0	46.2	3.3	7.2
174	Pulses	Leaf development BBCH 10-19	medium herbivorous/grani vorous bird "pigeon"	Wood pigeon (Columba palumbus)	Herbivorous	Ground	490	0.79	100% leaves	Non-grass herbs	1	28.7	70.3	22.7	55.6



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175	Pulses	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8
176	Pulses	BBCH≥20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.7	25.2
177	Root and stem vegetables	BBCH 10 - 39	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.7
178	Root and stem vegetables	BBCH≥40	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	0.3	40.2	87	3.4	7.4
179	Root and stem vegetables	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
180	Root and stem vegetables	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
181	Root and stem vegetables	BBCH 10 - 39	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8
182	Root and stem vegetables	BBCH≥40	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.3	28.7	70.3	19.4	47.6
183	Root and stem vegetables	BBCH 10 - 39	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
184	Root and stem vegetables	BBCH≥40	Single diet for T1	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.3	40.2	87	2.8	6.1
185	Root and stem vegetables	BBCH 10 - 39	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0



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187	Root and stem vegetables	BBCH≥40	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.3	21.0	46.2	3.3	7.2
188	Root and stem vegetables	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8
189	Root and stem vegetables	BBCH≥20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.7	25.2
190	Straw- berries	BBCH 10 - 19	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
191	Straw- berries	BBCH≥20	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
192	Straw- berries	BBCH 10 - 39	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8
193	Straw- berries	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.4	28.7	70.3	25.9	63.5
194	Straw- berries	BBCH 10 - 39	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
195	Straw- berries	$BBCH \ge 40$	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.4	40.2	87	3.7	8.1
196	Straw- berries	BBCH 10 - 39	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
198	Straw- berries	BBCH≥40	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.4	21.0	46.2	4.4	9.6



ц	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
199	Straw- berries	Late (Flowering/ development of fruit/ Maturity of fruit) BBCH 61-89	Frugivorous bird "Starling"	Starling (Sturnus vulgaris)	Frugivorous	Fruit	82.3	1.62	100% fruit	Berries	1	8.3	16.7	13.4	27.0
200	Straw- berries	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.3	26.8
201	Straw- berries	BBCH≥20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.7	25.2
202	Sugar beet	late (summer/ autumn) (BBCH 30-49)	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	1	40.2	87	11.4	24.7
203	Sugar beet	early (spring) (BBCH 10-19)	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
204	Sugar beet	early (spring) (BBCH 10-19)	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8
205	Sugar beet	early (spring) (BBCH 10-19)	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
206	Sugar beet	early (spring) (BBCH 10-19)	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
207	Sugar beet	BBCH 10-19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.9	10.9
208	Sugar beet	BBCH 20 - 49	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.8	7.7
209	Sugar beet	BBCH 10-19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.9	10.9



п	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
210	Sugar beet	BBCH 20 - 49	Small insectivorous bird "wagtail"	yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.7	25.2
211	Sunflower	Early Germination/ leaf development) BBCH 00-19	Single diet for T1	Woodlark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
212	Sunflower	Early Germination/ leaf development) BBCH 00-19	Single diet for T1	Woodlark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	1	28.7	70.3	64.8	158.8
213	Sunflower	Early Germination/ leaf development) BBCH 00-19	Single diet for T1	Woodlark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	1	40.2	87	9.3	20.2
214	Sunflower	Early Germination/ leaf development) BBCH 00-19	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	1	21.0	46.2	10.9	24.0
215	Sunflower	Early (Germination/ leaf development) BBCH 00-19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	Insectivorous	Ground	17.6	0.79	50% ground arthropods, 50% foliar arthropods	Combination (ground invertebrates without interception)	1	14.3	34.0	11.3	26.8
216	Sunflower	Late (Flowering, seed ripening) BBCH 61-92	Small granivorous/insect ivorous bird "bunting"	Yellowhammer (Emberiza citronella)	granivorous, insecti- vourous	Ground	23	0.25	100% crop seeds	Small seeds	1	40.2	87	10.0	21.7
217	Vineyard	BBCH 10 - 19	Small insectivorous species "Redstart"	Black Redstart (Phoenicurus ochruros)	Insectivorous	Foliar/ ground	16.5	0.81	50% ground arthropods 50% foliar arthropods	ground invertebrates without interception	1	14.3	34.0	11.5	27.4



u	Crop	Scenario	Generic focal species	Representative species	Dict guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
218	Vineyard	BBCH≥20	Small insectivorous species "Redstart"	Black Redstart (Phoenicurus ochruros)	Insectivorous	Foliar/ ground	16.5	0.81	50% ground arthropods 50% foliar arthropods	ground invertebrates with interception	1	12.3	31.9	9.9	25.7
219	Vineyard	BBCH 10 - 19	Small granivorous bird "Finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	0.6	40.2	87	6.9	14.8
220	Vineyard	BBCH 20 - 39	Small granivorous bird "Finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	0.5	40.2	87	5.7	12.4
221	Vineyard	BBCH≥40	Small granivorous bird "Finch"	Linnet (Carduelis cannabina)	Granivorous	Ground	15.3	0.28	100% weed seeds	Small seeds	0.3	40.2	87	3.4	7.4
222	Vineyard	Ripening	Frugivorous bird "Trush/starling"	Song Thrush (Turdus philomelos)	Frugivorous	Fruit	66.6	1.73	100% grapes	Berries	1	8.3	16.7	14.4	28.9
223	Vineyard	BBCH 10 - 19	Single diet for T1	Wood Lark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates without interception	1	7.5	13.8	5.1	9.3
224	Vineyard	BBCH ≥ 20	Single diet for T1	Wood Lark (Lullula arborea)	Insectivorous	Ground	28.5	0.68	100% soil dwelling invertebrates	ground invertebrates with interception	1	3.5	9.7	2.4	6.6
225	Vineyard	BBCH 10 - 19	Single diet for T1	Wood Lark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.6	28.7	70.3	38.9	95.3
226	Vineyard	BBCH 20 - 39	Single diet for T1	Wood Lark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.5	28.7	70.3	32.4	79.4
227	Vineyard	BBCH≥40	Single diet for T1	Wood Lark (Lullula arborea)	Herbivorous	Ground	28.5	2.26	100% leaves	Non-grass herbs	0.3	28.7	70.3	19.4	47.6
228	Vineyard	BBCH 10 - 19	Single diet for T1	Wood Lark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.6	40.2	87	5.6	12.1
229	Vineyard	BBCH 20 - 39	Single diet for T1	Wood Lark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.5	40.2	87	4.7	10.1
230	Vineyard	$BBCH \ge 40$	Single diet for T1	Wood Lark (Lullula arborea)	Granivorous	Ground	28.5	0.23	100% seeds	Small seeds	0.3	40.2	87	2.8	6.1
231	Vineyard	BBCH 10 - 19	Small omnivorous bird "lark"	Wood Lark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground	Combination (invertebrates without interception)	0.6	21.0	46.2	6.5	14.4



u	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Interception	Mean	90th	Shortcut value for mean RUDs	Shortcut value for 90th percentile RUDs
									arthropods						
232	Vineyard	BBCH 20 - 39	Small omnivorous bird "lark"	Wood Lark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.5	21.0	46.2	5.4	12.0
233	Vineyard	BBCH≥40	Small omnivorous bird "lark"	Wood Lark (Lullula arborea)	Omnivorous	Ground	28.5	0.52	25% crop leaves 25% weed seeds 50% ground arthropods	Combination (invertebrates without interception)	0.3	21.0	46.2	3.3	7.2



## MAMMAL TIER 1 TABLES

Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
1	Bare soils	BBCH < 10	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
2	Bare soils	BBCH < 10	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
3	Bare soils	BBCH < 10	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.24	50% weed seeds, 50% ground arthropods	Combination (ground invertebrates without interception)	1	23.8	59.4	5.7	14.3
4	Bulbs & onion like crops	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
5	Bulbs & onion like crops	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
6	Bulbs & onion like crops	BBCH≥40	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.6	54.2	102.3	43.4	81.9
7	Bulbs & onion like crops	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
8	Bulbs & onion like crops	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
9	Bulbs & onion like crops	BBCH 00-40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
10	Bulbs & onion like crops	BBCH 40 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.6	40.2	87.0	4.0	8.6



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
11	Bulbs & onion like crops	BBCH 00-40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
12	Bulbs & onion like crops	BBCH 40 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.6	28.7	70.3	29.0	71.0
13	Bulbs & onion like crops	BBCH 10 - 39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
14	Bulbs & onion like crops	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.6	29.2	64.5	4.7	10.3
15	Bush & cane fruit	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
16	Bush & cane fruit	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
17	Bush & cane fruit	BBCH 10-19	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.6	54.2	102.3	43.4	81.9
18	Bush & cane fruit	BBCH 20 - 39	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.5	54.2	102.3	36.1	68.2
19	Bush & cane fruit	BBCH≥40	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
20	Bush & cane fruit	Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse"	Garden dormouse (Eliomys quercinus)	Frugivorous	Fruit	57.5	1.16	100% fruit	Berries	1	8.3	16.7	9.7	19.4
21	Bush & cane fruit	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1



	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
<b>Z</b> 22	Bush & cane fruit	BBCH ≥ 20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
23	Bush & cane fruit	BBCH 10-19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.6	40.2	87.0	4.0	8.6
24	Bush & cane fruit	BBCH 20 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.5	40.2	87.0	3.3	7.2
25	Bush & cane fruit	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
26	Bush & cane fruit	BBCH 10-19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.6	28.7	70.3	29.0	71.0
27	Bush & cane fruit	BBCH 20 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.5	28.7	70.3	24.2	59.2
28	Bush & cane fruit	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
29	Bush & cane fruit	BBCH 10-19	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.6	29.2	64.5	4.7	10.3
30	Bush & cane fruit	BBCH 20 - 39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.5	29.2	64.5	3.9	8.6
31	Bush & cane fruit	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.3	29.2	64.5	2.3	5.2
32	Cereals	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6



N	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Dict of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
33	Cereals	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
34	Cereals	BBCH≥40	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
35	Cereals	Early (shoots)	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.41	100% cereal shoots	Grass + cereals	1	54.2	102.3	22.3	42.1
36	Cereals	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
37	Cereals	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
38	Cereals	BBCH 10-29	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
39	Cereals	BBCH 30 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.5	40.2	87.0	3.3	7.2
40	Cereals	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
41	Cereals	BBCH 10-29	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
42	Cereals	BBCH 30 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.5	28.7	70.3	24.2	59.2
43	Cereals	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
44	Cereals	BBCH 10-29	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	1	29.2	64.5	7.8	17.2
45	Cereals	BBCH 30 - 39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.5	29.2	64.5	3.9	8.6
46	Cereals	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.3	29.2	64.5	2.3	5.2
47	Cotton	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
48	Cotton	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
49	Cotton	BBCH 40 - 49	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	1	54.2	102.3	72.3	136.4
50	Cotton	BBCH≥50	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.25	54.2	102.3	18.1	34.1
51	Cotton	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
52	Cotton	$BBCH \ge 20$	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
53	Cotton	BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
54	Cotton	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.25	40.2	87.0	1.7	3.6



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
55	Cotton	BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
56	Cotton	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.25	28.7	70.3	12.1	29.6
57	Cotton	BBCH 10-49	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	1	29.2	64.5	7.8	17.2
58	Cotton	BBCH≥50	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.25	29.2	64.5	1.9	4.3
59	Fruiting vegetables	Fruit stage BBCH 71-89	Frugivorous mammal "rat"	Brown rat ( <i>Rattus norvegicus</i> )	Frugivorous	Fruit	290	0.73	100% fruit	Gourds	1	34.3	61.5	25.2	45.2
60	Fruiting vegetables	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
61	Fruiting vegetables	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
62	Fruiting vegetables	BBCH 10 - 49	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	1	54.2	102.3	72.3	136.4
63	Fruiting vegetables	BBCH≥50	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
64	Fruiting vegetables	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
65	Fruiting vegetables	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
66	Fruiting vegetables	BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
67	Fruiting vegetables	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
68	Fruiting vegetables	BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
69	Fruiting vegetables	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
70	Fruiting vegetables	BBCH 10-49	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
71	Fruiting vegetables	BBCH≥50	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds50% weed seeds25% ground arthropods	Combination (invertebrates without interception)	0.3	29.2	64.5	2.3	5.2
72	Grassland	All season	Large herbivorous mammal "lagomorph"	Brown Hare ( <i>Lepus</i> europaeus)	Herbivorous	Ground	3800	0.32	100% grass	Grass + cereals	1	54.2	102.3	17.3	32.6
73	Grassland	late	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
74	Grassland	All season	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	1	54.2	102.3	72.3	136.4
75	Grassland	Late season (seed heads)	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
76	Grassland	New sown grass seeds	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Granivorous	Foliar/ ground	21.7	0.17	100% grass seeds	Small seeds	1	40.2	87.0	6.6	14.4



N	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Dict of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
77	Нор	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
78	Нор	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
79	Нор	BBCH≥40	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
80	Нор	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
81	Нор	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
82	Нор	BBCH 10-19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
83	Нор	BBCH 20 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.5	40.2	87.0	3.3	7.2
84	Нор	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
85	Нор	BBCH 10-19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
86	Нор	BBCH 20 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.5	28.7	70.3	24.2	59.2
87	Нор	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
88	Нор	BBCH 10-19	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds50% weed seeds25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
89	Нор	BBCH 20 - 39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.5	29.2	64.5	3.9	8.6
90	Нор	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.3	29.2	64.5	2.3	5.2
91	Leafy vegetables	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
92	Leafy vegetables	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
93	Leafy vegetables	BBCH 40-49	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	1	54.2	102.3	72.3	136.4
94	Leafy vegetables	BBCH≥50	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
95	Leafy vegetables	All season	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% leaves	Non-grass herbs	1	28.7	70.3	14.3	35.1
96	Leafy vegetables	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
97	Leafy vegetables	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
98	Leafy vegetables	BBCH 00-49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
99	Leafy vegetables	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
100	Leafy vegetables	BBCH 00-49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
101	Leafy vegetables	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
102	Leafy vegetables	BBCH 10-49	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
103	Leafy vegetables	BBCH≥50	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds50% weed seeds25% ground arthropods	Combination (invertebrates without interception)	0.3	29.2	64.5	2.3	5.2
104	Legume forage	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
105	Legume forage	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
106	Legume forage	BBCH 40 - 49	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	1	54.2	102.3	72.3	136.4
107	Legume forage	BBCH≥50	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
108	Legume forage	Leaf development BBCH 21-49	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	1	28.7	70.3	14.3	35.1
109	Legume forage	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
110	Legume forage	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
111	Legume forage	BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
112	Legume forage	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
113	Legume forage	BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
114	Legume forage	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
115	Legume forage	BBCH 10-49	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	1	29.2	64.5	7.8	17.2
116	Legume forage	BBCH≥50	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.3	29.2	64.5	2.3	5.2
117	Maize	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Omnivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
118	Maize	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Omnivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
119	Maize	BBCH 10 -29	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	All maize shoots + later grass	Grass + cereals	1	54.2	102.3	72.3	136.4
120	Maize	BBCH 30 - 39	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	All maize shoots + later grass	Grass + cereals	0.5	54.2	102.3	36.1	68.2



N	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
121	Maize	BBCH≥40	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	All maize shoots + later grass	Grass + cereals	0.25	54.2	102.3	18.1	34.1
122	Maize	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
123	Maize	$BBCH \ge 20$	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
124	Maize	BBCH 10 -29	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
125	Maize	BBCH 30 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.5	40.2	87.0	3.3	7.2
126	Maize	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.25	40.2	87.0	1.7	3.6
127	Maize	BBCH 10 -29	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
128	Maize	BBCH 30 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.5	28.7	70.3	24.2	59.2
129	Maize	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.25	28.7	70.3	12.1	29.6
130	Maize	BBCH 10-29	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	1	29.2	64.5	7.8	17.2
131	Maize	BBCH 30 - 39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.5	29.2	64.5	3.9	8.6



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
132	Maize	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.25	29.2	64.5	1.9	4.3
133	Oilseed rape	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
134	Oilseed rape	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
135	Oilseed rape	BBCH≥40	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.25	54.2	102.3	18.1	34.1
136	Oilseed rape	All season	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% crop leaves	Non-grass herbs	1	28.7	70.3	14.3	35.1
137	Oilseed rape	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
138	Oilseed rape	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
139	Oilseed rape	BBCH 10-29	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
140	Oilseed rape	BBCH 30 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
141	Oilseed rape	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.25	40.2	87.0	1.7	3.6
142	Oilseed rape	BBCH 10-29	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4



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N	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
143	Oilseed rape	BBCH 30 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
144	Oilseed rape	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.25	28.7	70.3	12.1	29.6
145	Oilseed rape	BBCH 10-29	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	1	29.2	64.5	7.8	17.2
146	Oilseed rape	BBCH 30 - 39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.3	29.2	64.5	2.3	5.2
147	Oilseed rape	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.25	29.2	64.5	1.9	4.3
148	Orchards	Application crop directed BBCH <10 or not crop directed	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	Ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
149	Orchards	Application crop directed BBCH <10 or not crop directed	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	1	54.2	102.3	72.3	136.4
150	Orchards	Application crop directed BBCH 10- 19	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.8	54.2	102.3	57.8	109.2
151	Orchards	Application crop directed BBCH 20- 40	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.6	54.2	102.3	43.4	81.9
152	Orchards	Application crop directed BBCH $\ge$ 40	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9

Mammal Tier 1



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
153	Orchards	Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse"	Garden dormouse (Eliomys quercinus)	Frugivorous	Fruit	57.5	1.16	100% fruit	larger fruits	1	19.5	41.1	22.7	47.9
154	Orchards	Application crop directed BBCH <10 or not crop directed	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	1	28.7	70.3	14.3	35.1
155	Orchards	Application crop directed BBCH 10- 19	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	0.8	28.7	70.3	11.5	28.1
156	Orchards	Application crop directed BBCH 20- 40	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	0.6	28.7	70.3	8.6	21.1
157	Orchards	Application crop directed BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	0.3	28.7	70.3	4.3	10.5
158	Orchards	Application crop directed BBCH <10 or not crop directed	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
159	Orchards	Application crop directed BBCH 10- 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	0.8	3.5	9.7	1.2	3.4
160	Orchards	Application crop directed BBCH 20- 40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	0.6	3.5	9.7	0.9	2.6
161	Orchards	Application crop directed BBCH ≥ 40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	0.3	3.5	9.7	0.5	1.3
162	Orchards	Application crop directed BBCH <10 or not crop directed	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
163	Orchards	Application crop directed BBCH 10- 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.8	40.2	87.0	5.3	11.5
164	Orchards	Application crop directed BBCH 20- 40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.6	40.2	87.0	4.0	8.6
165	Orchards	Application crop directed BBCH ≥ 40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
166	Orchards	Application crop directed BBCH <10 or not crop directed	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
167	Orchards	Application crop directed BBCH 10- 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.8	28.7	70.3	38.7	94.7
168	Orchards	Application crop directed BBCH 20- 40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.6	28.7	70.3	29.0	71.0
169	Orchards	Application crop directed BBCH ≥ 40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
170	Orchards	Application crop directed BBCH <10 or not crop directed	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
171	Orchards	Application crop directed BBCH 10- 19	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.8	29.2	64.5	6.2	13.8
172	Orchards	Application crop directed BBCH 20- 40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.6	29.2	64.5	4.7	10.3



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
173	Orchards	Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds50% weed seeds25% ground arthropods	Combination (invertebrates without interception)	0.3	29.2	64.5	2.3	5.2
174	Ornamen- tals/nursery	Application to plant – exposure to underlying ground	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	Ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
175	Ornamen- tals/nursery	BBCH 40 - 49	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	1	54.2	102.3	72.3	136.4
176	Ornamen- tals/nursery	BBCH≥50	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.5	54.2	102.3	36.1	68.2
177	Ornamen- tals/nursery	Application crop directed BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	Ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
178	Ornamen- tals/nursery	Application crop directed BBCH ≥ 50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	Ground dwelling invertebrates with interception	0.5	3.5	9.7	0.8	2.1
179	Ornamen- tals/nursery	Application crop directed BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
180	Ornamen- tals/nursery	Application crop directed BBCH ≥ 50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.5	40.2	87.0	3.3	7.2
181	Ornamen- tals/nursery	Application crop directed BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
182	Ornamen- tals/nursery	Application crop directed BBCH $\geq 50$	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.5	28.7	70.3	24.2	59.2
183	Ornamen- tals/nursery	Application crop directed BBCH 10 - 49	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	1	29.2	64.5	7.8	17.2

Mammal Tier 1



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
184	Ornamen- tals/nursery	Application crop directed BBCH ≥ 50	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.5	29.2	64.5	3.9	8.6
185	Potatoes	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
186	Potatoes	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
187	Potatoes	BBCH≥40	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
188	Potatoes	BBCH 10 - 40	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	1	28.7	70.3	14.3	35.1
189	Potatoes	BBCH≥40	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	0.3	28.7	70.3	4.3	10.5
190	Potatoes	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
191	Potatoes	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
192	Potatoes	BBCH 10 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
193	Potatoes	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
194	Potatoes	BBCH 10 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4



Z	Сгор	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
195	Potatoes	$BBCH \ge 40$	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
196	Potatoes	BBCH 10 - 39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds50% weed seeds25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
197	Potatoes	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.3	29.2	64.5	2.3	5.2
198	Pulses	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
199	Pulses	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
200	Pulses	BBCH 40 - 49	Small herbivorous mammal "vole	Common vole ( <i>Microtus arvalis</i> )	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	1	54.2	102.3	72.3	136.4
201	Pulses	BBCH≥50	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
202	Pulses	BBCH 10 - 49	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	1	28.7	70.3	14.3	35.1
203	Pulses	BBCH≥50	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	0.3	28.7	70.3	4.3	10.5
204	Pulses	Pre harvest seed BBCH 81-99	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% seeds	Small seeds	1	40.2	87.0	6.6	14.4
205	Pulses	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
206	Pulses	BBCH ≥ 20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
207	Pulses	BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
208	Pulses	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
209	Pulses	BBCH 10 - 49	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
210	Pulses	BBCH≥50	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
211	Pulses	BBCH 10 - 49	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
212	Pulses	$BBCH \ge 50$	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds50% weed seeds25% ground arthropods	Combination (invertebrates without interception)	0.3	29.2	64.5	2.3	5.2
213	Root &stem vegetables	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
214	Root & stem vegetables	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
215	Root & stem vegetables	BBCH $\ge$ 40	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
216	Root & stem vegetables	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1



N	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
217	Root & stem vegetables	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
218	Root & stem vegetables	BBCH 10-39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
219	Root & stem vegetables	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3
220	Root & stem vegetables	BBCH 10-39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
221	Root & stem vegetables	$BBCH \ge 40$	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
222	Root & stem vegetables	BBCH 10-39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
223	Root & stem vegetables	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.3	29.2	64.5	2.3	5.2
224	Straw- berries	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
225	Straw- berries	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
226	Straw- berries	BBCH $\ge$ 40	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.4	54.2	102.3	28.9	54.6
227	Straw- berries	BBCH 10-39	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	1	28.7	70.3	14.3	35.1



N	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
228	Straw- berries	$BBCH \ge 40$	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	0.4	28.7	70.3	5.7	14.0
229	Straw- berries	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
230	Straw- berries	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
231	Straw- berries	BBCH 10-39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
232	Straw- berries	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.4	40.2	87.0	2.7	5.7
233	Straw- berries	BBCH 10-39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
234	Straw- berries	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.4	28.7	70.3	19.3	47.4
235	Straw- berries	BBCH 10-39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
236	Straw- berries	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds50% weed seeds25% ground arthropods	Combination (invertebrates without interception)	0.4	29.2	64.5	3.1	6.9
237	Sugar beet	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
238	Sugar beet	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4



N	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Dict of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
239	Sugar beet	BBCH≥40	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.25	54.2	102.3	18.1	34.1
240	Sugar beet	BBCH 10-39	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% crop leaves	Non-grass herbs	1	28.7	70.3	14.3	35.1
241	Sugar beet	BBCH≥40	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% crop leaves	Non-grass herbs	0.25	28.7	70.3	3.6	8.8
242	Sugar beet	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
243	Sugar beet	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
244	Sugar beet	BBCH 10-39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
245	Sugar beet	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.25	40.2	87.0	1.7	3.6
246	Sugar beet	BBCH 10-39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
247	Sugar beet	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.25	28.7	70.3	12.1	29.6
248	Sugar beet	BBCH 10-39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	1	29.2	64.5	7.8	17.2
249	Sugar beet	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates with interception)	0.25	29.2	64.5	1.9	4.3



N	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
250	Sunflower	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6
251	Sunflower	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
252	Sunflower	BBCH≥40	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.25	54.2	102.3	18.1	34.1
253	Sunflower	BBCH 10-19	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	1	28.7	70.3	14.3	35.1
254	Sunflower	BBCH 20 - 39	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	0.5	28.7	70.3	7.2	17.6
255	Sunflower	BBCH≥40	Large herbivorous mammal "lagomorph"	Rabbit (Oryctolagus cuniculus)	Herbivorous	Ground	1543	0.50	100% Non-grass herbs	Non-grass herbs	0.25	28.7	70.3	3.6	8.8
256	Sunflower	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
257	Sunflower	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
258	Sunflower	BBCH 10-19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
259	Sunflower	BBCH 20 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.5	40.2	87.0	3.3	7.2
260	Sunflower	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.25	40.2	87.0	1.7	3.6



Z	Сгор	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
261	Sunflower	BBCH 10-19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
262	Sunflower	BBCH 20 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.5	28.7	70.3	24.2	59.2
263	Sunflower	BBCH≥40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.25	28.7	70.3	12.1	29.6
264	Sunflower	BBCH 10-19	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.5	29.2	64.5	3.9	8.6
265	Sunflower	BBCH 20 - 39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.25	29.2	64.5	1.9	4.3
266	Sunflower	BBCH≥40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
267	Vineyard	Application ground directed	Large herbivorous mammal "lagomorph"	Brown Hare ( <i>Lepus</i> europaeus)	Herbivorous	Ground	3800	0.39	100% Plant matter	Non-grass herbs	1	28.7	70.3	11.1	27.2
268	Vineyard	BBCH 10-19	Large herbivorous mammal "lagomorph"	Brown Hare ( <i>Lepus</i> europaeus)	Herbivorous	Ground	3800	0.39	100% Plant matter	Non-grass herbs	0.6	28.7	70.3	6.7	16.3
269	Vineyard	BBCH 20 - 39	Large herbivorous mammal "lagomorph"	Brown Hare ( <i>Lepus</i> europaeus)	Herbivorous	Ground	3800	0.39	100% Plant matter	Non-grass herbs	0.5	28.7	70.3	5.5	13.6
270	Vineyard	BBCH≥40	Large herbivorous mammal "lagomorph"	Brown Hare ( <i>Lepus</i> europaeus)	Herbivorous	Ground	3800	0.39	100% Plant matter	Non-grass herbs	0.3	28.7	70.3	3.3	8.1
271	Vineyard	BBCH 10 - 19	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	4.2	7.6



N	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
272	Vineyard	BBCH≥20	Small insectivorous mammal "shrew"	Common shrew (Sorex araneus)	Insectivorous	Ground	9.7	0.55	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.9	5.4
273	Vineyard	Application ground directed	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	1	54.2	102.3	72.3	136.4
274	Vineyard	Application crop directed BBCH 10 - 19	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.6	54.2	102.3	43.4	81.9
275	Vineyard	Application crop directed BBCH 20 - 39	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.5	54.2	102.3	36.1	68.2
276	Vineyard	Application crop directed BBCH $\ge 40$	Small herbivorous mammal "vole	Common vole (Microtus arvalis)	Herbivorous	Ground	25	1.33	100% grass	Grass + cereals	0.3	54.2	102.3	21.7	40.9
277	Vineyard	BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates without interception	1	7.5	13.8	3.3	6.1
278	Vineyard	BBCH≥20	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Insectivorous	Ground	21.7	0.44	100% ground arthropods	ground dwelling invertebrates with interception	1	3.5	9.7	1.5	4.3
279	Vineyard	Application ground directed	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	1	40.2	87.0	6.6	14.4
280	Vineyard	Application crop directed BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.6	40.2	87.0	4.0	8.6
281	Vineyard	Application crop directed BBCH 20 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.5	40.2	87.0	3.3	7.2
282	Vineyard	Application crop directed BBCH ≥ 40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Granivorous	Ground	21.7	0.17	100% weed seeds	Small seeds	0.3	40.2	87.0	2.0	4.3



Z	Crop	Scenario	Generic focal species	Representative species	Diet guild	Foraging strata	bw (g)	FIR/BW	Diet of generic focal species in crop (%)	RUD unit	Deposition factor	Mean RUD	90th percentile RUD	Short cut value for mean RUDs	Short cut value for 90th percentile RUDs
283	Vineyard	Application ground directed	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	1	28.7	70.3	48.3	118.4
284	Vineyard	Application crop directed BBCH 10 - 19	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.6	28.7	70.3	29.0	71.0
285	Vineyard	Application crop directed BBCH 20 - 39	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.5	28.7	70.3	24.2	59.2
286	Vineyard	Application crop directed BBCH ≥ 40	Single diet for T1	Wood mouse (Apodemus sylvaticus)	Herbivorous	Ground	21.7	1.68	100% weeds	Non-grass herbs	0.3	28.7	70.3	14.5	35.5
287	Vineyard	Application ground directed	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	1	29.2	64.5	7.8	17.2
288	Vineyard	Application crop directed BBCH 10 - 19	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.6	29.2	64.5	4.7	10.3
289	Vineyard	Application crop directed BBCH 20 - 39	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.5	29.2	64.5	3.9	8.6
290	Vineyard	Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse (Apodemus sylvaticus)	Omnivorous	Ground	21.7	0.27	25% weeds 50% weed seeds 25% ground arthropods	Combination (invertebrates without interception)	0.3	29.2	64.5	2.3	5.2



## **APPENDIX B**

# COMBINED EFFECTS OF SIMULTANEOUS EXPOSURE TO SEVERAL ACTIVE SUBSTANCES

The basic concept of the risk assessment for birds and mammals is that animals are exposed to residues of active substances in the environment, e.g. via their food. Thus, the following steps do not refer to an assessment of formulation toxicity as such, but of the expected effects from exposure to a mixture of active substances (and possibly also toxic co-formulants) in the environment resulting from use of that formulation.

#### General assessment scheme

Typically, toxicity studies for birds with formulated products or mixtures of active substances are not available. For the assessment of acute effects (mortality), a surrogate  $LD_{50}$  should be calculated according to Step 1. Sublethal effects and effects on reproduction should be assessed on a case-by-case basis according to Step 2. If formulation studies are available, their results should be checked against the active substance data before they are used in the risk assessment (Step 3).

Acute mammalian toxicity tests with formulated products are more often available than for birds, because they are used for classification and labelling. Nevertheless, a surrogate  $LD_{50}$  for the assessment of acute effects (mortality) should normally be calculated according to Step 1. This will serve as a basis for checking the applicability of the available formulation toxicity for the risk assessment (Step 2). As for birds, sublethal effects and effects on reproduction should be assessed on a case-by-case basis according to Step 3.

Finally, Step 4 provides guidance on the calculation of appropriate exposure estimates for a risk assessment based on calculated or experimentally determined mixture toxicity.

#### Step 1

#### Calculation of surrogate LD<sub>50</sub> values for acute effects (mortality)

An often used model for estimating the toxicity of mixtures is the assumption of dose or concentration additivity of toxicity (Loewe and Muischnek, 1926; frequently referred to as 'Finney's equation'). There is evidence that such  $LD_{50}$  values predicted on the assumption of a similar mode-of-action should normally give a more conservative estimate of actual mixture toxicity than models based on the assumption of independent action (Junghans *et al.*, 2006; Van Leeuwen and Vermeire, 2007; EFSA, 2007; EFSA, 2008). The following equation can be used for deriving a surrogate  $LD_{50}$  for a mixture of active substances with known toxicity assuming dose additivity:

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix B. EFSA Journal 2009; 7(12):1438. [5 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu



$$LD_{50}(mix) = \left(\sum_{i} \frac{X(a.s._{i})}{LD_{50}(a.s._{i})}\right)^{-1}$$

With:

 $X(a.s._i) = \text{fraction of active substance } [i] \text{ in the mixture;}$  $(please note that the sum <math>\sum X(a.s._i) \text{ must be } 1$ )  $LD_{50}(a.s._i) = \text{acute toxicity value for active substance } [i]$ 

It should be noted that it might be necessary to include also formulants with known toxicity in the equation to achieve a reliable result.

Measured  $LD_{50}$  values should only be replaced in the risk assessment by modelled data if a significant change of the predicted risk is to be expected. To achieve a basis for a comparison of single active substance and mixture toxicity in terms of potential risk, a "tox per fraction" quotient can be calculated for each active substance and compared to the corresponding quotient for the mixture.

tox per fraction (a.s.) = 
$$\frac{\text{LD}_{50}(\text{a.s.}_i)}{\text{X}(\text{a.s.}_i)}$$
  
tox per fraction (mix) =  $\frac{\text{LD}_{50}(\text{mix})}{\sum_{i} \text{X}(\text{a.s.}_i)}$ 

Note that these "tox per fraction" quotients themselves have no biological meaning; they are only to be used for comparison. If one active substance can be identified where the two quotients "tox per fraction (a.s.)" and "tox per fraction (mix)" deviate by  $\leq 10$  %, this indicates that this active substance will contribute to  $\geq 90$  % to mixture toxicity, while the other components of the mixture will only have a marginal impact on the predicted risk. Consequently, the risk assessment can be performed for the most toxic active substance alone. No further considerations according to Steps 2 - 4 are necessary. Otherwise, the predicted LD<sub>50</sub>(mix) should be used in the risk assessment together with appropriate exposure estimates (Step 4).

When different environmental fate parameters are considered for individual active substances in a higher tier assessment, this might result in a changed composition of residues as compared to the initial mixture. In that case, the equations above have to be expanded as follows using multiple application factors (MAF):

$$LD_{50}(mix) = \left(\sum_{i} X(a.s._{i}) \times MAF_{i}\right) \times \left(\sum_{i} \frac{X(a.s._{i}) \times MAF_{i}}{LD_{50}(a.s._{i})}\right)^{-1}$$
  
tox per fraction (a.s.) =  $\frac{LD_{50}(a.s._{i})}{X(a.s._{i}) \times MAF_{i}}$ 

tox per fraction (mix) =  $\frac{\text{LD}_{50}(\text{mix})}{\sum_{i} X(\text{a.s.}_{i}) \times \text{MAF}_{i}}$ 

With:

 $MAF_i$  = multiple application factor for active substance [*i*]

To be consistent with the assessment for single active substances, always their respective relevant LD50 values should be considered in the calculation of mixture toxicity, regardless for what species they were

determined. Data for other species should only be used where clear evidence is available for a different specific mechanism of toxicity in one of the tested species for one of the active substances considered.

Neither occurrence nor magnitude of synergistic effects can be predicted with Finney's equation. Therefore, if synergism is expected, targeted studies may be required. See also EFSA (2008).

#### Step 2a

#### Assessment of available formulation toxicity data (dose/response tests)

Where the  $LD_{50}$  of a formulated product with more than one active substance is available, this value should be compared with the predicted mixture toxicity assuming dose additivity (see Step 1). A different form of the equation than in Step 1 is used.

$$\sum_{i} \frac{X(a.s._{i})}{LD_{50}(a.s._{i})} = \frac{1}{LD_{50}(mix)}$$

With:

X(a.si)	= fraction of active substance [ <i>i</i> ] in the mixture (here: formulation)
$LD_{50}(a.si)$	= acute toxicity value for active substance [ <i>i</i> ]
$LD_{50}(mix)$	= measured acute toxicity value for the mixture (here: formulation)

A greater value on the right side of the equation indicates that the formulation is more toxic than predicted from the toxicity of the individual components (active substances and co-formulants of known toxicity). This may be due to, e.g. further toxic co-formulants, toxicokinetic interaction or synergism/potentiation of effect. It may also reflect the inherent variability of toxicity testing. In all these cases, the use of the  $LD_{50}$  for the formulation (together with appropriate exposure estimates, see Step 4) is recommended for the first-tier assessment, because it cannot be excluded that such effects would also occur after exposure of animals to residues in the environment.

Dismissing the  $LD_{50}$  of the formulation from the risk assessment would only be acceptable at a higher tier if any observed greater toxicity in the test could be clearly and unambiguously ascribed to a factor that would not be relevant under environmental exposure conditions.

If, in contrast, the measured toxicity of a formulation is lower than predicted, the predicted mixture toxicity according to Step 1 should be used in the first-tier risk assessment, together with appropriate exposure estimates (Step 4).

It is obvious that the predicted mixture toxicity calculated according to the model of dose or concentration additivity will always be greater than the individual measured toxicity of each contributing compound. It will also be greater than the toxicity predicted with other models (independent action) as long as synergism is excluded (Junghans *et al.*, 2006). As there is currently no clear evidence for synergistic effects to become manifest under environmental conditions, the use of the predicted mixture toxicity values is, for the time being, acknowledged to constitute a sufficiently conservative starting point for the first-tier assessment. The use of alternative prediction models or experimental data may be considered on a case-by-case basis at higher tier.

#### Step 2b

#### Assessment of available formulation toxicity data (limit tests for classification and labelling)

Acute toxicity studies with formulations in mammals are mainly performed for classification and labelling and normally are not designed for the derivation of a precise  $LD_{50}$ . Still, these studies should be considered in the ecotoxicological risk assessment as they might provide indications for greater toxicity than expected from the studies with active substances due to, e.g. toxic co-formulants or synergism. In such cases, the use of 'greater than'  $LD_{50}$  from a formulation study would be more precautionary and appropriate than a predicted  $LD_{50}$ .



#### Step 3

#### Consideration of mixture toxicity for sublethal effects and effects on reproduction

As regards the risk to reproduction from exposure to more than one active substance, it is currently not recommended to consider the use of predicted toxicity values as surrogates in the risk assessment. Although it would be, in principle, possible to apply the concept of dose or concentration additivity of toxicity also to effect data for biological endpoints from long-term and reproductive toxicity testing, reliable results would only be expected for combinations of  $EC_x$  values for the same biological endpoint. Moreover, additional bias would be introduced in the calculations if the values applied do not represent  $EC_x$  values with defined x, but NOAELs, since these may represent varying risk or response levels for different compounds, depending on dose-spacing.

Nevertheless, there is also evidence that mixtures of chemicals can cause effects even though all their constituents were present in the environment at concentration levels around their individual NOECs ("something from nothing"). This has to be expected for mixtures of compounds acting in the same way on defined molecular targets, e.g., the estrogen receptor (ER- $\alpha$ ) (Kortenkamp, 2007). If a given formulation contains several active substances all known to cause similar effects via a similar biochemical mechanism (e.g. aromatase inhibition) and if this type of effects is actually driving the risk assessment, it is thus recommended to perform an assessment for combined effects on a case-by-case basis.

In a simple approach, all active substances belonging to the same group could be expressed in terms of the most toxic representative (on a molar basis to account for differences in molar weight) and the risk assessment performed for the group applying the corresponding NOEC for the most toxic compound. The potential for more elaborated modelling (e.g., quantification of toxicity relative to an index compound; see relative potency approach in EFSA, 2008) depends on the availability and quality of data.

#### Step 4

## Appropriate exposure estimates for a risk assessment based on calculated or experimentally determined mixture toxicity

An  $LD_{50}$  for a mixture of active substances calculated assuming dose additivity can be conceived as an  $LD_{50}$  of a single virtual compound. It is thus deemed the most logical approach to also base the exposure side of the risk assessment on the same assumption. Content in the formulation and application rate per hectare should thus be expressed in terms of this virtual compound. As long as only a single application is intended or considered, no changes in the composition as compared to the formulated product will occur and no adjustment of environmental residues is necessary.

If several applications must be considered, the default MAF values of Tier 1 can also be applied to the mixture as a single virtual compound. However, if the assessment should be refined using specific environmental fate data for individual active substances, the composition of the residues might be changed as compared to the original mixture. Using substance-specific MAF values, a residue level C(mix) after two or more applications can be calculated as follows.

$$C(\min) = \sum_{i} C_0(a.s._i) \times MAF_i$$

With:

 $C_0(a.s._i)$  = residue levels of active substance [i] after one application of the original mixture MAF<sub>i</sub> = multiple application factor for active substance [i]

The  $MAF_i$  values are then also required for adjusting the mixture toxicity according to the changed composition as compared to the original mixture – see Step 1 for the respective equation.

If the risk assessment is based on experimental toxicity data for the formulated product, no differentiation according to environmental fate parameters of individual active substances is possible. As



described above for mixtures in general, also a formulation may be conceived as a single virtual compound and the default MAF values of Tier 1 may be applied.

In principle, the concept of the single virtual compound could also be applied to calculate time-weighted average concentrations for mixtures or formulations. However, the current proposed approach for assessing combined effects of simultaneous exposure to several active substances is restricted to the assessment of acute effects where time-weighted averages are not considered.

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## **APPENDIX C**

## EVALUATION OF THE LEVEL OF PROTECTION PROVIDED BY THE FIRST-TIER ASSESSMENT PROCEDURES

This Appendix documents the basis on which the first-tier risk assessments provided in the Guidance Document were judged to provide an appropriate level of protection. In addition, the tables presented in this Appendix may be a useful starting point for case-by-case consideration of the level of protection achieved in refined (higher tier) assessments (see section 6.9 of Guidance Document).

#### Protection goals for first-tier assessment procedures

#### Interpretation of actual protection goals

Directive 91/414/EEC does not contain a precise definition of the level of protection in first-tier assessments. Annex VI to this Directive specifies a decision rule (TER  $\ge$  10 for acute risks, TER  $\ge$  5 for long-term risks). However, the level of protection actually achieved also depends on the precise manner in which the toxicity endpoints for the TER are selected and how the exposure component of the TER is calculated. This is not specified in detail by the Directive. Therefore, in developing the first-tier assessment procedures, careful consideration was given to how this should be addressed.

The first-tier assessment should be designed to ensure at least the same level of protection as is required in higher-tier assessments, as it would not be logical to authorise at Tier 1 substances that would fail at higher tiers. The level of protection required at higher tiers is indicated by C.1 point 2.5.2.1 in Annex VI of Directive 91/414/EEC (the 'uniform principles'). This states that when a refined assessment for birds is required, "no authorisation shall be granted ... unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product under the proposed conditions of use."

The meaning of 'no unacceptable impact' is not defined in the Directive. However, Annex VI C.1, Number 5 to the Directive specifies a particular responsibility for Member States: "...MS shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species". This makes clear that long-term effects on

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abundance and diversity<sup>1</sup> are not acceptable. However, this still does not precisely define the protection goal. For example, it does not define the temporal scale (how long is long-term?) nor the spatial scale (local, regional, etc.) on which changes in abundance and diversity should be assessed<sup>2</sup>. This is important because it makes it uncertain what level of short-term impacts on mortality or reproduction can be tolerated without threatening the long-term population goal. Furthermore, the directive does not state explicitly whether short-term effects can be unacceptable in themselves.

The previous Guidance Document stated that "appreciable mortality without population level consequences may be judged unacceptable" (EC, 2002, page 3). A survey conducted by EFSA (2008) confirmed that both individual mortality and population effects are of concern. The Commission and some Member States stated concern about mortality related to 'visible' mortality (e.g. animals dying in public places or in noticeable numbers)<sup>3</sup>.

The 'unless clause' in Annex VI (quoted above) states that no authorisation shall be granted unless it is 'clearly established' that the unacceptable impacts will not occur. Although it is not defined, 'clearly established' suggests that a high level of certainty is required.

Based on these considerations, it is concluded that approaches for first-tier assessment should be designed to provide a high level of certainty and that there will be no visible mortality and no long-term repercussions for abundance and diversity.

## Addressing the protection goals

In principle, it would be desirable to assess or model visible mortality or population impacts directly, since these are protection goals. This is currently not practical for first-tier assessments<sup>4</sup>, although it may be an option for higher tiers. Therefore, this opinion continues the approach of previous guidance, using TERs as the primary quantitative measure of risk in first-tier assessments, except for acute risk of sprayed pesticides, where TER and  $LD_{50}s/m^2$  are presented as alternative options. Consequently, it is necessary to design these procedures in such a way that the protection goals are achieved, e.g. in order to ensure a high certainty of the absence of visible mortality or of long-term repercussions if the relevant TER trigger value in Annex VI is exceeded. This requires judgements about the levels of TER or  $LD_{50}/m^2$  that would lead to visible mortality or population impacts. These judgements are inevitably very uncertain. For example, it is often suggested that animal populations are sufficiently resilient to absorb some level of mortality or reproductive failure but (a) it is uncertain what levels could be tolerated, and (b) given that farmland bird populations have been declining in any case, it is possible that any resilience they possess is already exhausted.

#### Definition of surrogate protection goal for first-tier assessments

It is concluded that the uncertain definition of the protection goals and their uncertain relationship to the measures of risk that are practical for first-tier assessment makes it very difficult to achieve the required level of certainty ('clearly establish'). The practical solution is to design the first-tier assessment procedures in order to make any mortality or reproductive

<sup>&</sup>lt;sup>1</sup> It is assumed that 'abundance' refers to population size or density for individual species and 'diversity' refers to the number and variety of different species.

<sup>&</sup>lt;sup>2</sup> In EFSA's survey of Member States and stakeholders, some respondents indicated that population effects should be considered at local level, whereas others indicated they should be considered at regional level.

<sup>&</sup>lt;sup>3</sup> 'Visible mortality' is a social or political criterion, rather than an ecological one.

<sup>&</sup>lt;sup>4</sup> Modelling population impacts requires data on population parameters and the spatial distributions of wildlife and pesticide use that are not available in many Member States. Estimating visible mortality would require modelling the factors that influence the visibility of casualties, which would be difficult to quantify.



effects unlikely. This is referred to as a 'surrogate protection goal'. It allows a scientific judgement on the appropriate design of the first-tier assessment with much more confidence than would be possible if the actual protection goals were assessed directly. Additionally, the first-tier assessment should be sufficient to ensure a high certainty of avoiding visible mortality and long-term population repercussions. It should also ensure that there will be no short-term repercussions, the acceptability of which is not defined (see above).

The surrogate protection goal of making any mortality or reproductive effects unlikely is more conservative than the actual protection goal of clearly establishing that there will be no visible mortality and no long-term repercussions for abundance and diversity. Specifically, it means that first-tier procedures should assess exposure and effects for a *realistic worst-case individual*, i.e. a sensitive individual of a sensitive species, experiencing the upper end of realistic exposures. This degree of conservatism is necessary in the first tier because of the uncertain definition of the actual protection goals and the uncertainty in assessing them with the simple risk measures that are practical for first-tier assessments. It is consistent with normal practice in risk assessment, i.e., for first-tier assessment procedures to be more protective than higher-tier assessments.

It is essential to emphasise that the surrogate protection goal is not a replacement for the actual protection goal but is a surrogate for use in first-tier assessments. The actual protection goal remains the ultimate criterion. Higher-tier assessments may address the actual protection goal directly (e.g. assess the probability of visible mortality or the probability of long-term repercussions for abundance and diversity). However, higher-tier assessments may also be based on the surrogate protection goal, if that is a more practical option for the case in hand (e.g. a refined TER calculation, see section 6 of Guidance Document).

## *Cumulative effects<sup>5</sup>*

It is current practice to assess the ecological risks of different pesticides independently, unless they are coformulated in a single product. However, there is some ambiguity about whether or not the actual protection goal relates to individual pesticides and/or to the cumulative effects of multiple products. As mentioned above, Annex VI C.1, Number 5 states: "...MS shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species". The 'use of plant protection products' (plural) could be interpreted as implying that the goal is to ensure no long-term repercussions when authorised products are considered collectively. However, it is also possible that this clause was intended to refer to the effects of pesticides considered individually. The former is consistent with the aspiration, expressed by some Member States when responding to the EFSA (2008) survey, that ideally they would like to address the combined effects of multiple pesticides<sup>6</sup>. The latter interpretation is consistent with current practice and also with the recognition by the above mentioned respondents that assessing effects of individual pesticides is more practical. Deciding between these interpretations is a risk management issue. However, the surrogate protection goal is compatible with both interpretations, because if effects are unlikely for individual pesticides they should also be unlikely if pesticides were considered collectively.

#### Summary

<sup>&</sup>lt;sup>5</sup> Note that in this section 'cumulative' is used in the general sense of the cumulation of impacts of pesticide use as a whole, including for example effects on different individuals exposed to different pesticides, and not in the narrower sense of the combined toxic effect for (an) individual exposed simultaneously to multiple pesticides,

<sup>&</sup>lt;sup>6</sup> Note that assessing cumulative effects for multiple pesticides is an explicit aspiration in the legislation relating to consumer risk assessments and MRL-setting (Regulation (EC) 396/2005).



In summary, the procedures described in the Guidance Document for first-tier assessment are designed to achieve the surrogate protection goal of making any mortality or reproductive effects unlikely. At higher tiers, assessments may be directed either at the surrogate protection goal or at the actual protection goal of clearly establishing that there will be no visible mortality and no long-term repercussions for abundance and diversity. If the actual protection goals are defined more precisely in future, then the surrogate protection goal and first-tier procedures should be reviewed and revised accordingly.

## Methods used for evaluating the level of protection

For each first-tier assessment procedure, it was evaluated whether the surrogate protection goal (i.e. to make *any* mortality or reproductive effects unlikely) was met. This was based mainly on expert judgement of the conservatism of the data and assumptions used in the first-tier assessment. For each element of the assessment, the extent to which the element could be lower or higher for the most at-risk individuals was evaluated: in other words, the degree to which the first-tier assumptions are distanced from a realistic worst case<sup>7</sup>. This evaluation was conducted by constructing uncertainty tables in the format recommended for higher-tier assessments (section 6.8 of Guidance Document). In the case of acute risks from sprayed pesticides, additional lines of evidence were provided. These came from historical records of poisoning incidents and comparison of the first-tier assessment with data on mortality in field studies. These three lines of evidence were evaluated together using the weight-of-evidence approach recommended in section 6.9 of the Guidance Document.

The following sections document the basis on which it was judged that this goal is met by the procedures proposed for first tier assessment procedures. To illustrate the approach, the evaluation for acute risks to birds is presented in detail in the following section. The justification for other first-tier procedures is documented more briefly but uses the same principles.

## Acute risk to birds from sprayed pesticides, assessed using TERs

This section documents the judgements made regarding the level of protection (LoP) for the first-tier assessment using a TER calculation. An alternative first-tier approach for acute risks based on lethal doses applied per square meter ( $LD_{50}/m^2$ ) is considered more briefly in the following section.

Three lines of evidence are available for evaluating the LoP: the conservatism of the assessment assumptions (Table 1); comparison between calculated TERs and evidence on the occurrence of mortality in field studies (Table 2); and historical records of poisoning incidents (Table 3). Overall conclusions about the conservatism of the proposed procedure were derived by considering the relative weights of these three lines of evidence (Table 4).

The left hand column of Table 1 lists all of the factors used in calculating exposure for the acute TER for sprayed pesticides, including the parameters used to estimate daily food intake (daily energy requirement, food energy and moisture contents, energy assimilation efficiency, and body weight), residues on foods eaten by birds (residue per unit dose, half-life, multiple application factor, interception factor) and behaviour (dietary composition and proportion of diet obtained from treated area). It also enumerates factors that affect the conservatism of the toxicity endpoint used in the assessment (variation between and within species, regurgitation), and the

<sup>&</sup>lt;sup>7</sup> As explained in the previous section, it is necessary to focus on the most at-risk individuals in order to make any mortality or reproductive effects unlikely.



uncertainty factor of 10 that is implied by comparing the final TER to the decision criterion from Annex VI of the Directive. It also lists three important factors that are not included in the first-tier TER assessment, i.e. avoidance, metabolism and non-dietary routes of exposure.

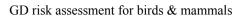
The second and third columns of Table 1 evaluate the extent to which the 'true' worst case for each parameter could make the risk lower than implied by the first-tier calculation. Similarly, the fourth and fifth columns of Table 1 evaluate the extent to which the 'true' worst case for each parameter could heighten the risk. It is recognised that, although some variables have an identifiable realistic upper or lower bound (e.g. the proportion of diet obtained in treated area can realistically be one but not higher), for other variables the realistic worst case is much harder to judge (e.g. residues). Nevertheless it was possible to make the approximate, relative judgements that are required in Table 1.

Focussing on a 'true' or realistic worst-case individual is necessary to address the surrogate protection goal of making any mortality unlikely, as explained in preceding sections. For example, although an estimate of the 90<sup>th</sup> percentile is used for determining the residue per unit dose, this nonetheless allows the true worst case to be higher since a small proportion of individuals will experience higher residues. This, together with other factors (summarised in column 5 of Table 1), lead the to the conclusion that for some pesticides the true worst-case RUD could be five times higher than the default value (hence two plus symbols in column 4). On the other hand, it is also possible that the worst-case is overestimated for some pesticides. This is because the estimated 90<sup>th</sup> percentile RUD is based on data for multiple pesticides, so it is probable that the true 90<sup>th</sup> percentile varies between pesticides to some extent and it is possible that the realistic worst-case for some individual pesticides is less than the 90<sup>th</sup> percentile averaged across all pesticides (hence a minus symbol in column 2). These evaluations take account of the range of variation of each parameter and its influence on the TER. For example, only an average value is used for body weight but the range of variation for this parameter is small. As it appears twice in the exposure calculation (once to estimate food intake, and once to convert absolute to relative dose), its effect nearly cancels out. Therefore, its influence on exposure is small (no symbols for effect via exposure, although it has more influence via toxicity as shown further down the table).



**Table 1.** Evaluation of conservatism of the first-tier assessment of acute avian risks assessed using a TER, in relation to the surrogate protection goal of making any mortality unlikely. Each row evaluates a separate input, assumption or omission of the TER calculation. Symbols are used to indicate the extent to which it is judged the 'true worst' case for that element could decrease (-) or increase (+) the risk of causing any mortality. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect: three symbols (e.g. - - ) indicates a factor that would change the risk by an amount equivalent to changing the TER by about a factor of 10, two symbols indicates a factor of about 5, and one symbol indicates a factor of about 2. The number of symbols does not reflect the variability of that particular parameter but its potential influence on the risk. The overall evaluation at the bottom of the table gives an overall judgement on the combined effect of the various factors on the overall conservatism of the assessment. This is based on expert judgement of how the factors interact and is not a simple summation.

Parameter, assumption or omission	Potential to lower 'true worst- case' risk	Explanation	Potential to highten 'true worst- case' risk	Explanation
Screening assessment indicator species and type of food	-	Realistic worst case – relatively small species eating only the most contaminated food type. Real worst case could be lower in some scenarios.		Realistic worst case – relatively small species eating only the most contaminated food type. Negligible potential to be worse.
Tier 1 generic focal species and type of food		Mixed diet based on average of available data on dietary composition. Worst case cannot be lower than average.	+	Mixed diet based on average of available data on dietary composition. Some individual birds will eat more than average proportion of most contaminated food on individual days.
Body weight (impact on exposure)	_	In some scenarios such small species may not occur. However, this has only a limited impact on risk due to scaling of food intake with body weight.		For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight.
Body weight (impact on toxicity)		Relatively few exposed species are larger than species used in toxicity tests.	+	Focal species tend to be smaller than species used in toxicity tests. General trend for smaller species to be more sensitive (Mineau et al., 1996) is not taken into account in assessment. This is unlikely to exceed a 3-times difference in most cases.
Daily food intake	_	Average, but taken from demanding period (e.g. breeding season). Energy expenditure and risk could be lower in less demanding periods.	+	True worst case unlikely to be more than two times more than assumed value except in extreme cases, e.g. fattening for migration.
Percent of diet taken by individual in treated area	_	Likely only a few scenarios where true worst case individual is less than 0.5 (i.e. factor of 2 reduction).		Absolute worst case; cannot be higher.
Residue per unit dose	_	90 <sup>th</sup> percentile of data for multiple pesticides and application events. True distribution for pesticide under assessment could be lower than generic distribution used in assessment, so true worst case could be lower than generic 90 <sup>th</sup> percentile.	++	90 <sup>th</sup> percentile of data for multiple pesticides and application events. True 90 <sup>th</sup> percentile for pesticide under assessment could be higher than generic 90 <sup>th</sup> percentile used in assessment. In addition, 10 % of concentrations are expected to be higher than 90 <sup>th</sup> percentile. Furthermore, measuring RUD values relate to pooled samples and may underestimate peak concentration on highly-exposed food types.





Parameter, assumption or omission	Potential to lower 'true worst- case' risk	Explanation	Potential to highten 'true worst- case' risk	Explanation
Half-life on food (DT <sub>50</sub> )		Affects only multiple applications, and then only part of total exposure. Default value of 10 days is conservative: most pesticides have $DT_{50}$ s below 10.	+	Affects only multiple applications, and then only part of total exposure. Some pesticides have $DT_{50}s$ longer than 10 days (e.g. 19 % of pesticides registered in Canada in 2005 <sup>8</sup> ). Also dissipation in first few days is often faster than implied by assumption of first order kinetics.
Model for deriving multiple application factor from DT <sub>50</sub> and RUD			+	Affects only multiple applications, and then only part of total exposure. Uncertainty about what proportions of variability in existing RUD data represent within and between field variation. Maximum difference between MAF <sub>90</sub> and MAF <sub>mean</sub> does not exceed 30 % under realistic scenarios so any increase in risk would be minor.
Interception factors		Interception factors are based on those used in FOCUS Step 2, which were derived from field measurements and are considered to be a realistic worst case for spray reaching the ground.		Interception factors are based on those used in FOCUS Step 2, which were derived from field measurements and are considered to be conservative for spray reaching the ground. Within each growth stage a conservative (early) value is used.
Non-dietary exposure			+/++	Ignored. True contribution uncertain, but could increase risk by up to two times or more (Driver et al., 1991).
Variation of toxicity between species		Focal species could be over one order of magnitude more or less sensitive than standard species (Fig. 1).	+++	Focal species could be over one order of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases.
Variation of toxicity between individuals			+/+++	Most sensitive individuals could be $2 - 10$ times (i.e. + to +++) more sensitive than LD <sub>50</sub> (Fig. 2).
Uncertainty factor		TER is compared with trigger value of 10.		
Avoidance of contaminated food	-/	Ignored. True contribution varies between pesticides and species. Could be negligible, or could prevent mortality even for most sensitive species.		
Effect of metabolism		Ignored. True contribution varies between pesticides and species. Could be negligible or very substantial.		

<sup>&</sup>lt;sup>8</sup> Based on <u>http://www.wsi.nrcs.usda.gov/products/W2Q/pest/winpst.html#pst%20ppd</u>



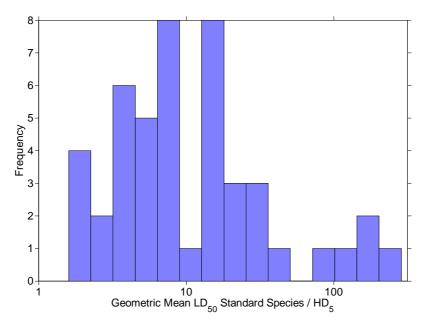
Parameter, assumption or omission	Potential to lower 'true worst- case' risk	Explanation	Potential to highten 'true worst- case' risk	Explanation
Regurgitation		Should not cause under-estimation of risk if use of $LD_{50}$ studies where regurgitation occurred is avoided. May partially reduce mortality for some species in field, although not all individuals will regurgitate.	Case Hisk	
Overall	metabolism	Biases connected with the exposure calculation are relatively small (mostly within a factor of about 2) compared to the influence of toxicity, avoidance and metabolism. For pesticides with strong avoidance and rapid metabolism <sup>9</sup> , Tier 1 will substantially overestimate risk. For substances with little or no avoidance and slow metabolism, true risk for a sensitive species could be higher and some mortality could occur above TER = 10.		

<sup>&</sup>lt;sup>9</sup> No general statement can be made about the degree of avoidance and metabolism required for this, but it could be an option for case-by-case investigation in higher-tier assessments.



The overall evaluation at the bottom of the table gives an overall judgement on the combined effect of the various factors on the overall conservatism of the assessment. This is based on expert judgement of how the factors interact. It is not a simple summation of the plus and minus symbols.

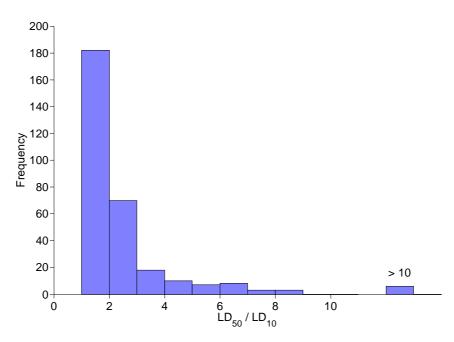
Overall, it is considered that the calculation of dietary exposure might be relatively close to a realistic worst case, but that the conservatism of other aspects is much more uncertain. Possibly the largest single source of uncertainty is the extrapolation of toxicity from a test species to the species exposed in the field, which for some pesticides may be over an order of magnitude more or less sensitive (shown in Table 1 as +++ and - - -). Evidence for this is illustrated in Figure 1, which shows the manner in which the ratio of the geometric mean of two standard test species to the HD5 (estimated fifth percentile species) varies between pesticides. Another important factor affecting the conservatism of the assessment is that within a species, sensitive individuals may be 2-10 times more sensitive than the LD<sub>50</sub> value that is used in the TER calculation (see Figure 2). On the other hand, both avoidance and metabolism are ignored in the TER calculation but could greatly reduce the risk for some pesticides. Consequently, the overall conservatism of the first-tier TER calculation will vary widely between pesticides. If the focal species happens to be much more sensitive than the standard test species, and if there is little or no avoidance and metabolism, then the true risk could be higher than implied by the first-tier assumptions, and some mortality might then occur when the Tier 1 TER = 10. For pesticides that are subject to strong avoidance and metabolism, the first-tier assessment will substantially over-estimate risk.



**Figure 1.** Frequency histogram for the ratio of the geometric mean of the  $LD_{50}$  values for two standard test species (which is used in TER calculations) to the estimated HD5 in 46 different pesticides, plotted on a log10 scale. The HD5 is taken as an arbitrary example of a sensitive species. For some pesticides, the estimated HD5 is nearly 100 times more sensitive than the  $LD_{50}$  used in the TER calculation<sup>10</sup>.

 $<sup>^{10}</sup>$  HD5 is 5<sup>th</sup> percentile of variation in LD<sub>50</sub> between species for the same pesticide, estimated by the method of Aldenberg and Slob (1993). Analysis restricted to pesticides with over 10 tested species, in order to limit sampling error in estimating the HD5 from small samples.





**Figure 2.** Frequency histogram for the ratio of the  $LD_{50}$  to the  $LD_{10}$  in 307 different toxicity studies with different species and pesticides, plotted on a  $log_{10}$  scale. The  $LD_{10}$  is taken as an arbitrary example of a sensitive individual. The lethal dose for sensitive individuals is within a factor of 2 of the  $LD_{50}$  in about 50 % of cases, and is nearly always within an order of magnitude.<sup>11</sup>

The second line of evidence for evaluating the LoP of the acute avian assessment for sprayed pesticides is derived from the comparison between calculated TERs and evidence on the occurrence of mortality in a total of 99 field studies with 28 different pesticides (seven carbamates, 19 organophosphorus pesticides, and two others). Uncertainties affecting extrapolation from organophosphates (OPs) and carbamates to other pesticides are discussed in detail below. A detailed account of the analysis is presented in Appendix 2 of EFSA, 2008.

The details and quality of the methods varied between field studies, as did the level of detail contained in the study reports. As a consequence, interpretation of the studies is inevitably subjective and uncertain. The evaluation addressed this in two ways. First, a method of evaluation was devised that allowed the evaluator to reflect their uncertainty about the attribution of effects. Second, each study was evaluated independently by three or four separate evaluators. In addition, the uncertainties affecting this and other aspects of the analysis are evaluated in detail below.

The measure used for evidence of field effects is the subjective probability of lethal effects. This was obtained by asking each assessor to evaluate the results of each field study, and to judge whether direct acute toxic effects on birds actually occurred in each study. Specifically, the evidence for the truth of each of the following statements was evaluated:

1. The pesticide application(s) caused no direct acute impact on adult birds. Absence of obvious sublethal or lethal effects.

<sup>&</sup>lt;sup>11</sup> Analysis for same pesticides as Figure 1, but restricted to toxicity studies for which both an  $LD_{50}$  and slope were available.  $LD_{10}$  is the dose lethal to 10 % of animals tested.

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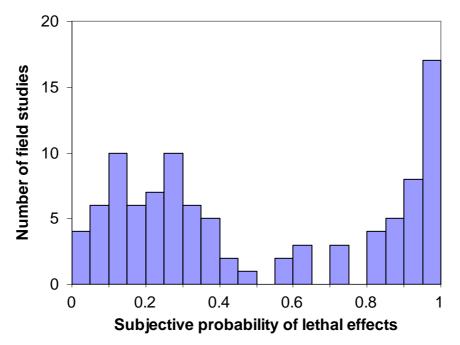
- 2. The pesticide application(s) caused direct sublethal effects on adult birds. Changes in behaviour or physiology (e.g. choline esterase inhibition) were present but no immediate lethality.
- 3. The pesticide application(s) caused mortality of adult(s) in a single bird species.
- 4. The pesticide application(s) caused mortality of adults in two to five species of birds.
- 5. The pesticide application (s) caused mortality of adults in more than five species of birds.

The evaluators each expressed their own evaluation of each study by stating their subjective probability (i.e. degree of belief) for each statement being true. Because the protection goals relate to mortality and population effects (see earlier), it was decided to sum the probabilities assigned by each evaluator to statements 3-5 for each study, as an estimate of their subjective probability that the pesticide caused any mortality. Comparison of the results for the four evaluators showed a high degree of consistency in their interpretation of nearly all the studies (see Appendix 2 of EFSA, 2008). Consequently, the probabilities were averaged across evaluators for each study.

Caution is required in interpreting these probabilities. They express the likelihood (as assessed by four evaluators) that mortality occurred in each field study. This is a measure of the *strength of evidence* that mortality had actually occurred in that particular field study. It is not a measure of frequency. For example, a probability of 0.9 for a particular study means that after reviewing the reported results, the evaluators were (on average) 90 % sure that mortality caused by the pesticide had occurred in that study. It is not, and should not be interpreted as, an estimate of how often mortality would occur if the field study was repeated many times.

A histogram of the mean subjective probabilities assigned by the evaluators is shown in Figure 3. The probabilities fall mainly in two groups, one group between 0 and 0.4, and the other group between 0.8 and 1. The group between 0.8 and 1 relate to field studies where the evaluators considered the evidence of lethal effects to be strong (e.g. dead birds were found), with some evidence that they were caused by the pesticide (e.g. residues, cholinesterase inhibition, or comparison with unsprayed control sites). Probabilities in the lower group (between 0 and 0.4) imply less evidence of lethal effects. Those between 0 and 0.2 relate mostly to field studies with reasonable methodology that found no evidence of lethal or sublethal effects. Some of the probabilities around 0.2 - 0.3 relate to field studies without evidence of direct toxic effects but in which the methodology was not strong enough to provide confidence of detecting effects. Probabilities from 0.3 to 0.4 mostly relate to studies with evidence of sublethal effects (cholinesterase inhibition, the finding of a single debilitated bird founding a few cases, and indications of reduced nestling success in a few cases).





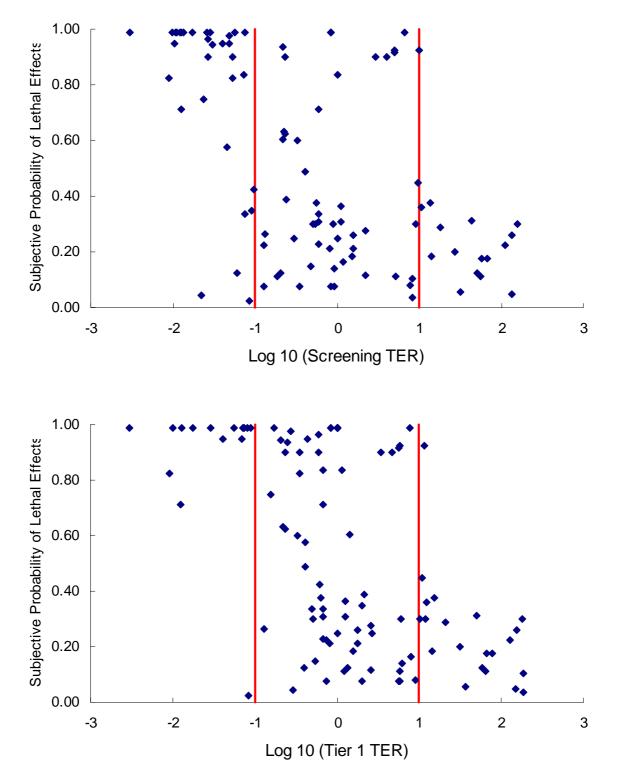
**Figure 3.** Histogram of subjective probabilities of lethal effects evaluated for a total of 99 field studies with 28 different sprayed pesticides. Each probability is the mean of values assigned by three or four evaluators, and represents their assessment of the strength of evidence that lethal effects were caused by the pesticide under study.

The probabilities assigned by the evaluators take account of the fact that the detection of sublethal effects increases the chance that lethal effects occurred but were not detected. Therefore, probabilities below 0.5 cannot be interpreted as implying absence of any mortality. On the other hand, they can be interpreted with reasonable confidence as implying an absence of 'visible mortality', if this is interpreted as birds dying in numbers noticeable to the public, since the methods employed in the field studies involved active searching and monitoring that substantially increase the chance of detection.

To evaluate the level of protection provided by proposed assessment procedures, screening and first-tier TERs were calculated<sup>12</sup> for the pesticides and crops involved in each field study, and were compared to the subjective probabilities of effects in the field studies. The results of these comparisons are shown in Figure 4. The TERs are shown on the horizontal axis, and the field study results on the vertical axis.

<sup>&</sup>lt;sup>12</sup> TERs were based on exposures calculated according to the Guidance Document, and geometric means of LD50s for bobwhite quail and mallard duck, as these are the standard species most commonly submitted for risk assessment. Where data for bobwhite quail were lacking, Japanese quail was substituted if available.





**Figure 4.** Relationship between evidence of lethal effects in field studies and the TER for each field study, calculated using the proposed default values for screening assessments (top graph) and first-tier assessments (bottom graph). Excludes avicidal applications. Horizontal axis is plotted on log10 scale. Vertical lines are at -1 and +1 (i.e. TER = 0.1 and 10).



The two graphs in Figure 4 are each divided into three regions, as illustrated by the vertical lines:

- 1. an area above about TER = 10, in which one or none of the field studies had a high probability of lethal effects;
- 2. an area below about TER = 0.1, in which most of the studies had a high probability of lethal effects;
- 3. an intermediate area between TER = 0.1 and 10, in which some studies had a high probability of lethal effects and others a low probability.

With regard to the pesticide uses represented in the field studies, these results are interpreted as suggesting that those with TER > 10 would rarely cause visible mortality. This conclusion takes account of the fact that, although some of the field studies with TER > 10 had probabilities of lethal effects in the region of 0.3, this overestimates the probability of visible mortality. This is due to the greater detectability of effects in field studies (which involve active searching) compared to normal use.

Pesticide uses with TERs between 0.1 and 10 caused detectable mortality in some of the field studies but not others, while those with TER < 0.1 caused detectable mortality in a high proportion of field studies. It is difficult to assess how often this mortality would reach a sufficient level to be 'visible'. It seems clear, however, that uses with TERs below 10 cannot be regarded as achieving the surrogate protection goal of any mortality being unlikely.

It is essential to consider the uncertainties affecting this use of the field study data. Uncertainties are summarised in Table 2, evaluated in terms of their potential to make the critical TER (at which any mortality becomes unlikely) higher or lower than the value of 10 specified in Annex VI of Directive 91/414/EEC. Uncertainties relating to the field studies and their interpretation are evaluated first, followed by uncertainties relating to differences between pesticides and use scenarios. The latter includes an evaluation of differences between the pesticides and scenarios found in the field studies and those encountered in EU regulatory assessments.

It is considered that most of the uncertainties have only minor impacts (factor of 2 or less) on identification of the critical TER value. Two factors stand out as potentially causing larger increases in the critical value. First, the possibility that some undetected mortality occurred in some of the field studies with TER > 10. Although it is considered that such mortality is unlikely to be 'visible', it would breach the surrogate protection goal of making any mortality unlikely. Second, all but two of the pesticides in the field studies were OPs or carbamates, all of which are likely to elicit moderate or strong avoidance responses. If these responses were much reduced or absent, as may occur for some other types of pesticide, then it would be expected that mortality – perhaps visible mortality – would occur at higher TERs than seen in the field studies, i.e. higher than 10. If it were desired to guard against these possibilities, then it might be prudent to increase the conservative value for any of the inputs, or by adding an extra factor to the calculation. If it was decided not to increase the conservatism of the assessment, it would mean that some undetected mortality could occur occasionally for pesticides with TER > 10, and that visible mortality might occur for such pesticides if they had little or no avoidance.

In some cases, it might be possible to apply for some pesticides a lower critical TER value than for others, if a reliable way could be found to identify them (e.g. based on common toxicological properties). There are some signs in the data that such differences may exist. For example, in seven field studies with methiocarb that showed TER values in the region of 0.1,



only one of them was evaluated as indicating a high probability of lethal effects. However, even if the critical TER is lower for methiocarb, the causing factors are not clear (possible candidates include avoidance, reversibility, rapid metabolism, and reduced dermal exposure or uptake). Therefore, it is not possible to identify with confidence other pesticides to which the same factors apply. Statistical analyses show that a combination of the octanol-water partition coefficient ( $K_{ow}$ ) and the need for activation<sup>13</sup> substantially improve the prediction of mortality in the field studies (Appendix 2 of EFSA, 2008). However, the form and mechanism of these relationships are very uncertain and, on the basis of current evidence, there is insufficient confidence that these can be extrapolated to other pesticides (see Appendix 2 of EFSA, 2008). Furthermore, it is possible that much or all of the broad range of TER values over which both high and low probabilities of mortality occur (Figure 4) could be due to factors that are common to all pesticides. These include variation in exposure between field studies (e.g. species and individuals present in any given field study, as well as variation in exposure between field studies (e.g. species and individuals with high PT may be present in some field studies but not others, and residues may vary between different applications of the same pesticide).

<sup>&</sup>lt;sup>13</sup> Some pesticides require activation within the body to produce their toxic metabolite, e.g. some OPs, see Appendix 2 of EFSA (2008).

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**Table 2.** Evaluation of uncertainties affecting comparison of the first-tier TER assessment of acute avian risks with data on mortality in field studies. The aim is to find the critical TER value above which any mortality will be unlikely (surrogate protection goal). Symbols are used to indicate the extent to which the true critical TER could be lower (-) or higher (+) than 10. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that could increase the critical value by a factor of 10.

Source of uncertainty	Potential to decrease critical TER	Explanation	Potential to increase critical TER	Explanation
Uncertainties affecting the	he evaluation o			
Variable quality of field studies	-	Evaluators took account of study quality when assigning subjective probabilities. It is possible that in doing so they might have overstated the probability of effects for poorer studies.	+	It is possible that evaluators might have understated the probability of effects for poorer studies.
Matching field studies to TER scenarios		Two of the field study evaluators matched the field studies to the TER scenarios, which were then checked by a third person.		
Subjectivity of evaluation		Four evaluators gave similar results. Average values used for analysis.		
Relationship of results to actual effects			+	Probable that some field studies with $TER > 10$ caused some undetected (hence not visible) mortality (see discussion in text).
Uncertainties affecting the	he form of the r	elationship between TER and field effects and its extrapolation from the a	vailable studies	
Toxicity		Most field study pesticides had mean $LD_{50} < 100 \text{ mg/kg}$ bw but relationship of TER to field effects is expected to be similar for less toxic pesticides	+	The geometric mean is more uncertain if LD50 is available for only one species, but in most cases at least 2 species are available.
Molecular weight		Larger substances with lower uptake may present less hazard, but this should be reflected in $LD_{50}$ .		
Other pesticide properties		Field study pesticides cover the general range for Kow, need for activation, and reversibility of effects. It is possible that these or other factors reduce critical TER substantially for some pesticides but they are not well enough understood to be included in the first-tier assessment (see text).	+	Field study pesticides cover the general range for Kow, need for activation, and reversibility of effects. It is possible that these or other factors increase critical TER to a limited extent for some pesticides (see text).
Application method		Many field studies used aerial applications but in a separate analysis, effect of application method was not significant ( $p > 0.05$ ).		
Multiple applications	-	Few studies with multiple applications, no obvious difference. TER calculations include theoretically appropriate adjustment. However, possible that MAF factors over-represent the contribution of repeat applications, which would cause critical TER to be lower.		Possible that more studies with multiple applications might have indicated a higher critical TER. Possible that MAF factors under- represent the contribution of repeat applications, which would cause critical TER to be higher.
Crops	<ul> <li>Studies cover wide range of crops, no sign of consistent differences.</li> <li>Possible some crops not included in field studies may have lower critical TER.</li> </ul>		+	Possible that some crops not included in field studies may have higher critical TER.



Source of uncertainty	PotentialExplanationto decreasecriticalTER		Potential to increase critical TER	Explanation	
Bird species exposed	_	Mostly North American studies, but ecological equivalents to EU. Possibly, some EU scenarios have species with lower potential for exposure, hence critical TER could be a little lower for those scenarios. Field studies on rangeland may have had higher bird densities than EU agricultural land, leading to increased effects and thus over-estimating critical TER.	+	Possible that some EU scenarios have species with higher potential for exposure, hence critical TER could be a little higher for those scenarios.	
Dietary exposure		Variation in factors affecting dietary exposure (e.g. diet, use of treated area, residues, etc.) in field studies is expected to be representative for the scenarios that were included.			
Non-dietary exposure	_	Contributions from non-dietary exposure routes (dermal, water, etc.) in field studies expected to be representative for the scenarios that were included. May have been increased to some extent in the studies with aerial spraying (though not detectable in analysis).			
Variation of toxicity between species	-	Sufficient field studies to include representative range of variation in extrapolation from test species to those exposed in field. Possible that in some cases the sensitivity of field species relative to test species could be still lower, making critical TER a little lower.	+	Possible that in some cases the sensitivity of field species relative to tested species could be higher than in the field studies, making critical TER a little higher.	
Variation of toxicity between individuals		Sufficient field studies to ensure that some include sensitive individuals.			
Uncertainty factor		Standard uncertainty factor is taken into account by examining evidence for mortality above TER = $10$ (see Figure 4).			
Avoidance of contaminated food	_	Field study pesticides are mostly moderately or strongly avoided. Unlikely that new pesticides with similar toxicity will be more avoided than the most strongly avoided examples in the analysis. Less toxic pesticides will have more opportunity for avoidance.	+++	Risk could be higher for pesticides that are less avoided than those in the field study analysis, and much higher for any which are not avoided at all.	
Effect of metabolism	_	For pesticides with lower toxicity but similar metabolism to those in the field studies, the opportunity for avoidance to occur before obtaining a lethal dose is increased, hence risk is decreased.	+	Field study pesticides cover a range of metabolism rates but some newer pesticides have lower metabolism rates, which would increase risk and imply a higher critical TER.	
Regurgitation	_	Field studies expected to include representative range of species with regard to regurgitation ability. Regurgitation may have increased some of the LD50s used in the analysis. If this was reliably identified in regulatory evaluations, the critical TER might decrease.			
Overall	entirely to O and avoidan	dies include a range of crops and species and the critical TER for othe Ps and carbamates but in most respects their properties cover the ran ce responses to OPs and carbamates, visible mortality is unlikely abov e is more opportunity for avoidance to reduce risk. For pesticides that	ge of variation e TER = 10 bu	seen in other pesticides. For pesticides with similar toxicity t some undetected mortality may occur. For pesticides with low	



The third line of evidence available for evaluating the level of protection for the assessment of acute risks to birds is the historical record of reported poisoning incidents in practical use. In general, the frequency of such reports has been extremely low in Europe during the last 20 years. Even in countries with organised systems for investigation of reported incidents, very few are reported each year and of these even fewer (e.g. one or two per year per country) are attributed to approved use of pesticides (e.g. Fletcher and Grave 1992; de Snoo et al., 1999). For countries with organised schemes, the frequency of incidents can be regarded as a measure of visible mortality. When considering the total areas treated with pesticides, the frequency of incidents suggests that the frequency of 'visible mortality' has been very low, at least in those European countries where systematic records are kept, and that the risk assessment procedures used in the last 20 years have been adequate to achieve the protection goal of a high certainty of no visible mortality. This conclusion is likely to hold also for the acute risk assessment procedures proposed in this opinion, as they provide a level of protection similar to the existing procedures (Appendix D).

However, there are important reasons why the number of reported incidents is certain to underestimate the number of mortalities actually occurring, and furthermore is likely to underestimate it to a substantial degree. These factors are summarised in Table 3. The fact that some visible mortalities have occurred, and that they are likely to be a substantial underestimate of the true level of mortality, makes it probable that the risk assessment procedures of the last 20 years have not achieved the surrogate protection goal of making any mortality unlikely.

The factors listed in Table 3 also make the incident record an uncertain indicator for the other actual protection goal, of preventing long-term repercussions on abundance and diversity. This is because the factors in Table 3 show that it is possible that the frequency of undetected mortality could be quite high. It cannot be ruled out that this would be sufficient to cause some level of sustained decrease in bird populations, at least on a local scale. This might not be compatible with the protection goal of achieving a high certainty of no long-term repercussions on abundance and diversity, given that the temporal and spatial scales of that goal are undefined.

It is concluded that the historical record of incidents provides good evidence regarding the actual protection goal of preventing visible mortality, weaker evidence regarding the actual protection goal of preventing long-term population effects, and very weak evidence regarding the surrogate protection goal of making any mortality unlikely. Hence it is important to consider the historical record together with other lines of evidence when making an overall evaluation of the level of protection expected from the proposed procedures (see below).



**Table 3.** Evaluation of uncertainties affecting interpretation of historical record of reported poisoning incidents involving birds and mammals. Symbols are used to indicate the extent to which the true frequency of individual mortality could be lower (-) or higher (+) than the level recorded. The number of symbols provides a subjective evaluation of the potential magnitude of the effect, e.g. +++ indicates a factor that could make the true frequency of mortalities much higher than the recorded frequency.

Source of uncertainty	Effect on true level of impacts	Explanation
Low probability of dead animals being visible to humans	+++	Animals dying in dense crops are unlikely to be visible to casual observers. For small animals, even a low crop cover will prevent visibility. Animals receiving a life-threatening exposure in open habitats are likely to seek cover before they die (demonstrated for birds by Fryday <i>et al.</i> 1996 and likely to be true also for mammals). Carcasses in the open are rapidly removed by scavengers. Kills involving small numbers (e.g. non-flocking species) of small-bodied individuals unlikely to be found. Flocking species may not be the most vulnerable.
Low probability of dead animals being reported by public	++	Members of the public are unlikely to consider reporting single dead bodies but more likely to report larger kills. Even in countries with organised incident schemes, public awareness of them is low. Kills involving small numbers of small-bodied individuals are unlikely to be reported.
Proportion of reported incidents investigated for pesticide involvement	+	Even in countries with organised incident schemes, involvement of pesticides is only investigated where there is circumstantial evidence to suggest it (e.g. known application in direct vicinity of location where animal was found). Kills involving small numbers of individuals are unlikely to be fully investigated.
Probability of a pesticide mortality being positively identified as such	+/+++	When chemical analysis is carried out, it is usually limited to a subset of pesticides that have historically caused incidents (e.g. OPs and carbamates, organochlorines, anticoagulants). Incidents caused by other pesticides are less likely to be detected. Even if the correct pesticide is analysed, there may be insufficient remaining residue for officials to record it as a lethal exposure. There is a potential bias in that there may be inadequate methods of analysis for new chemistries and hence they are unlikely to be looked for and hence detected.
Lack of organised schemes in most countries	+++	Organised schemes for investigating and documenting reported incidents exist in only a small number of EC Member States (e.g. UK and France).
Overall	frequency of inc However, the fac underestimate tl	h an organised scheme for investigating and documenting incidents, the idents can be regarded as a measure of the frequency of visible mortality. ctors evaluated above imply that the frequency of incidents could greatly he frequency of undetected mortality. For individual pesticides, incidents can bredicted risk, but absence of incidents does not necessarily indicate a low

Tables 1 to 3 evaluate three separate lines of evidence on the conservatism of the proposed screening and Tier 1 TER assessment procedures for acute risks to birds from sprayed pesticides. It is important to give appropriate weight to each line of evidence in reaching an overall conclusion. To assist with this, the three lines of evidence are summarised together in Table 4, together with the main uncertainties affecting them.

The pattern of uncertainties affecting the three lines of evidence is markedly different. In particular, the general magnitude of uncertainties is lower for the assessment based on comparison with field studies, because the field studies take account of some factors that are very uncertain or omitted in the TER calculation. Furthermore, the historical record of incidents underestimates the frequency of undetected mortality. On the other hand, in those countries with organised schemes, the historical incident record may be regarded as a measure of visible mortality. These differences are taken into account in reaching overall conclusions.



The field studies showed evidence of mortality occurring below about TER=10, but little evidence of mortality at TER > 10 (Figure 4). Evaluation of the TER calculation is subject to large uncertainties, but is compatible with the finding in the field studies of mortality below TER = 10. In addition the evaluation of the TER calculation indicates that, for some pesticides, mortality might occur above TER = 10. Although this was not seen in the field studies, they do not rule it out since there might have been undetected mortality, and since the studies were restricted mostly to OPs and carbamates. For both these lines of evidence, mortality above TER = 10 is more likely for pesticides with high toxicity, and that elicit low avoidance and slow metabolism. These conclusions are compatible with the historical incident record, because it is likely to greatly underestimate the level of undetected mortality. Overall, it is therefore concluded that some mortality can be expected below TER = 10, and that, especially for pesticides with high toxicity, low avoidance and slow metabolism, some undetected mortality may occur when TER > 10.

On the other hand, the historical incident record provides good evidence that, in general, visible mortality is unlikely when TER > 10. The other two lines of evidence both leave open the possibility that mortality could occur above TER = 10 for pesticides with high toxicity, low avoidance and slow metabolism. Overall, it is concluded that visible mortality is unlikely when TER > 10 for pesticides in general.

The conclusion that some mortality may occur when TER > 10 implies a possibility that the proposed assessment procedure may not satisfy the surrogate protection goal of making any mortality unlikely, especially for pesticides with high toxicity, low avoidance and slow metabolism. If it were desired to protect against these possibilities, then it might be prudent to increase the conservatism of the screening and first-tier TER calculations. This could be done by taking a more conservative value for any of the inputs, or by adding an extra factor to the calculation.

The conclusion that visible mortality is unlikely when TER > 10 suggests that the proposed assessment procedure might be regarded as satisfying the actual protection goal of ensuring high certainty that no visible mortality will occur (depending on the interpretation of 'clearly establish'). It might be thought that this would over-ride the surrogate protection goal of making any mortality unlikely, but this is not necessarily true. This is because the uncertainties affecting the historical incident record (Table 3) make it possible that the frequency of undetected mortality could be quite high, and it cannot be ruled out that this would be sufficient to cause some level of sustained decrease in bird populations, at least on a local scale. Three types of uncertainty combine here, the uncertainty about the level of undetected mortality, the uncertainty about the level of mortality required to cause sustained population reductions, and the uncertainty about what temporal and spatial scale of population change would be of concern to risk managers. These uncertainties imply that even though the assessment procedure may be regarded as satisfying the protection goal of no visible mortality, it is uncertain whether it achieves the protection goal of no long-term repercussions on abundance and diversity. As above, if it were desired to protect against this uncertainty, then it might be prudent to increase the conservatism of the screening and first-tier TER calculations, by taking a more conservative value for any of the inputs, or by adding an extra factor to the calculation.

In summary, it is concluded that the proposed first-tier assessment procedure for acute risks to birds from sprayed pesticides could be regarded as satisfying the protection goal of no visible mortality. However, it probably does not achieve the surrogate protection goal of making any mortality unlikely, and it is uncertain whether it achieves the actual protection goal of no long-



term repercussions on abundance and diversity. If it were desired to have a high certainty of achieving both actual protection goals, as well as the surrogate protection goal for all pesticides, then it might be prudent to increase the conservatism of the screening and first-tier TER calculations, by taking a more conservative value for any of the inputs, or by adding an extra factor to the calculation. Determining the level of certainty required involves risk management judgements.

# Risk management considerations

The preceding paragraph summarises the outcome of the scientific assessment of the level of protection provided by the proposed first-tier TER assessment procedure for acute risks to birds from sprayed pesticides. There is some uncertainty whether the procedure will meet both of the protection goals. Deciding whether this uncertainty is sufficient to merit increasing the conservatism of the assessment procedure involves risk management judgements.

In addition to the assessment of the level of protection, risk managers may also wish to consider the impact that the proposed procedures would have on the proportions of pesticides requiring higher-tier assessment. An analysis of this is presented in Appendix D of the Guidance Document. **Table 4.** Comparison of three lines of evidence on conservatism of the first-tier TER assessment of acute avian risks. The bottom rows of the table summarise the overall conclusions. The upper part of the table summarises the main uncertainties that have taken into account (see Tables 1-3 for details). Symbols indicate the potential for the 'true' critical TER value for ensuring any mortality is unlikely (surrogate protection goal) to be higher (+) or lower (-) than 10.<sup>14</sup>

		Lines of evidence				
	Assessment of TER assumptions	Comparison of TERs with evidence from field studies	Historical record of poisoning incidents			
Main contributions to						
uncertainty:						
Dietary exposure	_/+		0			
Non-dietary exposure	+/++	-				
Variation of toxicity between	/+++	- /+				
species						
Variation of toxicity between	+/+++					
individuals						
Uncertainty factor						
Avoidance of contaminated	- /	- /+++				
food						
Effect of metabolism		- /+				
Other properties of some	?	/+				
pesticides	÷	, .				
Relationship of field study		+				
results to actual effects						
Low probability of dead			+++			
animals being visible						
Low probability of dead			+++			
animals being reported,						
investigated and confirmed						
Lack of organised schemes for			+++			
documenting incidents in most						
countries						
Conclusions for individual	For pesticides with strong	For pesticides with	The very low frequency of			
lines of evidence	avoidance and rapid	toxicity and avoidance	documented incidents suggests a			
miles of evidence	metabolism, Tier 1 will	responses similar to	very low frequency of visible			
	substantially over-estimate	those of OPs and	mortality, but might greatly			
	risk. For substances with	carbamates, visible	underestimate the frequency of			
	little or no avoidance and	mortality is unlikely	undetected mortality.			
	slow metabolism, the true	above TER = $10$ but				
	risk for a sensitive species	some undetected				
	might be higher and some	mortality might occur.				
	mortality might occur	For pesticides with little				
	above TER = $10$ .	avoidance, some visible				
		mortality might occur				
		above TER=10.				
Overall conclusion	Some undetected mortality r		especially for pesticides with high			
regarding likelihood of any	toxicity, low avoidance and slow metabolism.					
mortality above TER = 10						
Overall conclusion	Visible mortality is unlikely when $TER > 10$ for pesticides in general. Theoretically it might					
regarding likelihood of			nd slow metabolism but there is no			
visible mortality above TER	evidence of this from the inc					
= 10						

<sup>&</sup>lt;sup>14</sup> Athough the -/+ symbols are defined in different ways in Tables 10a-c, they actually have comparable meaning, because they are all equivalent to indicating the potential for the 'true' critical TER value (for ensuring any mortality is unlikely) to be higher (+) or lower (-) than 10. Number of symbols indicates magnitude of effect.

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#### Evaluation of level of protection for first-tier assessment of reproductive risk to birds

Only one line of evidence is available to evaluate the LoP of the proposed procedure for assessing reproductive risk to birds. Evaluation by comparison with field studies is not useful since too few field studies exist on the reproductive effects of pesticides on birds. Evaluation by comparison with historical incidents is also not useful. Severe and widespread reproductive impacts have been detected in the past: the historical declines of raptor populations due to eggshell-thinning caused by DDT and DDE. However, much lower levels of effect would be sufficient to breach the protection goal of no long-term repercussions on abundance and diversity, and it is extremely unlikely that these lower levels of effect would be detected by casual observation.

Consequently, the only line of evidence for evaluating the LoP of the reproductive risk assessment is to examine the conservatism of the inputs and assumptions of the assessment procedure. This is done using the same approach as in the first line of evidence when evaluating the LoP of the TER assessment procedure for acute risks (see above).

The first tier reproductive assessment allows two alternative choices for the time-weighted average to use in the TER calculations, depending the mechanism of effects (see section 4.3 in the Guidance Document). This in effect leads to two alternative assessments:

- The long-term exposure assessment (LTE), which assumes reproductive effects are caused only by long-term exposures, assessed using an exposure period of 21 days. (It should be noted that the selection of a 21-day time window is arbitrary and has only been selected to try to differentiate between those substances that may cause an effect following a short-term exposure and those that may cause an effect following long-term exposure.)
- The short-term exposure (STE) assessment, which assumes reproductive effects are caused by 1-day exposures<sup>15</sup>.

The LoP of assessments using these alternative assumptions is evaluated in Tables 5a and 5b respectively. The inputs, assumptions and omissions of the assessment are listed in the left hand column of each table, and the remaining columns evaluate the conservatism of each one in relation to a 'true' realistic worst case. Factors that were evaluated to cause relatively minor uncertainty are listed separately in Table 5c.

As explained at the start of this Appendix, the focus on a true or realistic worst-case scenario is necessary to address the surrogate protection goal of making any reproductive effects unlikely. For acute risks, the availability of field studies and historical incident data made it possible to evaluate one of the actual protection goals more directly (prevention of visible mortality). This is, however, not possible for reproductive risks due to the absence of adequate field studies or incident data. Therefore the evaluation in this section is focussed on the surrogate protection goal of making any reproductive effects unlikely.

The STE assessment (Table 5a) makes an extreme worst-case assumption regarding the exposure duration required to cause NOAEL effects. Uncertainties exist in both directions, but most will tend to make the 'true' worst-case risk lower. One exception is the use of mean RUD

<sup>&</sup>lt;sup>15</sup> It is intended to develop further guidance on criteria for determining which effects could be caused by short-term exposures. The Joint Working Group decided that, until such guidance is available, it should be assumed as a default that the effects are caused by LTE, unless there is specific evidence for the pesticide under assessment that the effect could be caused by STE.

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for residues, which is likely to underestimate worst-case exposure if effects really are caused by 1-d exposures. Another exception is the overspray of eggs and nestlings, which may be significant in some cases. However, these factors may be outweighed by the collective effect of uncertainties working in the other direction, and some species may be able to recover part or all of any lost reproductive output by re-nesting. Overall it is concluded that when TER  $\geq$  5 the STE assessment is likely to achieve the surrogate protection goal for most pesticides. However, reproductive effects may occur for some individuals of sensitive species after application of pesticides that are slowly metabolised, weakly avoided, or have high non-dietary exposure.

The LTE assessment (Table 5b) assumes that the exposure duration required to cause NOAEL effects is 21 days. (It should be noted that the time window is arbitrary.) Uncertainties exist in both directions, but most will tend to make the 'true' worst-case risk lower. One exception is the use of  $1/10 \text{ LD}_{50}$  as a proxy for longer-term effects, although this is likely to be outweighed by the collective effect of uncertainties working in the other direction. Some species may be able to recover part or all of any lost reproductive output by re-nesting. Overall it is concluded that when TER  $\geq 5$  the LTE assessment is likely to achieve the surrogate protection goal for those pesticides that do not cause reproductive effects through short-term exposures. However, reproductive effects may still occur for some individuals of the most sensitive species.

# Risk management considerations

This section presents an assessment of the likelihood that the reproductive assessment procedure for birds will satisfy the protection goals. Deciding whether this provides an appropriate level of protection involves risk management judgements.

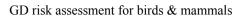
In addition to the level of protection, risk managers may also wish to know what impact the proposed procedures would have on the proportions of pesticides requiring higher-tier assessment (see Appendix D).



**Table 5a.** Evaluation of conservatism of the STE (short term exposure) scenario first-tier assessment of avian reproductive risks. The STE scenario assumes that all reproductive effects are caused by 1-day exposures. Each row evaluates a separate input, assumption or omission of the screening and first-tier assessment procedure. + and - are used to indicate the extent to which it is judged that the 'true worst' case for that parameter could decrease or increase the risk of causing any reproductive effect (the surrogate protection goal). The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that would increase the risk by an amount equivalent to reducing the TER by about a factor of 10. If the effect varies between pesticides or is uncertain, lower and upper evaluations are given (e.g. +/+++).

Parameter, assumption or omission	Potential for 'true worst- case' risk to be lower	Explanation	Potential for 'true worst- case' risk to be higher	Explanation
Screening assessment indicator species and type of food	0 to -	Realistic worst case – relatively small species eating only the most contaminated food type. Real worst case could be lower in some scenarios.		Realistic worst case – relatively small species eating only the most contaminated food type. Negligible potential to be worse.
Tier 1 generic focal species and type of food		Mixed diet based on average of available data on dietary composition. Worst case cannot be lower than average.	+	Mixed diet based on average of available data on dietary composition. Some individual birds will eat more than average proportion of most contaminated food on individual days.
Body weight (impact on exposure)	0 to -	In some scenarios such small species may not occur. However, this has only a limited impact on exposure due to scaling of food intake with body weight.		For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight.
Body weight (impact on toxicity)		Relatively few exposed species are larger than species used in toxicity tests.	0 to +	Focal species tend to be smaller than species used in toxicity tests. General trend for smaller species to be more sensitive (Mineau et al., 1996) is not taken into account in assessment. Relevant to endpoints based on $1/10^{\text{th}} \text{ LD}_{50}$ . Bias can be up to four times but only one + given because this is partly represented by overall between-species variability (see below).
Percent of diet taken by individual in treated area	0 to	Likely only a few scenarios where true worst-case individual is less than 0.5 (i.e. factor of 2 reduction) for short term exposures, could be lower for longer term exposures.		Absolute worst case is used, hence cannot be higher.
Half-life of residues on food (DT <sub>50</sub> )		$DT_{50}$ s often lower but only affect multiple applications in STE assessments and only part of the total exposure.	+	Some pesticides have $DT_{50}$ s longer than 10 days (e.g. 19 % of pesticides registered in Canada in 2005 <sup>16</sup> ).

<sup>&</sup>lt;sup>16</sup> Based ondata from http://www.wsi.nrcs.usda.gov/products/W2Q/pest/winpst.html.





Parameter, assumption or omission	Potential for 'true worst- case' risk to be lower	Explanation	Potential for 'true worst- case' risk to be higher	Explanation
Residue per unit dose		Average of data for multiple pesticides and application events. True average for pesticide under assessment could be lower. However, if reproductive effects are caused by short-term exposure, realistic worst case could still be close to or even above general average.	++	True distribution for pesticide under assessment could be higher than average RUD used in assessment, so true worst case could be higher than average RUD. Also, RUD values may underestimate peak concentration on highly-exposed food items. Any under protection would be more pronounced where reproductive effects are the result of short-term exposure.
Non-dietary exposure of adults			+ to ++	This parameter is ignored, however, the true contribution uncertain, but could, increase risk by up to two times or more (Driver et al. 1991).
Duration of exposure required to cause reproductive effects	0 to	STE assessment assumes NOAEL effects can be caused by 1-d exposures: could be true for some pesticides but greatly over- estimating risk for others.		STE assessment assumes NOAEL effects can be caused by 1-d exposures: this is an extreme worst case.
Relevance of reproduction toxicity study design			+	Not all critical phases of avian reproduction are adequately covered by existing protocol. Altricial species especially may differ – e.g. parental care is much more important for these species and not assessed in the current study.
Uncertainty of no- effect levels	0 to -	Reproduction study has limited power to detect differences between dose levels. True NOAEL could be higher or lower.	0 to +	
Relevance of 1/10 LD <sub>50</sub> as proxy for chick toxicity	-	True 'incapacitation' of chicks may not occur until higher levels than $1/10 \text{ LD}_{50}$ .		$1/10 \text{ LD}_{50}$ is realistic worst case for LOEL for incapacitation (protective for 95 % of studies). Potential for individual variability is considered below.
Variation of toxicity between individuals			+ to ++	Most sensitive individuals could be more sensitive for both $1/10 \text{ LD}_{50}$ and NOAEL endpoints (n.b. NOAELs used are based on average and not individual effects).
Variation of toxicity between species and/or stages within species		Focal species could be up to two orders of magnitude more or less sensitive than standard species (Fig. 1). If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (Luttik et al., 2005) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity.	++/+++	Focal species could be up to two orders of magnitude more or less sensitive than standard species (Fig. 1), although the potential for this is reduced when assessment is based on the most sensitive of several species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion ( <i>Luttik</i> et al., 2005) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity.
Uncertainty factor		TER is compared with trigger value of 5.		



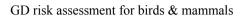
Parameter, assumption or omission	Potential for 'true worst- case' risk to be lower	Explanation	Potential for 'true worst- case' risk to be higher	Explanation
Avoidance of contaminated food or of treated area as a whole	0 to	Parameter is ignored, which would be realistic for non-avoided pesticides. Potential effect of avoidance less than for acute mortality. In STE assessments, $1/10 \text{ LD}_{50}$ represents sublethal effects which occur at doses closer to avoidance threshold and thus less likely to be prevented.		
Effect of metabolism	- to	In the STE assessment, risk for the $1/10 \text{ LD}_{50}$ endpoints would be reduced by metabolism; reduction could be very substantial for rapidly metabolised pesticides.		
Recovery from effects	0 to	Affected individuals may be able to recover and reproduce at a later date. This may partially or wholly replace the reproductive output that was lost.		
Overall	The STE assessment makes an extreme worst-case assumption regarding the exposure duration required to cause effects. Uncertainties exist in both directions, but most will tend to make the 'true' worst-case risk lower. One exception is the use of mean RUD for residues, which is likely to underestimate worst-case exposure if effects really are caused by 1d exposures, although this may be outweighed by the collective effect of uncertainties working in the other direction. Some species may be able to recover part or all of the any lost reproductive output by re-nesting. Overall it is concluded that when TER ≥ 5 the STE assessment is likely to achieve the surrogate protection goal for most pesticides, but reproductive effects may occur for some individuals of sensitive species for pesticides that are slowly metabolised, weakly avoided, or have high non-dietary exposure.			



**Table 5b.** Evaluation of conservatism of the LTE (long-term exposure) scenario first-tier assessment of avian reproductive risks. The LTE scenario assumes that all reproductive effects are caused by long-term (21-d) exposures. + and - are used to indicate the extent to which it is judged that the 'true worst' case for that element could decrease or increase the risk of causing any reproductive effect (the surrogate protection goal). See Table 5a legend for more details.

Parameter, assumption or omission	Potential for 'true worst- case' risk to be lower	Explanation	Potential for 'true worst- case' risk to be higher	Explanation
Screening assessment indicator species and type of food	0 to -	Realistic worst case – relatively small species eating only the most contaminated food type. Real worst case could be lower in some scenarios.		Realistic worst case – relatively small species eating only the most contaminated food type. Negligible potential to be worse.
Body weight (impact on exposure)	0 to -	In some scenarios such small species may not occur. However, this has only a limited impact on exposure due to scaling of food intake with body weight.		For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight.
Percent of diet taken by individual in treated area	0 to	Likely only a few scenarios where true worst-case individual is less than 0.5 (i.e. factor of 2 reduction) for short term exposures, could be lower for longer term exposures.		Absolute worst case is used, hence cannot be higher.
Half-life of residues on food $(DT_{50})$	0 to	Default value of 10 days for the various time-weighted average (TWA) measurements is conservative: most pesticides have $DT_{50}$ s below 10. Also dissipation in first few days is often faster than implied by assumption of first order kinetics.	+	Some pesticides have $DT_{50}$ s longer than 10 days (e.g. 19 % of pesticides registered in Canada in 2005 <sup>17</sup> ).
Non-dietary exposure			0 to ++	Dermal and inhalation routes will increase exposure to some degree, but limited to first few days after spray application and therefore less important if effects require longer exposure.
Duration of exposure required to cause reproductive effects	0 to -	LTE assessment uses a TWA exposure over 21 d (an arbitrary choice). For some pesticides NOAEL endpoints might require longer exposures, but the reduction in TWA would be limited.	0 to +	For some pesticides, reproductive effects might result from exposures shorter than 21 d, but the increase in TWA would be limited (e.g. two times with default $DT_{50}$ of 10 d).
Relevance of reproduction toxicity study design		Exposure over 21 weeks in current protocol is much longer than is likely in most field situations and than considered in the 21-d LTE assessment. NOAELs likely to be lower over more relevant exposure periods, so true risk is lower.	+	Not all critical phases of avian reproduction are adequately covered by existing protocol. Altricial species especially may differ – e.g. parental care is much more important for these species and not assessed in the current study.

<sup>&</sup>lt;sup>17</sup> Based on data from http://www.wsi.nrcs.usda.gov/products/W2Q/pest/winpst.html.





Parameter, assumption or omission	Potential for 'true worst- case' risk to be lower	Explanation	Potential for 'true worst- case' risk to be higher	Explanation
Uncertainty of no- effect levels	0 to -	Reproduction study has limited power to detect differences between dose levels. True NOAEL could be higher or lower.	0 to +	
Variation of toxicity between individuals			+ to ++	Most sensitive individuals could be more sensitive for NOAEL endpoints, as they are based on average and not individual effects.
Relevance of $1/10$ LD <sub>50</sub> as an endpoint in LTE scenario			+ to ++	$1/10 \text{ LD}_{50}$ endpoint is derived from acute study and not strictly relevant to LTE scenario. Effects may occur at lower levels when caused by longer exposures.
Variation of toxicity between species and/or stages within species		Focal species could be up to two orders of magnitude more or less sensitive than standard species (Fig. 1). If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (Luttik et al., 2005) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity.	++/+++	Focal species could be up to two orders of magnitude more or less sensitive than standard species (Fig. 1), although the potential for this is reduced when assessment is based on the most sensitive of several species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion ( <i>Luttik</i> et al., 2005) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity.
Uncertainty factor		TER is compared with trigger value of 5.		
Avoidance of contaminated food or of treated area as a whole	0 to	Parameter is ignored, which would be realistic for non-avoided pesticides. Potential effect of avoidance less than for acute mortality. Longer time scales increase potential for learned avoidance, but area under curve effects may occur at intakes below avoidance threshold.		
Recovery from effects	0 to	Affected individuals may be able to recover and reproduce at a later date. This may partially or wholly replace the reproductive output that was lost.		
Overall	The LTE assessment assumes the exposure duration required to cause NOAEL effects is 21 days. Uncertainties exist in both directions, but most will tend to make the 'true' worst-case risk lower. One exception is the use of $1/10 \text{ LD}_{50}$ as a proxy for longer-term effects, although this is likely to be outweighed by the collective effect of uncertainties working in the other direction. Some species may be able to recover part or all of any lost reproductive output by re-nesting. Overall it is concluded that when TER > 5 the LTE assessment is likely to achieve the surrogate protection goal for those pesticides that do not cause reproductive effects through short-term exposures. However, reproductive effects may still occur for some individuals of the most sensitive species.			



Parameter, assumption or omission	Potential for 'true worst- case' risk to be lower	Explanation	Potential for 'true worst- case' risk to be higher	Explanation
Daily food intake		Data taken from breeding season.		Data taken from breeding season.
Interception factors				Interception factors are based on those used in FOCUS Step 2, which were derived from field measurements and are considered to be realistic worst case for spray reaching ground. Within each growth stage a conservative (early) value is used.
Proportion of the population exposed		The surrogate protection goal relates to a realistic worst case individual, which would be exposed.		
Timing of applications		Assessment assumes worst-case exposure in all phases of reproduction for same individual, whereas in practice exposure is likely to peak in different phases for different individuals. However, it is likely that at least some individuals will be exposed in most sensitive phase, so not over-conservative for surrogate protection goal.		The model assumes that every phase of reproduction coincides with spray time, so true worst case cannot be worse.
Regurgitation		Regurgitation unlikely at sublethal doses $(1/10 \text{ LD}_{50})$ so unlikely to reduce risk in field.		Should not cause under-estimation of risk if avoid using $LD_{50}$ studies where regurgitation occurred.
Overall	These factor	rs are not thought to add significantly to the uncertainties consid	ered in Tables	5a and 5b.

**Table 5c.** Factors assessed as causing minor uncertainty, likely to cause less than two times difference between assessment and 'true worst-case' risk. They are listed separately to facilitate reading of Tables 5a and 5b. See legend of Table 5a for explanation of symbols.



## Acute risk to mammals from sprayed pesticides, assessed using TERs

Three lines of evidence are available for evaluating the level of protection (LoP) of the acute mammalian assessment based on TER (toxicity-exposure-ratio):

- the conservatism of the assessment assumptions;
- the historical record of reported impacts attributed to pesticide use;
- the comparison between calculated TERs and evidence on effects in field studies.

The first two of these lines of evidence are very similar to those for birds (see earlier), so only differences are discussed here.

The <u>first line of evidence</u> is evaluation of the conservatism of the assessment assumptions. The conservatism of the TER calculation for birds is documented in Table 1 above. Only two items differ for mammals:

- Acute LD<sub>50</sub> scales positively with body weight for birds (average scaling factor about 1.2, small species are more sensitive, Mineau et al., 1996, 2001) but scaling is absent or slightly negative for mammals (scaling factor 0.94, Sample and Arenal, 1999).
- Regurgitation in toxicity tests is less common for mammals than birds. It is therefore not a source of bias in mammalian acute toxicity data, and unlikely to provide significant protection to mammals in the wild.

Therefore, both these factors have little impact on the LoP for mammals, whereas they have minor but opposite effects on the LoP for birds. Taking this into account, the overall assessment of the TER calculation for mammals is the same as for birds (copied from Table 1 above):

• Biases connected with the exposure calculation are relatively small (mostly within a factor of about two) compared to the influence of toxicity, avoidance and metabolism. For pesticides with strong avoidance and rapid metabolism<sup>18</sup>, Tier 1 will substantially overestimate risk. For substances with little or no avoidance and slow metabolism, true risk for a sensitive species could be higher and some mortality could occur above TER = 10.

The <u>second line of evidence</u>, based on the historical record of poisoning incidents, is essentially the same for mammals and birds. The conclusion, copied from Table 3 above, is:

• In those countries that have an organised scheme for investigating and documenting incidents, the frequency of incidents can be regarded as a measure of the frequency of visible mortality. However, the factors evaluated (in Table 3 above) imply that the frequency of incidents could greatly underestimate the frequency of undetected mortality. For individual pesticides, incidents can confirm a high predicted risk, but absence of incidents does not necessarily indicate a low risk.

The <u>third line of evidence</u> is comparison between calculated TERs and evidence on the occurrence of population changes in field studies. This differs substantially from the analysis of field studies for birds, and is therefore evaluated separately here. More details on these data are presented in Appendix 19 of EFSA (2008), which also contains an exploration of other assessment approaches.

<sup>&</sup>lt;sup>18</sup> No general statement can be made about the degree of avoidance and metabolism required for this, but it could be an option for case-by-case investigation in higher tier assessments.



Fewer studies on effects in the field were available for mammals than birds. Of 23 studies with sprays, eight were unenclosed field studies and 15 were studies in experimental enclosures. They included a total of eight active substances. One substance, azinphos-methyl, was the subject of eight studies at various application rates<sup>19</sup>.

All the studies used trapping methods to monitor changes in small mammal populations (nearly all with voles, some including also mice). Consequently the effects measured in these studies are population changes, which could be the result of mortality, reproductive effects, or both. The results are therefore relevant to evaluating the surrogate protection goal of making any mortality or reproductive effects unlikely. They also have some relevance to the actual protection goal, in that they measure changes in abundance.

Due to limitations of time, these studies were evaluated in a simpler way than the bird studies: a single evaluator scored the outcome of each study as positive (1) where the evidence indicated a population response (14 studies), and negative (0) where it did not (9 studies). A population response was defined as reductions in some age or sex cohorts which could indicate mortality, or changes in reproductive rates (e.g. pregnancy rates etc...) indicative of a more targeted effect on the reproductive process. With the selection of compounds represented in the dataset, the majority of effects were of the first type with only a few pesticides (e.g. carbaryl) showing reproductive effects per se.

Figure 5 shows these results plotted against Tier 1 TER for the focal species scenario relevant for each study, calculated with the rat  $LD_{50}$ .

We first consider the results in Figure 5 in relation to the surrogate protection goal of making any mortality and reproductive effects unlikely. Population effects were seen at TERs between 1 and 10, implying that mortality and/or reproductive effects occurred at this level. The positive studies in this range were all enclosure studies, an effect of which is to restrict the study animals to the treated area  $(PT = 1)^{20}$ . This is a worst case, but it is a realistic worst case, because radio-tracking studies of free-ranging small mammals in arable crops showed that some individuals stayed within the crop during the whole period they were followed (e.g. EFSA, 2004). Given the limited number of studies and the very limited range of active substances, crops and focal species examined, it is clearly conceivable that other cases might show population effects above TER = 10. This implies that a TER trigger of 10 might not be sufficient to achieve the surrogate protection goal of making any mortality or reproductive effects unlikely. The field data can neither refute nor confirm this, because only one (negative) study had a TER above 10.

The fact that population responses were seen at TERs between 1 and 10, and that they might conceivably occur above TER = 10, might be considered to threaten the actual protection goal of preventing long-term repercussions on abundance and diversity. However, this is subject to several uncertainties. First, as already stated, there is only one study above TER = 10. Second, it is uncertain how long the population responses seen in the studies persisted<sup>21</sup>. Third, the positive studies with TERs between 1 and 10 were all conducted in enclosures: as well as restricting the study animals to the treated area, this prevents losses being replaced by immigration and therefore increases the chance that a measurable decrease in abundance will occur. It is notable that of the eight unenclosed studies, all four that showed population responses had TER < 1, and all four that showed no response had TER > 1. These studies are clearly too few to form firm conclusions, but they do make it conceivable that the TER trigger of 10 might be high enough to meet the actual protection goal of preventing long-term repercussions on abundance and

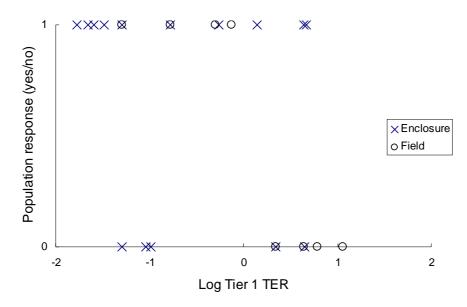
<sup>&</sup>lt;sup>19</sup> Five of these studies were positive for population effects; three at lower application rates were negative.

 $<sup>^{20}</sup>$  PT = Proportion of an animal's daily diet obtained in habitat treated with pesticide

<sup>&</sup>lt;sup>21</sup> Also, the Directive and its Annexes do not define what duration would be regarded as 'long term'.



diversity. Again, the very limited range of pesticides, crops and focal species examined makes extrapolation to other cases very uncertain.



**Figure 5.** Relationship between the occurrence of a population response of small mammals in field studies and the Tier 1 TER for those studies, calculated with rat  $LD_{50}$ . Each data point represents a single field study, using different symbols for field and enclosure studies.

No field studies were available for larger mammal species. However, it might be expected that a trigger value chosen on the basis of the results for small mammals would also be protective for acute risks to large mammals, considering their larger size (lower relative exposure) and larger home ranges (lower PT).

Uncertainties affecting interpretation of these studies are summarised in Table 6, evaluated in terms of their potential to make the critical TER for achieving the surrogate and actual protection goals higher or lower than the value of 10 specified in Annex VI of Directive 91/414/EEC. Overall it is concluded that the results could be compatible with a critical TER in the region of 10, but that there are very substantial uncertainties due to limited number of species, pesticides and studies, so the 'true' critical value could be significantly higher or lower.



**Table 6.** Evaluation of uncertainties affecting comparison of the first-tier TER assessment of acute mammalian risks with data on population effects in field studies. The aim is to find the critical TER value above which any population response will be unlikely (this is intermediate between the surrogate and actual protection goals). Symbols are used to indicate the extent to which the true critical TER could be lower (-) or higher (+) than 10. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that could increase the critical value by a factor of about10.

Source of uncertainty	Potential	Explanation	Potential to	
·	to decrease	•	increase	
	critical		critical TER	
	TER			
Uncertainties affecting th	he evaluation o	f the field studies		
Only one study with TER>10			0 to +++	Studies provide almost no direct test of whether critical TER could be higher than 10.
Effect of enclosures		Restrict animals to treated area, but this is realistic worst case for		
	0 to	individual free-ranging small mammals. Prevents replacement of		
		losses through immigration, thus exaggerating and prolonging		
		population effects compared to unenclosed populations.		
Matching field studies	_	Studied habitats (pasture, alfalfa, millet, clover, forest litter) match		
to TER scenarios		loosely to TER scenarios, based on structural similarity.	+	
Subjectivity of	_	Precise nature and strength of effects varied between studies and		
evaluation and quality		were subjectively evaluated and summarised as positive/negative	+	
of studies		by a single evaluator. Other evaluators might differ.		
Duration of population		Uncertain how long the effects seen in the field studies would		
responses	0 to	persist, and what duration risk managers would consider		
		unacceptable.		
	he form of the r	elationship between TER and field effects and its extrapolation from t	he available studi	
Limited range of		Only eight pesticides studied: five OPs, two carbamates and		Only eight pesticides studied: five OPs, two carbamates and endrin.
pesticides studied	- to	endrin. Other pesticides might have lower critical TER due to	+ to ++	Other pesticides might have higher critical TER due to different
T: :- 1 C		different properties e.g. DT <sub>50</sub> , vapour pressure, metabolism.		properties e.g. DT <sub>50</sub> , vapour pressure, metabolism.
Limited range of crops	4.5	Only five 'crops' studied (pasture, alfalfa, millet, clover, forest	1.40.1.1	Only five 'crops' studied (pasture, alfalfa, millet, clover, forest litter).
studied	- to	litter). Possible other crops may have lower critical TER due to	+ to ++	Possible other crops may have higher critical TER due to e.g. lower
Limited range of		e.g. higher interception and differing vegetative structure. Each study focuses on one to two small mammal species, mostly		interception and differing vegetative structure. Each study focuses on one to two small mammal species, mostly voles
Limited range of species exposed	- to	voles and mice. Other species might have lower critical TER due	+ to ++	and mice. Other species might have higher critical TER due to e.g.
species exposed	- 10	to e.g. differing diet (see below for toxicity)		differing diet (see below for toxicity)
Routes of exposure		Studies include dietary and non-dietary routes.		
Variation of toxicity		Most studies focussed on one to two species. Other species might		
between species		be one to two orders of magnitude more or less sensitive to the	+++	
oetween species		same pesticides.		
		sume pesticides.		



Source of uncertainty	Potential to decrease critical TER	Explanation	Potential to increase critical TER	
Variation of toxicity between individuals		Field studies sufficiently large to include sensitive individuals.		
Uncertainty factor		Standard uncertainty factor is taken into account by examining evidence for effects above TER=10.		
Avoidance of contaminated food	_	Most of the studied pesticides are moderately to very toxic and moderately or strongly avoided, although opportunity for avoidance limited in enclosure studies. Less toxic pesticides will have more opportunity for avoidance.	++	Risk could be higher for pesticides that are less avoided than those in the field studies, although opportunity for avoidance may be less than birds due to lower mobility (less easy to move to untreated area).
Overall	Study results compatible with a critical TER in the region of 10, but substantial uncertainties due to limited number of species, pesticides and studies, so true critical value could be significantly higher or lower.			



The preceding pages evaluate three separate lines of evidence on the conservatism of the proposed screening and Tier 1 TER assessment procedures for acute risks to mammals from sprayed pesticides. It is important to give appropriate weight to each line of evidence in reaching an overall conclusion. To assist with this, the three lines of evidence are summarised together in Table 7, together with the main uncertainties affecting them.

The pattern of uncertainties affecting the three lines of evidence is markedly different from one another. In addition, it is different from that for birds: in the case of birds, the general magnitude of uncertainties was lower for the assessment based on comparison with field studies, whereas for mammals the much smaller scope of the field studies makes their interpretation much more uncertain. The different degrees of uncertainty affecting the three lines of evidence for mammals are taken into account in reaching overall conclusions.

In summary, it is concluded that the first-tier assessment procedure for acute risks to mammals from sprayed pesticides probably satisfies the protection goal of no visible mortality, but it probably does not achieve the surrogate protection goal of making any mortality unlikely, and it is uncertain whether it achieves the protection goal of no long-term repercussions on abundance and diversity. If it were desired to have a higher certainty of achieving both actual protection goals for all pesticides, then the conservatism of the screening and Tier 1 TER calculations could be increased, by taking a more conservative value for any of the inputs, or by adding an extra factor to the calculation. Determining the level of certainty required involves risk management judgements.

**Table 7.** Comparison of three lines of evidence on conservatism of the first-tier TER assessment of acute risks to mammals for sprayed pesticides. The bottom rows of the table summarise the overall conclusions. The upper part of the table summarises the main uncertainties that have taken into account (see preceding pages for details). Symbols indicate the potential for the 'true' critical TER value for ensuring any mortality is unlikely (surrogate protection goal) to be higher (+) or lower (-) than 10.

	Lines of evidence				
	Assessment of TER assumptions	Comparison of TERs with evidence from field studies	Historical record of poisoning incidents		
Main contributions to					
uncertainty:					
Non-dietary exposure	+/++				
Variation of toxicity between	/+++	/+++			
species					
Variation of toxicity between	+/+++				
individuals					
Uncertainty factor					
Avoidance	-/	-/++			
Effect of metabolism		(included in next row)			
Other properties of some pesticides	?	/++			
Other crops		/++			
Other focal species		/++			
Effect of enclosures		/0			
Duration of effects		/0			
Lack of studies with TER>10		0 / +++			
Low probability of dead animals being visible			+++		
Low probability of dead animals being reported, investigated &			+++		
confirmed					
Lack of organised schemes for			+++		
documenting incidents in most countries					
Conclusions for individual lines of evidence	For pesticides with strong avoidance and rapid metabolism, Tier 1 will substantially over- estimate risk. For substances with little or no avoidance and slow metabolism, the true risk for a sensitive species could be higher and some mortality could occur above TER=10.	Study results compatible with a critical TER in the region of 10, but substantial uncertainties due to limited number of species, pesticides and studies, so true critical value could be significantly higher or lower.	The very low frequency of documented incidents suggests a very low frequency of visible mortality, but might greatly underestimate the frequency of undetected mortality.		
Overall conclusion regarding likelihood of any mortality above TER=10	Some undetected mortality may occur when TER>10, especially for pesticides with high toxicity, low avoidance and slow metabolism.				
Overall conclusion regarding likelihood of visible mortality above TER=10	Visible mortality is unlikely when TER>10 for pesticides in general. Theoretically it might occur for pesticides with high toxicity, low avoidance and slow metabolism but there is no evidence of this from the incident record.				



#### Level of protection for assessment of reproductive risks to mammals for sprayed pesticides

Many of the factors affecting the LoP for reproductive risks to mammals are similar to those for birds (see earlier). However, an important difference is that, in the assessment for mammals, uncertainty about the mode of action and relevant timescale for exposure is reduced because more information on this is available from the toxicology assessment done for human health purposes.

See Table 8 for evaluation and conclusions.

In this and subsequent sections, LoP evaluation tables are presented with limited discussion text, but the principles of the approach are the same as in preceding examples above.



**Table 8.** Evaluation of conservatism of the first-tier assessment of mammalian reproductive risks. Each row evaluates a separate input, assumption or omission of the screening and first-tier assessment procedure. + and - are used to indicate the extent to which it is judged that the 'true worst' case for that element could decrease or increase the risk of causing any reproductive effect (the surrogate protection goal). The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that would increase the risk by an amount equivalent to reducing the TER by about a factor of about 10. If the effect varies between pesticides or is uncertain, lower and upper evaluations are given (e.g. +/+++).

	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Relevance of reproduction toxicity study	-/	The ecological relevance of some of the endpoints to the goal of preventing reproductive effects is difficult to determine. This may lead to possible overprotection.		
Screening assessment indicator species and type of food	-	Realistic worst case – relatively small species eating only the most contaminated food type. Real worst case could be lower in some scenarios.		Realistic worst case – relatively small species eating only the most contaminated food type. Negligible potential to be worse.
Tier 1 generic focal species and type of food		Mixed diet based on average of available data on dietary composition. Worst case cannot be lower than average.	+	Mixed diet based on average of available data on dietary composition. Some individual mammals will eat more than average proportion of most contaminated food on individual days.
Body weight (impact on exposure)	-	In some scenarios such small species may not occur. However, this has only a limited impact on risk due to scaling of food intake with body weight.		For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight.
Body weight (impact on toxicity)		Less effect than for birds. Scaling of toxicity with body weight is close to 1 (0.94, Sample and Arenal, 1999).		
Daily food intake			+	According to the raw data for non-marine, non desert, eutherian mammals, 72% of records make no mention of breeding status or season., 22% of records indicate winter or non-breeding status and only 6% make a definite mention of animal in engaged in breeding (e.g. pregnant or lactating). On the basis of this information, it is likely that the daily food intake for an individual during breeding could be greater than used.
Percent of diet taken by individual in treated area	-	Likely only a few scenarios where true worst case individual is less than 0.5 (i.e. factor of 2 reduction).		Absolute worst case, cannot be higher.
Residue per unit dose		Average RUD is used for the reproductive assessment. It is not likely that a true worst case has a lower RUD.	++	True distribution for pesticide under assessment could be higher than average RUD used in assessment, so true worst case could be higher than average RUD.



r	D. ( ( )	E. L	Defendent 1	
	Potential	Explanation	Potential	Explanation
	for 'true		for 'true	
	worst		worst case'	
	case' risk		risk to be	
	to be		higher	
	lower			
				Also, RUD values may underestimate peak concentration on highly-exposed food items. Any underprotection would be more pronounced where long term effects are the result of short-term exposure.
Half-life on food (DT <sub>50</sub> )		Default value of 10 days for the various TWA measurements is conservative: most pesticides have $DT_{50}s$ below 10.	+	Some pesticides have $DT_{50}s$ longer than 10 days (e.g. 19% of pesticides registered in Canada in 2005 <sup>22</sup> ). Also dissipation in first few days is often faster than implied by assumption of first order kinetics.
Interception factors		Interception factors are based on those used in FOCUS Step 2, which were derived from field measurements and are considered to be conservative for spray reaching ground. Within each growth stage a conservative (early) value is used.		
Non-dietary exposure			+ /++	This parameter is ignored, however, the true contribution uncertain, but could, in short term, increase risk by up to two times or more although this is very uncertain as based on bird studies (Driver et al., 1991).
Variation of toxicity between species and/or stages within species		There is very little data on toxicity in mammalian species other than the standard species used for human toxicology. There is in principle no reason to believe variation in sensitivity between tested mammals and wild mammal species will be different to that for birds.	+++	
Variation of toxicity between individuals			+/++	Most sensitive individuals could be more sensitive (most NOAELs used are based on tests of significance between treatment group averages and not individual effects).
Uncertainty factor		TER is compared with trigger value of 5.		
Avoidance of contaminated food or of treated area as a whole	0 to	Parameter is ignored, which would be realistic for non-avoided pesticides. Potential effect of avoidance less for sublethal effects which occur at doses closer to avoidance threshold and thus less likely to be prevented. Longer time scales increase potential for learned avoidance, but effects may occur at intakes below avoidance threshold.		
Effect of metabolism		Effect of metabolism is incorporated in non-acute toxicity studies.		
Proportion of the population exposed		The surrogate protection goal relates to a realistic worst case individual, which would be exposed.		
Timing of applications		Assessment assumes worst case exposure in all phases of reproduction for same individual, whereas in practice exposure is		The model assumes every phase of reproduction coincides with spray time so true worst case cannot be worse.

<sup>&</sup>lt;sup>22</sup> Based on data from http://www.wsi.nrcs.usda.gov/products/W2Q/pest/winpst.html.



	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
		likely to peak in different phases for different individuals. However, it is likely at least some individuals will be exposed in most sensitive phase, so not over-conservative for surrogate protection goal.		
Recovery from effects	/0	Affected individuals may be able to recover and successfully reproduce at a later date.		
Overall	There are uncertainties in both directions. Because of the potential for wide variation in toxicity between species, some individuals in sensitive species may experience reproductive effects at TER>5, potentially breaching the surrogate protection goal. The assessment procedure is more likely to fulfil the actual protection goal of preventing long-term repercussions on abundance and diversity, due to variation in exposure between individuals and over space and time, and the potential for replacement through recovery and immigration.			



## Risk to birds and mammals from granular pesticides

This section documents judgements regarding the level of protection achieved for the first-tier assessment for the use of granules. It is based on the scenarios used in the TER calculation and applicable for acute risk assessment and reproductive risk assessment.

The evaluation of the assessment assumptions (Tables 9-11) suggests that the calculation of granular exposure might be relatively close to a realistic worst case, but the conservatism of other aspects is much more uncertain. Possibly the largest single source of uncertainty is the extrapolation of toxicity from one or two standard test species to the species exposed in the field, which could be up to two orders of magnitude more or less sensitive (see Figure 1 above). Another important factor affecting the conservatism of the assessment is that within a species, sensitive individuals may be up to ten times more sensitive than the LD<sub>50</sub>, which is used in the TER calculation (see also Figure 2 above). On the other hand, both avoidance and metabolism are ignored in the TER calculation but could greatly reduce the risk for some pesticides. Consequently, the overall conservatism of the Tier 1 TER calculation will vary widely between pesticides. If the focal species happens to be much more sensitive than the standard test species, and if there is little or no avoidance and metabolism, then the true risk could be higher than implied by the Tier 1 assumptions, and some mortality might then occur when the Tier 1 TER of 10 or effects on reproduction could be noticed when using the Tier 1 TER of 5. For pesticides with strong avoidance and metabolism, Tier 1 will substantially over-estimate risk.



Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Number of grit taken by a bird per day				
Acute risk     assessment	*	90%-ile of distribution taken, for the specific generic focal species the actual worst case value may be lower	*	90%-ile value taken, actual worst case for an individual bird may be higher
Reproductive risk     assessment			**	Geometric mean of distribution, the actual worst case for an individual may be significantly higher especially in case of reproductive effects after short term exposure
Turn over rate in gizzards	**	Distribution of true values unknown, default value is from a single study	**	Distribution of true values unknown, default value is from a single study
Number of soil particles			**	Default value is mean of 3 Dutch soils, the actual risk in peat soils may be higher due to the absence of natural grit sources
Density of granules at soil surface	*	Average density of granules (actual density may be lower)	*	Average density of granules (actual density may be higher)
Loading of granules			*	Nominal value taken, actual loading may be slightly higher
PT	*	Default PT is 1, actual value may be lower		
Half-life of active substance		Reported value from non-standard study, variability of such values are unknown		Reported value from non-standard study, variability of such values are unknown
Half-life of granules		Reported value from non-standard study, variability of such values are unknown		Reported value from non-standard study, variability of such values are unknown
Toxicity parameters, metabolism, uncertainty factor		see Table 1 above		

**Table 9.** Conservatism for granules ingestion by birds seeking grit (see for explanation legend of Table 1 above).



Parameter, assumption or omission	Potential for 'true worst case'	Explanation	Potential for 'true worst case' risk to be higher	Explanation
	risk to be lower			
Daily energy expenditure, Food energy, Moisture content and Assimilation efficiency		see Table 1 above		
Density of granules at soil surface, loading of granules and PT		see table 9 above		
Number of available seeds at soil surface (seed bank)		??	upper limit of known range (not conservative)	??
Choice of generic focal Species (influence on exposure)	*	Relatively small worst case species as default, actual focal species may be larger		
Half-life of active substance and granules		see table 9 above		
Non-dietary exposure Toxicity parameters, metabolism, uncertainty factor		see Table 1 above	*	Ignored. True contribution probably small

Table 10. Conservatism for granules ingestion by birds seeking seeds as food (see for explanation legend of Table 1 above)



**Table 11.** Conservatism granules ingestion by birds and mammals as part of the soil ingested with food (see for explanation legend of Table 1 above).

Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Daily energy expenditure, Food energy, Moisture content and Assimilation efficiency		see Table 1 above		
Body weight		Average body weight value for a small bird or mammals chosen as default. Actual focal species may be larger		Average body weight value for a small bird or mammals chosen as default. Individual at risk may be smaller
PT	*	Default PT is 1, actual value may be lower		
Concentration of a.s. in soil				
Acute risk     assessment	**	Active substance assumed to be homogenously mixed over layer of 1cm. Since granule application normally requires working the soil at or after treatment the actual mixing depth of the substance may be larger	*	Active substance assumed to be homogenously mixed over layer of 1cm. Acute exposure may be in a 'hot-spot' of the field where the actual concentration is somewhat higher
Reproductive risk     assessment	*	Active substance assumed to be homogenously mixed over layer of 5cm. Since granule application normally requires working the soil at or after treatment the actual mixing depth of the substance may be larger	*	Active substance assumed to be homogenously mixed over layer of 5cm. Where repro effects are due to short-term exposure the actual concentration in a 'hot-spot' in the field may be somewhat higher
Bulk density of soil		Assumed to be 1.5 kg/l, but actual densities in agricultural soil may vary 1.2-1.8 kg/l		Assumed to be 1.5 kg/l, but actual densities in agricultural soil may vary 1.2-1.8 kg/l
Half-life in soil	*	Average reported value used, but actual value in a particular soil-type may differ by factor 2	**	Average reported value used, but actual worst-case value in a particular soil-type may differ by factor 3
Type of food			*	Mixed diet (not worst case type of food)
Daily dry soil intake				
• Acute risk assessment			*	90 <sup>th</sup> percentile value of available information taken, but because data-base is relatively small, actual worst-case may be higher



Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
• Reproductive risk assessment			**	Geometric mean value of available information taken, but because data-base is relatively small, actual worst-case may be higher, especially where reproductive effects are caused by short-term exposure
Non-dietary exposure			*	Ignored. True contribution probably small
Toxicity parameters, metabolism, regurgitation, avoidance and uncertainty factor		see Table 1 above		



# Risk to birds and mammals from bioaccumulating pesticides

This section documents judgements regarding the level of protection achieved for the first-tier assessment for pesticides that could be accumulating through the food chain (e.g. soil – earthworm – earthworm eating birds and mammals and water – fish – fish eating birds and mammals). It is based on the scenarios used in the TER calculation and applicable reproductive risk assessment.

The evaluation of the assessment assumptions (Table 12) suggests that the calculation of bioaccumulative potential via the earthworm route might be relatively close to a realistic worst case (e.g. the choice of a relative small indicator species, the assumption that the species will spend 100 % of its time in the treated area, and by using the highest expected concentration in the season), but the conservatism of other aspects is much more uncertain. Possibly the largest single source of uncertainty is the extrapolation of toxicity from 1 or 2 standard test species to the species exposed in the field and that sensitive individuals may be up to ten times more sensitive than the LD<sub>50</sub>, which is used in the TER calculation (see Figure 2 above). On the other hand, metabolic clearance is ignored in the TER calculation but could greatly reduce the risk for some pesticides. Avoidance and regurgitation is believed not to play a role in this particular part of the risk assessment. Consequently, the overall conservatism of the Tier 1 TER calculation will vary widely between pesticides. If the focal species happens to be much more sensitive than the standard test species, and if there is little metabolism, then the true risk could be higher than implied by the Tier 1 assumptions, and some effects on reproduction could be noticed when using the Tier 1 TER of 5. For pesticides that are quickly cleared, Tier 1 will substantially overestimate risk.

The evaluation of the assessment assumptions (Table 13) suggests that the calculation of bioaccumulative potential via the fish route might be relatively close to a realistic worst case (e.g. the assumption that the species will spend 100 % of its time in the treated area, by using the highest expected concentration in the season and the assumption that the indicator species will be present in the relative small water body), but the conservatism of other aspects is much more uncertain (see for analysis of toxicity above). Metabolic clearance of the compound is ignored in the TER calculation but could greatly reduce the risk for some pesticides (and presumably if activating the compound could increase it for others?). Avoidance and regurgitation is believed not to play a role in this particular part of the risk assessment. Consequently, the overall conservatism of the Tier 1 TER calculation will vary widely between pesticides. If the focal species happens to be much more sensitive than the standard test species, and if there is little metabolism, then the true risk could be higher than implied by the Tier 1 assumptions, and some effects on reproduction could be noticed when using the Tier 1 TER of 5. For pesticides that are quickly cleared, Tier 1 will substantially over-estimate risk.



**Table 12.** Evaluation of conservatism of the first-tier risk assessment of potentially bioaccumulating compounds for earthworm eating birds and mammals. Each row evaluates a separate input, assumption or omission of the first-tier assessment procedure. – and + signs are used to indicate the extent to which it is judged that the 'true worst' case for that element could decrease or increase the risk of causing any reproductive effect. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that would reduce or increase the risk by an amount equivalent to reducing the TER by about a factor of about 10, ++ by a factor of about 5 and + by a factor of about 2. If the effect varies between pesticides or is uncertain, lower and upper evaluations are given (e.g. +/+++).

Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Relevance of reproduction toxicity study		Not all critical phases of avian reproduction are adequately covered by existing protocol.	+++	Not all critical phases of avian reproduction are adequately covered by existing protocol. Alticial species especially may differ $- e.g.$ parental care much more important.
Relevance of $1/10$ LD <sub>50</sub> as proxy for chick toxicity		True 'lethal incapacitation' of chicks may occur at lower level than $1/10 \text{ LD}_{50}$ based on adult signs of intoxication.	++	True 'lethal incapacitation' of chicks may occur at higher level than $1/10$ LD <sub>50</sub> based on adult signs of intoxication.
Body weight (impact on exposure)				For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight.
Body weight (impact on toxicity)		Relatively few exposed species are larger than species used in toxicity tests.	+ (for birds only)	Focal species tend to be smaller than species used in toxicity tests. General trend for smaller species to be more sensitive (Mineau et al., 1996) is not taken into account in assessment.
Daily energy expenditure DEE	-	Average, but from demanding period (e.g. breeding season). True worst case unlikely to be more than two times more or less than assumed value.	+	Average, but from demanding period (e.g. breeding season). True worst case unlikely to be more than two times more or less than assumed value.
Food energy FE	-	Average value. Best case unlikely to exceed two times.	+	Average value. Worst case unlikely to exceed two times.
Moisture content MC	-	Average value. Best case unlikely to exceed two times.	+	Average value. Worst case unlikely to exceed two times.
Assimilation efficiency AE	-	Average value. Best case unlikely to exceed two times.	+	Average value. Worst case unlikely to exceed two times.
Percent of diet taken by individual in treated area	- (for birds)	100%; for birds probably less than 100% (a reduction of a factor of 2 is possible), the home range of the small mammals could be rather small and therefore believed to fall sometimes completely in the treated area.		For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight.
Concentration in soil	-/	Period with highest concentration in the season (worst case) rather thin layer of soil		ž



Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Half-life in soil		Average (range between lowest and highest values two orders of magnitude)	++	Average (range between lowest and highest values two orders of magnitude)
Bulk density of soil	-	Average (range between lowest and highest values one order of magnitude)	+	
Partitioning coefficient octanol water	-	Average (range between lowest and highest values one order of magnitude)	+	
Organic carbon content	-	Average (range between lowest and highest values one order of magnitude)	+	
Organic carbon adsorption coefficient	-	Average (range between lowest and highest values one order of magnitude)	+	
Bioconcentration factor (BCF)	-/	The BCF is normally calculated by using a QSAR (a real BCF study is seldomly carried out. The 'true' BCF could be lower than the estimated factor and therefore the risk could be lower (No information available for the expected range))	+/++	The BCF is normally calculated by using a QSAR (a real BCF study is seldomly carried out. The 'true' BCF could be lower or higher than the estimated factor and therefore the risk could different (No information available for the expected range))
Non-dietary exposure		Ignored. True contribution uncertain, but could, in short term, increase risk by up to two times or more (Driver et al., 1991).	++	Ignored. True contribution uncertain, but could, in short term, increase risk by up to two times or more (Driver et al., 1991).
Variation of toxicity between species and/or stages within species		Focal species could be up to 2 orders of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (York workshop) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity.	+++	Focal species could be up to 2 orders of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (York workshop) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity.
Variation of toxicity between individuals		A logical extension of the above comment would suggest that this holds true for intra-specific variance as well.	+/+++	Most sensitive individuals could be two to ten times more sensitive than $LD_{50}$ .
Uncertainty factor		TER is compared with trigger value of 5.		
Avoidance of contaminated food or of treated area as a whole	-/	Ignored. True contribution varies between pesticides and species. Could be negligible, or could prevent reproductive effects for most sensitive species. Likely to be most important in case of short term exposure leading to long term effects; likely less important where long term exposure required to cause effect.		
Effect of metabolism	-/	Ignored. True contribution varies between pesticides and species. Could be negligible or very substantial for both short and long term exposure.		



Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Regurgitation	-	Should not cause under-estimation of risk if avoid using $LD_{50}$ studies where regurgitation occurred. May partially reduce the estimate of chick toxicity (1/10 $LD_{50}$ ).		
Proportion of the population exposed		The compound may only be used on a small area and hence only a small proportion of the population exposed. Similarly the proportion of birds co-existing with the crop at time of treatment may be small.		It is assumed all birds are similarly exposed
Timing of applications		The breeding phases of birds may not overlap directly with application of the pesticides.		The model assumes every breeding phase coincides with spray time
Overall	Biases connected with the exposure calculation are potentially large where overlap between application and breeding stages is minimal. The influence of toxicity, avoidance and metabolism is still potentially large. For pesticides with strong avoidance and rapid metabolism <sup>23</sup> , Tier 1 will substantially over-estimate risk. For substances with little or no avoidance and slow metabolism, or with effects not currently covered by the reproduction study, true risk for a sensitive species could be higher and some reproductive effects could occur above TER=5.			

<sup>&</sup>lt;sup>23</sup> No general statement can be made about the degree of avoidance and metabolism required for this, but it could be an option for case-by-case investigation in higher tier assessments.



**Table 13.** Evaluation of conservatism of the first-tier risk assessment of potentially bioaccumulating compounds for fish-eating birds and mammals. Each row evaluates a separate input, assumption or omission of the first-tier assessment procedure. – and + signs are used to indicate the extent to which it is judged that the 'true worst' case for that element could decrease or increase the risk of causing any reproductive effect. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that would reduce or increase the risk by an amount equivalent to reducing the TER by about a factor of about 10, ++ by a factor of 5 and + by a factor of 2. If the effect varies between pesticides or is uncertain, lower and upper evaluations are given (e.g. +/+++).

Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Relevance of reproduction toxicity study		Not all critical phases of avian reproduction are adequately covered by existing protocol.	+++	Not all critical phases of avian reproduction are adequately covered by existing protocol. Alticial species especially may differ $- e.g.$ parental care much more important.
Relevance of $1/10$ LD <sub>50</sub> as proxy for chick toxicity		True 'lethal incapacitation' of chicks may occur at lower level than $1/10 \text{ LD}_{50}$ based on adult signs of intoxication.	++	True 'lethal incapacitation' of chicks may occur at higher level than $1/10$ LD <sub>50</sub> based on adult signs of intoxication.
Body weight of focal mammalian species in the Tier 1 assessment		Realistic case – The otter serves as the model species in the mammalian scenario. Sometimes smaller mammals do eat fish like the Pyrenean Desman ( <i>Galemys pyrenaicus</i> ) but are not considered as relevant in the risk assessment for pesticides.		Sometimes smaller mammals do eat fish like the Pyrenean Desman ( <i>Galemys pyrenaicus</i> ) but are not considered as relevant in the risk assessment for pesticides.
Body weight of focal mammalian species in the Tier 1 assessment		The cormorant serves as the model species in the avian scenario.	+	There are smaller avian species that are sometimes eating fish (and sometimes only fish, particular in the winter period) like the Little Grebe ( <i>Tachybaptus ruficollis</i> ). Because of the higher daily energy expenditure of this species the 'true risk' could be higher (at the most a factor of 2)
Body weight (impact on toxicity)	- (only for birds)	Focal species tend to be larger than species used in toxicity tests. General trend for larger species to be less sensitive (Mineau et al., 1996) is not taken into account in assessment		
Body weight (impact on exposure)				Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight.
Daily energy expenditure DEE	-	Average, but from demanding period (e.g. breeding season). True worst case unlikely to be more than two times more or less than assumed value.	+	Average, but from demanding period (e.g. breeding season). True worst case unlikely to be more than two times more or less than assumed value.
Food energy FE	-	Average value. Worst case unlikely to exceed two times.	+	Average value. Worst case unlikely to exceed two times.
Moisture content MC	-	Average value. Worst case unlikely to exceed two times.	+	Average value. Worst case unlikely to exceed two times.
Assimilation efficiency AE	-	Average value. Worst case unlikely to exceed two times.	+	Average value. Worst case unlikely to exceed two times.



Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Percent of diet taken by individual in treated area		100% very probably less of the diet is taken from the treated ditch, fish eating species normally can be found in larger water body than the ditch that is used in the scenario		
Concentration in water		Period with the highest concentration in the season (which is based on an overall 90 <sup>th</sup> percentile drift value. Fish eating species are normally found in larger water bodies and therefore will be exposed to lower concentrations than assumed in the scenario.	+	Period with highest concentration in the season based on the 90 <sup>th</sup> percentile drift values, in 10 percent of the case higher values can be expacted in the surface water
Half-life in water	-	Average (one order of magnitude between lowest and highest values)	+	Average (one order of magnitude between lowest and highest values)
Dimensions of water body		Relative small (water body of target species is probably much larger)		
Bioconcentration factor	-	Average (normally only one study available, one order of magnitude between lowest and highest values)	+	Average (normally only one study available, one order of magnitude between lowest and highest values)
Non-dietary exposure		Ignored. True contribution uncertain, but could, in short term, increase risk by up to two times or more (Driver et al., 1991).	++	Ignored. True contribution uncertain, but could, in short term, increase risk by up to two times or more (Driver et al. ,1991).
Variation of toxicity between species and/or stages within species	+++	Focal species could be up to 2 orders of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (York workshop) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity.	+++	Focal species could be up to 2 orders of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (York workshop) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity.
Variation of toxicity between individuals		A logical extension of the above comment would suggest that this holds true for intra-specific variance as well.	+/+++	Most sensitive individuals could be two to ten times (i.e. $*$ to $***$ ) more sensitive than LD <sub>50</sub> .
Uncertainty factor	++	TER is compared with trigger value of 5.		
Avoidance of contaminated food or of treated area as a whole	+/+++	Ignored. True contribution varies between pesticides and species. Could be negligible, or could prevent reproductive effects for most sensitive species. Likely to be most important in case of short term exposure leading to long term effects; likely less important where long term exposure required to cause effect. Unknown whether it plays a role at all for fish eating birds and mammals (no information available).		
Effect of metabolism	+/+++	Ignored. True contribution varies between pesticides and species. Could be negligible or very substantial for both short and long term exposure.		
Regurgitation	+	Should not cause under-estimation of risk if avoid using $LD_{50}$ studies where regurgitation occurred. May partially reduce the estimate of chick toxicity (1/10 $LD_{50}$ ).		



Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation	
Proportion of the population exposed		The compound may only be used on a small area and hence only a small proportion of the population exposed. Similarly the proportion of birds co-existing with the crop at time of treatment may be small.		It is assumed all birds are similarly exposed	
Timing of applications		The breeding phases of birds may not overlap directly with application of the pesticides.		The model assumes each phase coincides with spray time	
Overall	Biases connected with the exposure calculation are potentially large where overlap between application and breeding stages is minimal. The influence of toxicity, avoidance and metabolism is still potentially large. For pesticides with strong avoidance and rapid metabolism <sup>24</sup> . Tier 1 will substantially over-estimate risk. For substances with little or no avoidance and slow metabolism, or with effects not currently covered by the reproduction study, true risk for a sensitive species could be higher and some reproductive effects could occur above TER=5.				

<sup>&</sup>lt;sup>24</sup> No general statement can be made about the degree of avoidance and metabolism required for this, and whether avoidance plays an important role, but it could be an option for case-by-case investigation in higher tier assessments.



# Acute risk to birds and mammals from treated seeds at Tier 1

The level of protection provided by the Tier 1 assessment procedure for acute risks to birds and mammals from treated seeds is evaluated in Table 14.



**Table 14.** Evaluation of the level of protection provided by the Tier 1 assessment procedure for acute risks to birds and mammals from treated seeds. See earlier tables for key to symbols.

Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Choice of species (effect on exposure)	-	Relatively small species chosen as default. Actual focal species may be larger	++	Relatively small species chosen as default, except for large seeds (maize, peas and beans) that are not assumed to be consumed by small birds. Data from Prosser (1999) show that even when small birds do not readily feed on large seeds, individual cases may occur.
РТ		Default PT is 1, which is ok as a worst-case estimate for the individual		
Diet	-	Assumed to be 100% treated seeds. Actual worst-case focal species a mixed diet		
Availability of untreated seeds	-	Diet at Tier 1 assumed to consist of 100% treated seeds, Actual feeding even for of the worst-case individual may be a mix of treated seeds and other non-treated seeds from the natural seed-bank		
Loading rate on seed Dissipation and degradation of active of seeds	-	Nominal loading rate cannot be higher than worst case Assessment assumes bird/mammal to feed on freshly drilled seeds	+	Nominal value taken, actual loading may be slightly higher
Mammals feeding on Pelleted seeds			++	Not considered a relevant scenario. Even if individual mammals may do so occasionally, they will probably 'crack' the pill before feeding on the seed and hence avoid exposure to a significant extent
Birds feeding on pelleted seeds		Scenario includes as equivalent to grit uptake		Scenario includes as equivalent to grit uptake
Herbivorous birds and mammals feeding on seedlings	-	Dilution factor between active ingredient present in the seed to active ingredient in the seedling is conservatively set at five (NAR/5) based on water content difference between seeds and seedlings. Actual information on concentration in seedlings is largely unknown The scenario assumes that when birds/mammal feed on seedlings they always consume the left-over of the seeds with it. This may be an overestimate	+	Dilution factor between active ingredient present in the seed to active ingredient in the seedling is conservatively set at five (NAR/5) based on water content difference between seeds and seedlings. Actual information on concentration in seedlings is largely unknown
Dehusking	-/	No de-husking assumed at Tier 1		
Avoidance	-/	Ignored, true contributions varies between species and pesticides. Could be negligible or could prevent mortality even for the most sensitive species		



Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation		
Variation of toxicity between species		Focal species could be up to 2 orders of magnitude less sensitive than standard species.	+++	Focal species could be up to 2 orders of magnitude more sensitive than standard species.		
Variation of toxicity between individuals			+/+++	Most sensitive individuals could be two to ten times more sensitive than reported $LD_{50}$ .		
Uncertainty factor		TER is compared with trigger value of 10.				
Overall	Although conservative, the scheme appropriately represents the risk to the worst case individuals, therefore it may often be necessary to refine the assessment in order to assess the product against the ultimate protection goals of visible mortality and long term repercussions for abundance and diversity					



## Risk to birds and mammals from contaminated drinking water

This section documents judgements how the level of protection is affected by the assumptions made for assessing the risk for birds and mammals due to uptake of contaminated drinking water. Generic issues on toxicity parameters and uncertainty factors are documented in Table 1 above.

As regards the expected concentrations of active substances in drinking water, the evaluation of the assessment assumptions (Table 15) suggests that these are likely to reflect a worst case. In particular, the settings of the proposed leaf scenario (pools in whorls) are fully based on observed incidents and values measured at the incident sites. The proposed puddle scenario makes use of equivalent assumptions as employed in FOCUS<sub>SW</sub> for estimation of runoff to surface water bodies. Higher  $PEC_{puddle}$  values would result for soils with a lower content of organic carbon; however, it is deemed less likely that longer-lasting puddles will be formed on such soils to a significant extent.

On the level of individuals, no combined exposure to residues in food and drinking water is currently considered. This is due to the incidental nature of occurrence of drinking water reservoirs on agricultural fields (as compared to the contamination of food items growing or dwelling on those fields). Combined exposure may occur for granivorous animals in case of toxic seed treatments, but there, the contribution of drinking water to the overall risk (according to the relevant puddle scenario) is probably low. For herbivorous and insectivorous animals, the calculated drinking water rates (DWR) are negative as long as the food uptake rates are based on the current DEE estimates (see Appendix L). Hence, the dietary risk assessment will most probably also cover a theoretical risk from drinking water uptake, due to typically higher residues in the food items.



Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Parameters for scenario A				
Concentration in spray solution		Fixed value, adjusted by spray operator, no distribution		Fixed value, adjusted by spray operator, no distribution
Dilution factor	*	Relative worst case (set to five), minimum dilution found in measured data from incident sites		Relation to spray solution concentrations does not necessarily reflect true driving forces for concentrations in leaf whorl pools. However, formation of such pools requires significantly higher water volumes than those used in standard spray applications (200-400 L water/ha). Pool formation without additional irrigation/precipitation may occur with high-volume sprays (≥ 1000-1500 L water/ha)
Parameters for scenario B				
Pore water term (reflects pore water volume at run-off)		Soil field capacity $0.4 \text{ m}^3/\text{m}^3$ – typical value for soil with high clay content. 50 % field capacity soil water content before precipitation reflects relative worst case. 10 mm precipitation is considered the minimum amount for causing run-off. Effect of each single parameter on PEC <sub>puddle</sub> remains < 10 %		Soil field capacity 0.4 m <sup>3</sup> /m <sup>3</sup> – sandy soils may have lower field capacity, but this results in lower likelihood of puddle formation Effect of each single parameter on $PEC_{puddle}$ remains < 10 %
Soil term (reflects soil density and sorptive capacity)	*	Bulk soil density 1.5 kg/L – standard assumption for PEC <sub>soil</sub> calculation 2 % organic carbon content represents a typical value for agricultural soils, actual values may be as high as 4-6 % (higher adsorption) Effect of each single parameter unlikely to result in a factor > 3 for PEC <sub>puddle</sub>	*	Bulk soil density 1.5 kg/L – standard assumption for $PEC_{soil}$ calculation – actual values may range from 1.2 to 1.8 2 % organic carbon content represents a typical value for agricultural soils, actual values may be as low as 0.5 % (lower adsorption) Effect of each single parameter unlikely to result in a factor > 3 for $PEC_{puddle}$
Adsorption coefficient (K <sub>OC</sub> )	**	Using of average value is proposed, relevant concentrations in puddles only expected for compounds with $K_{OC} < 500$ , actual values may be higher by 1 order of magnitude (interactions with soil clay content or due to electrostatic forces may result in higher variance of measured adsorption coefficients, however, this would typically weaken correlation to OC content of soil)	**	for compounds with $K_{OC} < 500$ , actual values may be lower by 1 order of magnitude (interactions with soil clay content or due to electrostatic forces may result in higher variance of measured adsorption coefficients, however, this would typically weaken correlation to OC content of soil)

Table 15. Evaluation of conservatism of the first-tier assessment of risk for birds and mammals due to uptake of contaminated drinking water



Parameter, assumption or omission	Potential for 'true worst case' risk to be lower	Explanation	Potential for 'true worst case' risk to be higher	Explanation
Indicator species (impact on water intake)	*	Granivorous species represent worst case guild with highest additional water demand, other feeding guilds will satisfy higher fraction of water demand via food intake		
Drinking water rate			*	Average, no reliable information available on dependency of water demand from typical environmental conditions.
Combined exposure to residues in food and drinking water			**	Not considered, due to incidental nature of puddle formation
Toxicity parameters, metabolism, uncertainty factor –		see table for dietary exposure assessment		



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<sup>&</sup>lt;sup>25</sup> Available at: <u>http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc19\_en.pdf</u>

<sup>&</sup>lt;sup>26</sup> Available at: http://www.pesticides.gov.uk/uploadedfiles/Web\_Assets/PSD/Research\_PN0907.pdf



## **APPENDIX D**

## PROPORTIONS OF LIST 3A SUBSTANCES FAILING UNDER CURRENT AND PROPOSED LOWER TIER PROCEDURES FOR ACUTE AND REPRODUCTIVE RISK ASSESSMENTS

Surveys and consultations identified the number of substances failing Tier 1 as an issue of concern to Member States and stakeholders, and the failure rate may be a legitimate consideration for policy-makers. Therefore, the proportions of assessments that would fail for List 3a substances<sup>1</sup> (listed in Table 1) were determined for both the acute and reproductive risks to birds and mammals. Note that, in this Appendix, "fail" refers only to the outcome of the first tier assessment, i.e. it refers to uses or substances that would require a higher tier assessment.

Only field spray uses were considered. Greenhouse and indoor uses, granular formulations and seed treatments were excluded. In addition, toxicity data were not available for a few substances.

Toxicity data and key uses were extracted for each substance from their respective EU Endpoint Lists and Draft Assessment Reports (DAR), and used to assign relevant scenarios for the assessments. The proposed assessment procedures were applied as described in the Guidance Document. For comparison, assessments were also carried out according to the previous guidance document (EC, 2002). For the previous procedure, the lowest  $LD_{50}$ s listed in the EU endpoint list were used. For the new procedures the geometric mean is used;<sup>2</sup> for birds, this was based on all the tested species found in the DAR (excluding any that were identified as unsuitable for use). The geometric mean approach was not used for reproductive toxicity. Due to lack of time it was not possible to search the DAR for all mammalian  $LD_{50}s$ , so only those listed in the EU Endpoint List were considered. Similarly, it was not practical to access the original studies for each endpoint so it was not possible to apply the new procedure for extrapolating avian  $LD_{50}$ s beyond limit doses (as provided for in section 2.1.2 of the new Guidance Document). This means that the results shown below might overestimate the proportion of substances that would fail under the new procedures, although probably not by a large degree. Also due to limited time, it was not possible to consider the selection of focal species in the same detail as would be done in a full regulatory assessment. Where the selection was doubtful (e.g. due to uncertainty about the precise growth stages where the pesticide is used), the more conservative option was taken, as might be done in a regulatory assessment.

The new reproductive assessment, at both screening and Tier 1 levels, require consideration of whether reproductive effects could be caused by short-term exposures. It is intended to develop further guidance on criteria for this issue. The Joint Working Group of the Commission, Member States and EFSA decided that, until such guidance is available, it should be assumed as a default that the effects are caused

<sup>&</sup>lt;sup>1</sup> Substances for which authorisation under Directive 91/414/EEC was reviewed in 'List 3a'.

 $<sup>^{2}</sup>$  In no case did the most sensitive species have an LD<sub>50</sub> more than a factor of 10 below the geometric mean.

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by long-term exposure (LTE), unless there is specific evidence for the pesticide under assessment that the effect could be caused by short-term exposure (STE). In the assessments for this Appendix, it was not practical to consider in detail the evidence on causation of reproductive effects, so the assessments were done twice, once assuming effects are caused by short-term exposures (STE) and once assuming effects are caused by short-term exposures (STE) and once assuming effects are caused by long-term exposure (LTE). STE assessments use a time-weighted average (TWA) factor of 1, whereas LTE assessments use a TWA factor of 0.53 (see sections 4.3 and 4.4 of Guidance Document).

The results are summarised in Tables 2-5. The grey cells show the proportions of uses that "fail", i.e. give toxicity-exposure ratios (TERs) above the trigger values of 10 and 5, for acute and reproductive assessment respectively. Results are also shown for other TER values, to show how sensitive the outcome would be to a change in the trigger value or to changes or refinements in the TER calculations.

**The principal findings** are that the "failure" rates under the new Tier 1 procedures are 7% for birds and 14% for mammals for acute assessments, 35% for birds and 68% for mammals for reproductive assessments (with the default assumption that reproductive effects are caused by long term exposure). The corresponding failure rates under the previous guidance are 15% for birds and 12% for mammals for acute assessments, 63% and 59% respectively for reproductive assessments. The higher failure rates for the new mammal assessments are largely associated with the exposure scenario involving voles.

Failure rates in the future may vary depending on the profile of the substances involved. The List 3a substances (listed in Table 1) were chosen for these assessments because it was considered that they are more likely to reflect the profile of future substances than earlier Lists, which contained a higher proportion of acutely toxic substances. The proportion of List 3a substances with acute endpoints of 2000 mg/kg bw or higher was 64% for birds and 50% for mammals.

Abamectin	Clomazone	Fenpyroximate	Pencycuron
Acetochlor	cetochlor Copper compounds		Propaquizafop
Amidosulfuron	Cyanamide	Fluazinam	Prosulfocarb
Benfluralin	Cycloxydim	Fludioxonil	Pyriproxyfen
Bifenox	Dicloran	Fluometuron	Quinoclamine
Bifenthrin	Diflubenzuron	Fluquinconazole	Tebufenozide
Bitertanol	Diflufenican	Flutolanil	Tetraconazole
Bromuconazole	Dimethipin	Fuberidazole	Thiobencarb
Buprofezin	Dithianon	Hexythiazox	Tralkoxydim
Butralin	Epoxiconazole	Imidacloprid	Triadimenol
Carbetamide	Etofenprox	Mepiquat	Triflumizole
Chloridazon	Fenazaquin	Metaldehyde	Triflumuron
Chloropicrin	Fenbuconazole	Metazachlor	Zeta-cypermethrin
Chlorthal-dimethyl	Fenoxaprop-P	Myclobutanil	
Clethodim	Fenpropidin	Napropamide	
Clofentezine	Fenpropimorph	Nicosulfuron	

 Table 1.
 List 3a substances considered for the assessments in this Appendix.



**Table 2.**Acute risk to birds: the proportion of 170 key uses of 55 List 3a substances with acute<br/>TERs below different levels. The grey shaded cells show the percentage of uses with<br/>TERs below the trigger value of 10, i.e. the failure rate.

BIRDS	% List 3a uses below each level of TER						
Acute TER	Previous procedure (EC, 2002)	New Tier 1 procedure					
0.01	0%	0%	0%				
0.03	0%	0%	0%				
0.1	0%	0%	0%				
0.3	0%	1%	0%				
1	2%	4%	1%				
3	4%	7%	4%				
5	8%	12%	4%				
10	15%	24%	7%				
30	28%	42%	18%				

**Table 3.**Acute risk to mammals: the proportion of 171 key uses of 55 List 3a substances with<br/>acute TERs below different levels. The grey shaded cells show the percentage of uses<br/>with TERs below the trigger value of 10, i.e. the failure rate.

MAMMALS	% List 3a uses below each level of TER						
Acute TER	Previous procedure	New screening procedure	New Tier 1 procedure				
	(EC, 2002)						
0.01	0%	0%	0%				
0.03	0%	0%	0%				
0.1	1%	1%	0%				
0.3	1%	1%	1%				
1	4%	5%	5%				
3	7%	9%	7%				
5	8%	16%	10%				
10	12%	24%	14%				
30	26%	46%	26%				



Table 4.Reproductive risk to birds: the proportion of 170 key uses of 55 List 3a substances with<br/>reproductive TERs below different levels. The grey shaded cells show the percentage of<br/>uses with TERs below the trigger value of 5, i.e. the failure rate. The new assessments<br/>with TWA=0.53 assume effects are caused by long-term exposure (the default), while<br/>those with TWA=1 assume effects are caused by short-term exposure (see text).

BIRDS	% List 3a uses below each level of TER					
Reproductive	Previous	New screening	New Tier 1	New screening	New Tier 1	
TER	procedure	procedure	procedure	procedure	procedure with	
	(EC, 2002)	with	with	with TWA=1	TWA=1	
		TWA=0.53	TWA=0.53			
0.01	0%	0%	0%	1%	0%	
0.03	1%	1%	0%	3%	1%	
0.1	5%	5%	2%	9%	4%	
0.3	12%	12%	6%	22%	6%	
1	27%	29%	13%	44%	24%	
3	50%	54%	29%	65%	38%	
5	63%	64%	35%	75%	46%	
10	79%	75%	48%	88%	59%	
30	94%	94%	75%	96%	85%	

**Table 5.**Reproductive risk to mammals: the proportion of 173 key uses of 55 List 3a substances<br/>with reproductive TERs below different levels. The grey shaded cells show the<br/>percentage of uses with TERs below the trigger value of 5, i.e. the failure rate. The new<br/>assessments with TWA=0.53 assume effects are caused by long-term exposure (the<br/>default), while those with TWA=1 assume effects are caused by short-term exposure<br/>(see text).

Reproductive	Previous	New screening	New Tier 1	New screening	New Tier 1
TER	procedure	procedure	procedure	procedure	procedure with
	(EC, 2002)	with	with	with TWA=1	TWA=1
		TWA=0.53	TWA=0.53		
0.01	1%	2%	0%	6%	1%
0.03	1%	6%	1%	9%	1%
0.1	2%	18%	2%	36%	12%
0.3	6%	45%	18%	58%	25%
1	20%	69%	27%	81%	49%
3	52%	88%	55%	92%	77%
5	59%	92%	68%	93%	86%
10	73%	94%	87%	97%	92%
30	92%	99%	93%	99%	94%

## References

EC (European Commission – DG Health and Consumer Protection), 2002. Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC. SANCO/4145/2000 – final 25 September 2002, pp 74.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> Available at: http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc19\_en.pdf



## **APPENDIX E**

## IMPACT OF CROP INTERCEPTION ON RESIDUES ON PLANT FOOD ITEMS

The residue unit doses (RUDs) for vegetation are derived from trials in which the crops are directly oversprayed. However, there will, be situations where particular food items for birds and mammals will have lower concentrations than expected due to the compound being partly intercepted by the crop before it reaches the food item.

As already proposed in EC (2002), interception by the crop may be considered as a minimising factor for residues on plant food items when canopy-directed applications of insecticides and fungicides to orchards, vineyards, hops or bush fruit are performed and undergrowth vegetation (assumed to be grass) is present. Also vegetables growing on trellis might fall under this category and would be treated similar to vineyards. Only one deposition factor of 0.6 was given in EC (2002) that corresponded to the lowest interception of 40 % in these scenarios according to the FOCUS surface water report for Step 2 PEC<sub>SW</sub> calculations (FOCUS, 2001, Table 2.4.2.-1). Taking into account the generic nature of FOCUS interception factors, it is now proposed that crop and growth-stage specific values according to FOCUS (2001) may be used in the Tier 1 scenarios. No interception factor may be applied for herbicide applications in those crops, since these are typically directly made to the grass vegetation. Also, no interception factor is applied for hops before side shoot formation, i.e. at growth stages BBCH 10-19 (BBA, 2001), because it is cultivated like an arable crop at this early stage.

As regards arable crops, some of them are rarely, if ever, eaten by birds and mammals (e.g. potatoes) whilst other crops become less attractive and hence less likely to be consumed as they grow (e.g. sugar beet). Whilst these crops may not be eaten, it is possible that other plants on the field will be available as food. At certain stages the crop may intercept some of the applied product and hence the amount of pesticide deposited on the food item is less than the application rate. Since measured residues of such food items at the appropriate growth stage of the crop are not available, only estimates can be used. However, further considerations were deemed necessary whether the FOCUS figures intended to reflect deposition on the soil surface (2-dimensional) may also be used for estimating residues on potential undergrowth vegetation (3-dimensional structures above the soil surface). In fact, the data given in both the FOCUS groundwater report (FOCUS, 2000) as well as in the FOCUS surface water report (FOCUS, 2001) represent datasets originating from different sources, which comprise calculations based on the leaf area index (LAI) as well as experimental measurements of either soil deposition or plant interception (Ganzelmeier, 1997; van de Zande *et al.*, 1999; Becker *et al.*, 1999; Linders, 2000). Nevertheless, a remarkable agreement between results obtained according to different methods was pointed out in FOCUS (2001) as well as by Linders *et al.* (2000).

It was concluded that estimation of residues on undergrowth vegetation using FOCUS interception factors would become increasingly uncertain with decreasing soil cover of the crop and increasing height of weeds in relation to the crop. Thus, reliable predictions are only deemed possible where the

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largest part of the soil surface is actually covered by the crop from a bird's eye view and undergrowth vegetation is clearly smaller than the crop plants. Weeds or grasses overgrowing the crop at those stages are deemed unlikely to occur in intensive agriculture, but would anyway not form a part of the diet of small to medium herbivores. Nevertheless, cases like desiccation of aboveground plant parts before harvesting subterranean crops might require specific consideration in that regard.

For identification of relevant BBCH crop stages that fulfil these criteria, it can be assumed that most arable crops will be sown or planted in a density to achieve maximum overall cover of soil at a growth stage where crop plants have occupied their foreseen standing room. This is done to maximise yields per hectare and to suppress emergence of weeds competing for water, nutrients and light. As soon as this certain growth stage is reached, small weeds growing in the field will normally no longer be directly and fully exposed to pesticide sprays. In Table 1, proposals are given for crop-specific BBCH growth stages that would correspond to such sufficient soil coverage.

Based on this assessment of growth stages, the corresponding crop interception values as used in the FOCUS surface water report (FOCUS, 2001) for Step 2 PEC<sub>SW</sub> calculations can be considered acceptable also in the context of bird and mammal risk assessment. These figures differ from the values listed in the FOCUS groundwater report (FOCUS, 2000) insofar as the more recent data by Linders *et al.* (2000) were additionally used in the framework of a conservative approach at an early stage of a tiered scheme. Table 2, giving deposition factors for bird and mammal plant food items according to BBCH growth stages, is thus based on Table 2.4.2.-1 of FOCUS (2001). The deposition factors provided for the different crops and growth stages are likely to reflect conservative estimates. In the context of a higher-tier assessment, the more detailed values of the FOCUS groundwater report (FOCUS, 2000) may therefore also be used in line with the explanations provided by FOCUS (2005).



Crop name	Stage	Description	Rationale for selection
(arable crops only)	Suge	Description	(considering downward-directed
			treatments with boom sprayer)
Cereals	≥ 30	Stem elongation	Maximum of tillers reached at preceding stage BBCH 29 (subsequent growth mainly in vertical direction)
Maize	≥ <b>3</b> 0	Stem elongation	9 or more leaves unfolded at preceding stage BBCH 19 (subsequent growth mainly in vertical direction)
Oilseed rape	≥30	Stem elongation	9 or more side shoots detectable at preceding stage BBCH 29 (subsequent growth mainly in vertical direction)
Faba bean (Vicia faba)	≥ 51	Inflorescence emergence	9 or more visibly extended internodes at preceding stage BBCH 39**
Sunflower	≥ 30	Stem elongation	9 or more leaves unfolded at preceding stage BBCH 19 (subsequent growth mainly in vertical direction)
Beet	$\geq$ 40	Rosette growth (crop cover)	Leaves cover 90% of ground at stage BBCH 39
Potato	≥40	Tuber formation	Crop cover complete: about 90 % of plants meet between rows at preceding stage BBCH 39
Strawberry*	≥41	Development of stolons and young plants	9 or more leaves unfolded at preceding stage BBCH 19
Cotton	≥ 51	Inflorescence emergence	Canopy closure: 90 % of plants meet between rows at preceding stage BBCH 39
Bulb vegetables (e.g. onion)	≥ 41	Development of main harvestable vegetative plant parts	9 or more leaves clearly visible at preceding stage BBCH 19 (subsequent growth mainly of harvestable subsoil parts, flowering stage typically not reached in commercial cropping)
Root and stem vegetables (e.g. carrot)	≥41	Development of main harvestable vegetative plant parts	9 or more true leaves unfolded at preceding stage BBCH 19 (subsequent growth mainly of harvestable (subsoil) parts, followed by shoot elongation and flowering)
Leaf vegetables (forming heads)	≥ 51	Inflorescence emergence	Typical size, form and firmness of heads reached at preceding stage BBCH 49
Leaf vegetables (not forming heads)	≥ 51	Inflorescence emergence	Typical leaf mass reached at preceding stage BBCH 49
Other brassica vegetables	≥ 51	Inflorescence emergence	Typical size and form reached, head tightly closed at preceding stage BBCH 49
Cucurbits	≥ 51	Inflorescence emergence	Side shoots developed in preceding stage BBCH 29/231
Solanaceous fruit (e.g. tomato, pepper, egg plant) – if not grown on trellis	≥ 51	Inflorescence emergence	Side shoots developed in preceding stage BBCH 29/2NX
Pea – if not grown on trellis	≥ 51	Inflorescence emergence	9 or more visibly extended internodes in preceding stage BBCH 39**
Bean – if not grown on trellis ( <i>Phaseolus vulgaris</i> )	≥ 51	Inflorescence emergence	9 or more side shoots visible in preceding stage BBCH 29

Table 1.	BBCH growth stages	corresponding to high soil	coverage by crop plants.

\* The strawberry scenario is different from other arable fields, because the crop is typically grown in rows separated by broad bare soil strips, with either crop-directed treatments using 3-nozzle fork sprayer (fungicides, insecticides) or between-row treatments (herbicides).

\*\* If plants are not grown on trellis, stem elongation of the main shoot will affect soil coverage of the crop plants.



**Table 2.**Deposition factors for bird and mammal plant food items according to BBCH growth<br/>stages (derived from FOCUS, 2001).

Сгор	Relevant principal BBCH growth stages	Interception according to FOCUS (2001)	Deposition factor
Bare soils	not applicable	-	-
Bulb vegetables	$\geq 4$	0.4	0.6
Bush and cane fruit	$\geq 1$	0.4	0.6
(not tabulated, surrogate value	$\geq 2$	0.5	0.5
from vineyard)	$\geq$ 4	0.7	0.3
Cereals	$\geq$ 3	0.5	0.5
	$\geq$ 4	0.7	0.3
Cotton	$\geq$ 5	0.75	0.25
Fruiting vegetables	$\geq$ 5	0.7	0.3
Grassland	not applicable	-	-
Нор	$\geq 1$	0.2	not applicable**
1	$\geq 2$	0.5	0.5
	$\geq$ 4	0.7	0.3
Leafy vegetables	$\geq$ 5	0.7	0.3
Legume forage	$\geq$ 5	0.7	0.3
Maize	≥3	0.5	0.5
	$\geq$ 4	0.75	0.25
Oilseed rape	≥3	0.7	0.3
1	$\geq$ 4	0.75	0.25
Orchards	$\geq 1$	0.2	0.8
	$\geq 2$	0.4	0.6
	$\geq$ 4	0.7	0.3
Ornamentals/nursery (not tabulated, surrogate value from leafy vegetables)	≥5	0.7	0.3
Potatoes	$\geq 4$	0.7	0.3
Pulses	$\geq$ 5	0.7	0.3
Root and stem vegetables	$\geq 4$	0.7	0.3
Strawberries*	≥4	0.6 (value from FOCUS, 2000)	0.4
Sugar beet	$\geq$ 4	0.75	0.25
Sunflower	≥3	0.5	0.5
	$\geq$ 4	0.75	0.25
Vineyard	$\geq 1$	0.4	0.6
-	$\geq 2$	0.5	0.5
	$\geq$ 4	0.7	0.3

\* The strawberry scenario is different from other arable fields, because the crop is typically grown in rows separated by broad bare soil strips, with either crop-directed treatments using 3-nozzle fork sprayer (fungicides, insecticides) or between-row treatments (herbicides).

\*\* No consideration of interception for hops before side shoot formation, because it is cultivated like an arable crop at this early stage.



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<sup>&</sup>lt;sup>1</sup> Available at: <u>http://viso.ei.jrc.it/focus/</u>, 2 pp.



## **APPENDIX F**

## RESIDUES OF PLANT PROTECTION PRODUCTS ON FOOD ITEMS FOR BIRDS AND MAMMALS

After the publication of the first Guidance Document for birds and mammals (EC, 2002) and the  $RIVM^1$  fact sheet "Residues of plant protection products on food items" by Luttik (2001) several new studies have been carried out:

- a) Baril *et al.* (2005) updated the database of Fletcher *et al.* (1994), to examine the validity of extrapolating residue unit dose values (RUD) across application rates, and to improve the categorization of crops using crop morphology and cultivation methods,
- b) Several studies were carried out by the industry (ECPA) and the Central Science laboratory (CSL) to provide information for RUD values on insects,
- c) The ECPA<sup>2</sup> provided databases for residues on cereals and grass and on non-grass weeds (see Appendices 17 and 18 of EFSA, 2008).

Baril *et al.* (2005) provided new RUD values for the following food items: small fruits from orchards (like apricot, cherry, date fig, kiwi or plum), large fruit from orchards (like apple, lemon, mandarin, nectarine, orange, pear or peach), berries (like black currant, blueberry, grape or raspberry), tomatoes, gourds and grains/ear. But their categories for cereals and grass could not be used for the assessment of the risk for wild birds and mammals. In the risk assessment proposed in this document only the first growth stages of the grasses and cereals are eaten (up to BBCH<sup>3</sup> stage 30, see BBA, 2001<sup>4</sup>) and not the later stages.

In the proposed risk assessment it is not assumed that birds and mammals will eat large leaves, nor that the birds and mammals will eat at all from the crop. It is assumed that the animals will eat monocotyledonous and dicotyledonous weeds or young crop plants (if palatable) and that these weeds will be always present. The category non-grass herbs of the Baril et al. database (2005) does not meet these criteria either.

Therefore, it was necessary to collect data for these food categories. These data were provided by the industry (see Appendix 17 of EFSA, 2008 for the leafy residue database of the ECPA with 307 entries for non-grass "weeds" like alfalfa, lettuce, oil seed rape spinach and broccoli and sugar beets (young

<sup>&</sup>lt;sup>1</sup> National Institute for Public Health and the Environment

<sup>&</sup>lt;sup>2</sup> European Crop Protection Association

<sup>&</sup>lt;sup>3</sup> The abbreviation **BBCH** derives from **B**iologische **B**undesanstalt Bundessortenamt and **CH**emical industry.

<sup>&</sup>lt;sup>4</sup> Available at: <u>http://www.bba.de/veroeff/bbch/bbcheng.pdf</u>

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix F. EFSA Journal 2009; 7(12):1438. [4 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu



stages) and with 95 entries for grass and Appendix 18 of EFSA, 2008 for the cereal residue database of the ECPA with 1253 entries).

The residue data collected for the PSD<sup>5</sup> (UK) by CSL for arthropods was merged with the data collected by the ECPA and resulted in three different invertebrate categories: one for foliage dwelling invertebrates, one for ground dwelling invertebrates with interception (ground directed applications on top of crops for BBCH growth stage of 4 or greater) and one for ground dwelling invertebrates without interception (applications on bare soil, or ground directed applications up to BBCH growth stage 3, and ground directed applications in orchards/vines, e.g. herbicides).

CSL also carried out studies with over-sprayed aphids on plants. The results of these studies provided very high concentrations on the aphids. Although aphids are mentioned in the literature as food for several birds species, aphids are not a very important/relevant part of the diet for most of birds. For two of the insectivorous focal species in the crop scenarios (yellow wagtail and fan-tailed warbler), the "Handbuch der Vögel Mitteleuropas" does not mention aphids as food and for the willow warbler. The number of aphids compared to the total number of prey items can be as much as 15 %, but the proportion based on wet weight is low compared to the total weight of the food. Therefore, the aphid measurements have been omitted from the database, because it would, due to the numbers of measurements available, influence the outcome of the risk assessment.

Almost no data are available for RUDs on seeds (small seeds, weed seeds). As a result of this it is proposed still to use the RUD values that are mentioned in the first Guidance Document for birds and mammals (EC, 2002).

The resulting RUDs are presented in Table 1. Besides the mean, standard deviation and the number of values on which the RUD is based, also the  $50^{th}$  and  $90^{th}$  percentile of the RUD distributions are provided. This table only refers to food items that have been used for the screening step and/or for the first tier risk assessment.

In the screening step and first-tier risk assessment it is assumed that all seeds are small. For higher tier assessment the category large seeds can be introduced (in most cases lower residue values). It is not possible to define large and small seeds. This should be judged from a bird's or mammal's perspective. A linnet probably will not eat peas or maize, but these types of seeds could be part of the food of a partridge. Small mice like the wood mouse will rather eat large seeds than small ones.

<sup>&</sup>lt;sup>5</sup> Pesticide Safety Directorate final Report (PS2323), available on the Defra website under (<u>http://randd.defra.gov.uk</u>). Please note that PSD joined the Health and Safety Executive on 1<sup>st</sup> April 2008.



**Table 1.** RUD table for different food items that are needed for calculating the exposure in the screening step and first-tier assessment.

Crop/category of insects	Crop stage	mean	Standard deviation	90 <sup>th</sup> percentile <sup>7</sup>	n	Source
Grass+cereals	BBCH 10-30	54.2	55	102.3	132	ECPA database <sup>6</sup>
Non-grass weeds	Whole season	28.7	27.5	70.3	230	ECPA database <sup>6</sup>
Small fruits from orchards <sup>1</sup>	Fruiting period	3.3	2.6	6.5	33	Baril <i>et al.</i> (2005)
Large fruit from orchards <sup>2</sup>	Fruiting period	19.5	16.8	41.1	33	Baril <i>et al.</i> (2005)
Berries <sup>3</sup>	Fruiting period	8.3	7.2	16.7	9	Baril <i>et al.</i> (2005)
Tomato	Fruiting period	12.8	14.6	30.6	86	Baril <i>et al.</i> (2005)
Gourds	Fruiting period	34.3	54.7	61.5	19	Baril <i>et al.</i> (2005)
Grains/ear	Fruiting period	15	25.4	13.0	21	Baril <i>et al.</i> (2005)
Seeds	Fruiting period	40.2	50.6	87.0	108	EC (2002)
Ground dwelling invertebrates without interception <sup>4</sup>	ground directed applications	7.5	12.0	13.8	21	ECPA
Ground dwelling invertebrates with interception <sup>5</sup>	applications directed to crop canopies	3.5	3.8	9.7	28	ECPA & CSL
Insects (foliar dwelling invertebrates <sup>8</sup> )	Whole season	21.0	21.6	54.1	35	ECPA & CSL (aphids)

1 = e.g. apricot, cherry, date fig, kiwi and plum

2 = e.g. apple, lemon, mandarin, nectarine, orange, pear and peach

3 = e.g. black currant, blueberry, grape and raspberry

4 = applications on bare soil, or ground directed applications up to principle growth stage 3, ground directed applications in orchards/vines (e.g. herbicides)

5 = applications directed to crop canopies (orchards/vines), ground directed applications on top of crops with principle growth stage of 4 or greater

6 = See Appendices 17 and 18 of EFSA, 2008 for individual RUD values

- 7 =RUD values for 50<sup>th</sup> and 90<sup>th</sup> percentile for the Baril *et al.* (2005) data are derived from the original data collected by Baril *et al.*
- 8 = No data are available for canopy dwelling invertebrates in winter or before the leaves appear (interception would be less).

### Refinement of measured data for higher tier assessment

For each of the relevant categories of food presented in Table 1 or for a food item introduced in higher tier assessment additional measured residue data can be provided for a particular compound. Recommendations for carrying out residue field studies can be found in sections 6.1.4.1, 6.1.4.2 and Appendix N. It should be noted that it has to be fully justified why new measured residue data will override the existing residue values presented in Table 1, as several studies were used to generate these generic RUDs. Therefore, it is unlikely that one study will be appropriate to replace the generic RUD value.



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<sup>&</sup>lt;sup>6</sup> Available at: <u>http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc19\_en.pdf</u>



## APPENDIX G

## CALCULATING EXPOSURE FOR THE DIETARY INTAKE APPROACH

### Estimated dietary intake

The estimated daily exposure, i.e. the uptake of a compound via a single food item is given by the following equation:

$$ETE = \frac{FIR}{bw} \times C \times PT \quad [mg/kg \ bw/d]$$

In which:

ETE = Estimated theoretical exposure

FIR = Food intake rate of indicator species [g fresh weight /d]

bw = Body weight [g]

C = Concentration of compound in fresh diet [mg/kg]

PT = Fraction of diet obtained in treated area (number between 0 and 1)

The concentration C will either be directly available (e.g. for treated seeds) or can be calculated using residue unit doses (RUD) for the relevant food items (see Appendix F).

If a mixed diet has to be considered, the ETE is calculated as the sum of ETEs for all food items. However, it is necessary to adjust the individual food intake rates for each food item [i] to account for its actual contribution to the daily energy expenditure (DEE) of the indicator species. This is described in more detail further below.

$$ETE = \frac{1}{bw} \times \sum_{i} (FIR_{i, fresh} \times C_i \times PT) \quad [mg/kg \ bw/d]$$

In which:

 $FIR_{i,fresh} =$ Food intake rate of food item [i] in mixed diet [g fresh weight/d] $C_i =$ Concentration of compound in food item [i] in fresh diet [mg/kg]

In case of multiple applications, it is necessary to apply a multiple application factor (MAF) to the concentration C. Further details are given in Appendix H.

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### Food intake rate (FIR)

The estimates of food intake are based on means of daily energy expenditure for free-ranging animals, energy and moisture content and assimilation efficiencies. The FIR can be calculated as follows:

FIR = 
$$\left(\frac{\text{DEE}}{\text{FE}*\left(1-\frac{\text{MC}}{100}\right)*\left(\frac{\text{AE}}{100}\right)}\right)$$
 [g fresh weight/d]

In which:

DEE = Daily energy expenditure of the indicator species [kJ/d]

- FE = Food energy [kJ/dry g]
- MC = Moisture content [%]
- AE = Assimilation efficiency [%]

## Daily energy expenditure (DEE)

Data for the DEE are derived from a research project carried out for DEFRA<sup>1</sup> (Anonymous, 2007). Relationship between body weight (bw in g) and daily energy expenditure (DEE in kJ) can be described by the equation:

 $\log DEE = \log a + b \times \log bw$ 

To obtain the specific equation for the relevant species group the respective log a and b from Table 2 have to be inserted.

**Table 2.** Species groups, log a and b, the standard errors for a and b (SE), the number of species in<br/>each group (N), and the proportion of variation explained by each equation  $(r^2)$ .

Species group	log a	SE log a	b	SE b	Ν	r <sup>2</sup>
Non passerines	0.839	0.161	0.669	0.063	18	0.87
Passerines <sup>(*)</sup>	1.032	0.058	0.676	0.045	44	0.84
Mammals <sup>(*)</sup>	0.814	0.046	0.715	0.019	46	0.97

<sup>(\*)</sup> = excluding desert passerines or desert and marine eutherians.

### Energy and moisture content of food items

The energy and moisture content presented in Table 3 are from Smit (2005), see also Appendix L. These are the values used for calculating the FIR for the scenarios defined for the species of concern (indicator species and generic focal species) of Tier 1. For higher tier assessments it is sometimes necessary to include other food categories. Data energy and moisture content for these food items can be found in Smit (2005), Buxton *et al.* (1998) and Crocker *et al.* (2002).

<sup>&</sup>lt;sup>1</sup> Department for Environment, Food and Rural Affairs



Food items	kJ/g dry	Moisture [%]
Grasses and cereal shoots	17.6	76.4
Non-grass herbs	17.8	88.1
Cereal seeds	18.4	14.7
Weed seeds	21.7	9.9
Fruit	14.8	83.9
Arthropods (including caterpillars)	22.7	68.8
Soil invertebrates	19.4	84.3
Fish	21.0	73.7
Aquatic invertebrates	20.9	76.3
Aquatic vegetation	15.0	81.4

#### **Table 3.**Different food items, their energy content [kJ/g dry] and moisture content [%].

### Assimilation efficiency

Assimilation efficiencies for birds are from Bairlein (1998), the assimilation efficiencies for mammals are from Crocker *et al.* (2002) and Smit (2005). For higher tier assessments it is sometimes necessary to include other food categories. Data for some food items can also be found in these three references (see also Appendix L).

Assimilation efficiency of different food items	Mammal	Passerine	Duck & geese	Pigeon	Fowl
Grasses and cereal shoots	0.47	0.76	0.41	n.a.	0.42
Non-grass herbs	0.76	0.76	0.41	0.53 <sup>b</sup>	0.42
Cereal seeds	0.84	0.80	0.83	n.a.	0.65
Weed seeds	0.84	0.80	0.83	0.76 <sup>a</sup>	0.65
Fruit	0.74	0.67	n.a.	n.a.	0.57
Arthropods (including caterpillars)	0.87	0.76	0.87	n.a.	0.70
Soil invertebrates	0.87	0.76	0.87	n.a.	0.70
Fish	0.87	0.76	0.87	n.a.	0.70
Aquatic invertebrates	0.87	0.76	0.87	n.a.	0.70
Aquatic vegetation	0.76	0.76	0.41	n.a.	0.42

**Table 4.** Assimilation efficiency of different food items for mammals and different bird species.

<sup>(a)</sup> = No data available for pigeons, the value for seeds is the average of 3 data (83% for duck/geese + 65% for fowl + 80% for passerines).

(b) = No data available for pigeons, the value for the assimilation efficiency of herbage is the average of 6 data (36% for ostriches, 59% for cranes/coots/rails, 41% for ducks/geese, 42% for fowl, 61% for woodpeckers and 76% for passerines).

It should be noted that all of the above data on moisture content and calorific content have been used to determine food intake rates for indicator species as well as generic focal species.



### **Consideration of mixed diets**

If a mixed diet must be considered, the food intake rate for food items is not simply achieved by applying the respective fraction as a factor to the respective FIR for a "pure" diet. Instead, the FIR has to be adjusted to reflect the actual contribution of each food item to the daily energy expenditure (DEE) of the indicator species.

Considering the fractions (PD<sub>*i*</sub>) of individual food items in a mixed diet together with data on their respective moisture (where relevant) and energy content, the specific energy content of the mixed diet is calculated (Step 1). This value is used to estimate the required amount of the mixed diet to satisfy the daily energy expenditure (DEE) of a bird or mammal (Step 2). In Step 3, individual food intake rates (FIR) for each food item are calculated using again the PD<sub>*i*</sub> values and the overall estimated theoretical exposure (ETE) is derived.

Based on a given diet composition, the specific available energy content (here related to 1 g for practical reasons) of the mixed diet is calculated, taking into account the respective specific energy contents of the food items (corrected for assimilation efficiency) according to their fractions in the diet. If the diet composition is given in terms of dry weight, the corresponding specific total diet energy content is thus calculated according to the following formula:

$$FE_{total,dry} = \sum_{i} \left( PD_{i,dry} \times FE_{i} \times \frac{AE_{i}}{100} \right)$$

In which:

$FE_{total,dry} =$	Food energy of total mixed diet [kJ/g dry weight]
$PD_{i,dry} =$	Fraction of food item [i] in mixed diet [related to dry weight]
$FE_i =$	Food energy of food item $[i]$ in mixed diet $[kJ/dry g]$
$AE_i =$	Assimilation efficiency of food item [i] in mixed diet [%]

If the diet composition is given in terms of fresh weight, a respective additional correction factor has to be considered in the formula:

$$\text{FE}_{total, fresh} = \sum_{i} \left[ \text{PD}_{i, fresh} \times \text{FE}_{i} \times \left( 1 - \frac{\text{MC}_{i}}{100} \right) \times \frac{\text{AE}_{i}}{100} \right]$$

In which:

$FIR_{total, fresh} =$	Food intake rate of total mixed diet [kJ/g fresh weight]
$PD_{i,fresh} =$	Fraction of food item [ <i>i</i> ] in mixed diet [related to fresh weight]
$MC_i =$	Moisture content of food item [ <i>i</i> ] in mixed diet [%]

Using the calculated specific energy content of the mixed diet,  $FIR_{tota}$ , the required amount of the mixed diet to reach the DEE of the indicator species can be determined.

$$FIR_{total,dry} = \frac{DEE}{FE_{total,dry}} \qquad \text{or} \qquad FIR_{total,fresh} = \frac{DEE}{FE_{total,fresh}}$$

To be compliant to the available residue data, the ETE equation makes use of fresh weight data. So, in case,  $PD_i$  and  $FIR_{total}$  are given in terms of fresh weight, the actual  $FIR_i$  for one food item [i] in the



mixed diet is achieved by multiplying  $FIR_{total}$  by the fraction for the respective food item and the ETE is calculated as follows.

$$ETE = \frac{1}{bw} \times \sum_{i} \left( PD_{i, fresh} \times FIR_{total, fresh} \times C_{i} \right)$$
$$= \frac{1}{bw} \times \sum_{i} \left( FIR_{i, fresh} \times C_{i} \right)$$

In which:

$FIR_{i,fresh} =$	Food intake rate of food item [ <i>i</i> ] in mixed diet [g fresh weight/d]
bw =	Body weight of indicator species
$C_i =$	Concentration of active substance in food item [i] [mg/kg]

Whereas, when  $PD_i$  and  $FIR_{total}$  are given in terms of dry weight, recalculation of the actual  $FIR_i$  values according to the moisture content of food items is required:

$$\begin{aligned} \text{ETE} &= \frac{1}{\text{bw}} \times \sum_{i} \left( \text{PD}_{i,dry} \times \text{FIR}_{total,dry} \times \frac{1}{\text{MC}_{i}} \times \text{C}_{i} \right) \\ &= \frac{1}{\text{bw}} \times \sum_{i} \left( \text{FIR}_{i,fresh} \times \text{C}_{i} \right) \end{aligned}$$

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## **APPENDIX H**

## MULTIPLE APPLICATIONS AND RESIDUE DYNAMICS IN THE ENVIRONMENT

## Background and general assessment scheme

This Appendix outlines how to determine multiple application factors (MAFs) as well as time-weighted averages (TWAs). It is proposed to use multiple application factors if there is more than one application, and a moving time window approach in determining time weighted average concentrations. It is generally assumed in this document that residue dynamics follow first-order kinetics. All calculations are therefore based on the integrated form of respective basic equation:

$$\mathbf{C} = \mathbf{C}_0 \times e^{-kt}$$

With:

C = actual concentration at time *t* 

 $C_0 =$  initial concentration

k = rate constant where  $k = \ln 2/DT_{50}$ 

Multiple applications of a compound may cause a build-up of residue levels and must be taken into account in the exposure assessment for the estimated theoretical exposure (ETE) equation. As long as only peak concentrations are considered in the risk assessment, residue dynamics can be expressed by a multiple application factor (MAF). The MAF is a function of the number of applications, application interval, and decline of residues, typically expressed as a  $DT_{50}$  assuming first order kinetics (single first order, SFO-DT<sub>50</sub>). Equations are presented for calculation of a MAF<sub>m</sub> for average residue levels and of a MAF<sub>90</sub> for 90<sup>th</sup> percentile residue levels.

It is assumed that certain effects observed in reproductive toxicity testing with constant dietary exposure are not triggered by exposure to a single peak concentration but require a longer exposure period of more than one day. In contrast, residue unit dose (RUD) values for residue levels in food items reflect the height of the exposure peak directly after application. Using the assumption of residue dissipation via first order kinetics, it is possible to calculate time-weighted average factors (TWA) that translate residue decline following peak exposure into a constant exposure concentration over a chosen time interval. Care must be taken when estimating TWA exposure in cases where multiple applications occur in short sequence. Simple multiplication of MAF<sub>m</sub> and TWA would reflect a scenario where the averaging period starts after the final application peak. However, depending on number of applications, application intervals and active substance  $DT_{50}$ , also TWA intervals starting already before the last application might give the worst-case MAF<sub>m</sub> × TWA factor. Therefore an assessment using a moving time window is necessary to identify the appropriate MAF<sub>m</sub> × TWA factor for the risk assessment.

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## Multiple application factor for average residue levels (MAF<sub>m</sub>)

In the calculation of the MAF, the build-up of residues on food items is expressed by the number of applications (n). A MAF<sub>m</sub> factor for use with average RUD data is calculated using the following equation.

$$\mathrm{MAF}_{\mathrm{m}} = \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

With:

k = $\ln(2)/\mathrm{DT}_{50}$  (rate constant)n =number of applicationsi =application interval (d)

By forming the limit value lim  $n \to \infty$  of the equation above, the term  $e^{-nki}$  becomes zero and a "plateau" MAF<sub>m</sub> for an infinite number of applications can be calculated.

Table 1.	$MAF_m$ for mean residue data for selected application intervals and $n = 1-8$ applications
	(considering a default $DT_{50}$ of 10 d on foliage).

Application interval (d)	MAF <sub>m</sub> for mean residue data for <i>n</i> applications								
	1	2	3	4	5	6	7	8	$\infty$
7	1.0	1.6	2.0	2.2	2.4	2.5	2.5	2.5	2.6
10	1.0	1.5	1.8	1.9	1.9	2.0	2.0	2.0	2.0
14	1.0	1.4	1.5	1.6	1.6	1.6	1.6	1.6	1.6

 $MAF_m$  values for other application intervals can be either calculated using the above formula or the values for the next lower application interval should be used. For higher number of applications with one of the tabulated intervals, the limit value in the rightmost column should be used.

# Multiple application factor for 90<sup>th</sup> percentile residue levels (MAF<sub>90</sub>)

In the calculation of  $MAF_{90}$  values to be used in an exposure scenario with 90<sup>th</sup> percentile RUDs, it must be considered that not each single application event but the total residue after the last application should represent a 90<sup>th</sup> percentile. In principle, this can be achieved by modifying the MAF<sub>m</sub> for the mean RUD values with a correction term, which also considers the variance of the RUD dataset and a respective MAF<sub>var</sub>. When assuming normally distributed residue data, an analytical solution is possible:

$$MAF_{90} = \frac{MAF_{m} \times RUD_{m} + f_{90} \times \sqrt{MAF_{var} \times \sigma^{2}}}{RUD_{90}}$$

With:

$$MAF_{m} = \frac{1 - e^{-nki}}{1 - e^{-ki}}$$
$$MAF_{var} = \frac{1 - e^{-2nki}}{1 - e^{-2ki}}$$



$f_{90} =$	1.28 (90 <sup>th</sup> percentile for standard normal distribution)
k =	$ln(2)/DT_{50}$ (rate constant)
<i>n</i> =	number of applications
<i>i</i> =	application interval (d)
$RUD_m =$	average RUD value
$RUD_{90} =$	90 <sup>th</sup> percentile RUD value
$\sigma^2 =$	variance of RUD dataset

However, from a fundamental viewpoint, the assumption of normal distribution for RUD values could be challenged, because residue concentrations below zero cannot occur. It was previously generally assumed that RUDs would follow a log-normal distribution, but on closer analysis, the best fit seems to be achieved to a gamma distribution. The fit to log-normal distribution is only slightly, if at all, better than to normal distribution. Visual inspection of plotted normal and log-normal distribution curves versus. the underlying measured data did not suggest superiority of one approach over the other, particularly with regard to mean and 90<sup>th</sup> percentile values. However, both gamma and log-normal distribution share the disadvantage that more complex terms are required to describe variance and specific percentiles than for the normal distribution. This is demonstrated below for the log-normal distribution.

$$\sigma_{\rm lognorm}^2 = \ln \left( \frac{\sigma_{\rm norm}^2}{\mu_{\rm norm}^2} + 1 \right)$$

 $f_{90,\text{lognorm}} = \exp(\mu_{\text{lognorm}} + \sigma_{\text{lognorm}} \times f_{90,\text{norm}})$ 

With:

$\sigma^2_{\text{lognorm}} =$	variance of RUD dataset for lognormal distribution
$\sigma^2_{\text{norm}} =$	variance of RUD dataset for normal distribution
$\mu_{\text{lognorm}} =$	mean of RUD dataset for lognormal distribution
$\mu_{\rm norm} =$	mean of RUD dataset for normal distribution
$f_{90,lognorm} =$	90 <sup>th</sup> percentile for lognormal distribution
$f_{90,\text{norm}} =$	1.28 (90 <sup>th</sup> percentile for standard normal distribution)

When both terms are inserted in the equation above, rearrangement of the variables to produce a generic analytical solution is no longer possible. The tabulated  $MAF_{90}$  values for the acute risk assessment in the former Guidance Document (EC, 2002) were hence obtained from a Monte Carlo simulation based on log-transformed mean and standard deviation figures. As a consequence of this complex determination of the MAF<sub>90</sub>, no option for refining these values using experimentally determined DT<sub>50</sub> values could be offered.

To provide a feasible solution, the two most relevant RUD data sets "grass + cereals" and "non-grass herbs" produced for this Guidance Document were analysed more closely. In addition, an adjusted version of the data set "grass + cereals" (elimination of one very large value as an outlier, resulting in a significantly better fit) was also considered. The differences between lognormal and normal 90<sup>th</sup> percentile RUDs, respectively, were in the range of 10 % or below in all cases, with higher values for the 90<sup>th</sup> percentile RUDs from the normal distribution. As already mentioned, visual inspection of distribution curves and plotted individual data points showed good agreement in the upper percentile range. Before that background, using approximate MAF<sub>90</sub> values based on the assumption of normally distributed RUD data is considered acceptable. As stated, analysis of the data was focussed on the three categories "grass + cereals" (n = 132), "grass + cereals (adjusted)" (n = 131) and "non-grass herbs" (n = 230) with the highest number of data points and greatest relevance for the standard risk assessment. The MAF<sub>90</sub> values obtained for the category "grass + cereals (adjusted)" turned out to be slightly higher than for "grass + cereals" and "non-grass herbs" as well as for all other data sets. Moreover, they match



remarkably well with the Monte-Carlo modelled figures from the preceding Guidance Document (EC, 2002) and should thus be used for standard as well as refined risk assessments.

$RUD_m =$	50.5 (average RUD value from fitted normal distribution)
RUD <sub>90</sub> =	95.0 (90 <sup>th</sup> percentile RUD value from fitted normal distribution)
$\sigma^2 =$	1206.9 (variance of RUD dataset from fitted normal distribution)

The following table gives the results of the calculation for the default  $DT_{50}$  of 10 days. In the same way as for the MAF<sub>m</sub>, a "plateau" MAF<sub>90</sub> for an infinite number of applications can be calculated by forming the limit value lim  $n \rightarrow \infty$  of the equation above (the terms  $e^{-nki}$  and  $e^{-nki}$  in the sub-equations for MAF<sub>m</sub> and MAF<sub>var</sub> both become zero).

**Table 2.** MAF<sub>90</sub> for 90<sup>th</sup> percentile residue data for selected application intervals and n = 1-8 applications (considering a default DT<sub>50</sub> of 10 d on foliage).

Application interval (d)		<b>MAF</b> <sub>m</sub> for mean residue data for <i>n</i> applications							
	1	2	3	4	5	6	7	8	$\infty$
7	1.0	1.4	1.6	1.8	1.9	1.9	1.9	1.9	2.0
10	1.0	1.3	1.5	1.5	1.6	1.6	1.6	1.6	1.6
14	1.0	1.2	1.3	1.3	1.4	1.4	1.4	1.4	1.4

 $MAF_{90}$  values for other application intervals can be either calculated using the formula above with the input parameters for "grass + cereals (adjusted)" or the values for the next lower application interval should be used. For higher number of applications with one of the tabulated intervals, the limit value in the rightmost column should be used.

Refinement of both  $MAF_{90}$  and  $MAF_m$  is possible if experimental values for the  $DT_{50}$  are available. These may be inserted in the respective equations to obtain MAF values for specific risk assessments.

The MAF concept is a generic scheme intended to represent the effect of substance degradation in the ETE model. Thus, using distribution data for other food categories in a refined risk assessment is considered not meaningful. Fairly consistent results for  $MAF_{90}$  were obtained for all analysed data sets, so the numerical worst case "grass and cereals (adjusted)" based on 131 independent measurements is deemed to provide a reliable basis for bird and mammal risk assessments.

## Time-weighted average factor (TWA) in connection with a single exposure peak

If no multiple applications have to be considered, a TWA factor is calculated using the following equation:

$$TWA = \frac{1 - e^{-ki}}{ki}$$

With:

 $k = \ln(2)/\mathrm{DT}_{50}$  (rate constant)

*i* = averaging interval



## Combination of MAF<sub>m</sub> and TWA for several applications

A MAF<sub>m</sub> × TWA factor for the time period *i* after the  $n^{\text{th}}$  application can be described by a simple equation that is, however, only valid if the  $n^{\text{th}}$  is the last application or if the averaging interval is shorter than the application interval between the  $n^{\text{th}}$  and the  $(n + 1)^{\text{th}}$  application:

$$MAF_m \times TWA = \frac{1 - e^{-nki}}{ki}$$

With:

 $k = \frac{\ln(2)}{DT_{50}} \text{ (rate constant)}$  n = number of applicationsi = TWA interval

If the averaging interval covers several applications from the first to the  $n^{\text{th}}$  application and ends directly before the  $(n + 1)^{\text{th}}$  application (i.e. is a multiple of the application interval), the equation has to be expanded. Basically, MAF<sub>m</sub> × TWA factors are calculated after each application event and are then averaged.

$$MAF_{m} \times TWA = \frac{1}{n} \times \sum_{n} \frac{1 - e^{-nki}}{ki}$$

However, if the TWA interval is no multiple of the application interval, which is most often the case, a weighted average of the individual  $MAF_m \times TWA$  factors after each application must be calculated, considering their different contributions to the overall MAF  $\times$  TWA factor. No generic equation is given for that. However, in practice, Excel-type spreadsheets or computer programs are available for such calculations. By varying the start of the time window in the spreadsheet or computer program, the highest MAF<sub>m</sub>  $\times$  TWA must be identified and used in the risk assessment.

## Use of MAF<sub>m</sub>, TWA and MAF<sub>m</sub> × TWA

The following figures intended to illustrate the use of  $MAF_m$ , TWA and  $MAF_m \times TWA$  in the exposure assessment for calculating an ETE. Please note that the time periods selected for those examples do not imply any statement on appropriate TWA intervals in an assessment of reproductive toxicity.

All calculations of  $MAF_m$ , TWA and  $MAF_m \times TWA$  are based on the same concept as they apply the basic equation for first-order kinetics in its integrated form.

$$\mathbf{C} = \mathbf{C}_0 \times e^{-kt}$$

With:

C = actual concentration at time *t* 

 $C_0 =$  initial concentration

k = rate constant where  $k = \ln 2/DT_{50}$ 



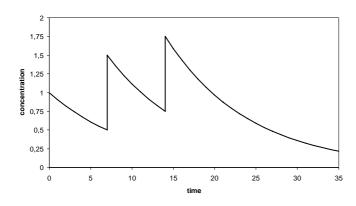


Figure 1. Time course of residues after three applications of a compound.

In the calculation of the MAF, the build-up of residues on food items is expressed by the number of applications (*n*). Their subsequent fate is described by a 1<sup>st</sup>-order kinetics model where the dissipation rate is dependent on the time interval after peak exposure but independent of the initial concentration. A MAF<sub>m</sub> factor for use with average RUD data can be easily calculated using the following equation.

$$\mathrm{MAF}_{\mathrm{m}} = \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

With:

 $k = \ln(2)/DT_{50} \text{ (rate constant)}$  n = number of applicationsi = application interval (d)

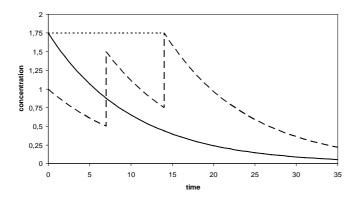


Figure 2. Expression of residue build-up by a MAF<sub>m</sub>.

As mentioned before, it is assumed that certain effects observed in reproductive toxicity testing with constant dietary exposure are not triggered by exposure to a single peak concentration but require a longer exposure period of more than one day. In contrast, RUD values for residue levels in food items reflect the height of the exposure peak directly after application. Using the assumption of residue dissipation via first order kinetics, it is possible to calculate time-weighted average factors (TWA) that translate residue decline following peak exposure into a constant exposure concentration over a chosen time interval. As long as no multiple applications must be considered, such a TWA factor can be easily calculated using the following equation.



$$TWA = \frac{1 - e^{-ki}}{ki}$$

With:

 $k = \ln(2)/DT_{50}$  (rate constant) i = averaging interval

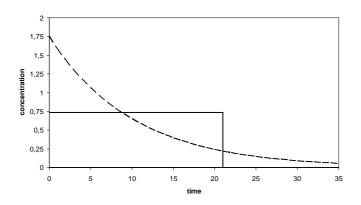


Figure 3. Translation of dissipation after peak exposure into constant TWA exposure.

Care must be taken when estimating TWA exposure in cases where multiple applications occur in short sequence. Simple multiplication of  $MAF_m$  and TWA would reflect a scenario where the averaging period starts after the final application peak. However, depending on number of applications, application intervals and active substance  $DT_{50}$ , also TWA intervals starting already before the last application might give the worst-case  $MAF_m \times TWA$  factor. Therefore an assessment using a moving time window is necessary to identify the appropriate  $MAF_m \times TWA$  factor for the risk assessment. Thus, a time window comprising two or more application events must be used. If the averaging interval covers several applications from the first to the  $n^{th}$  application and ends directly before the  $(n + 1)^{th}$  application (i.e. is a multiple of the application interval), the equation has to be expanded. Basically,  $MAF_m \times TWA$  factors are calculated after each application event and then averaged.

$$MAF_{m} \times TWA = \frac{1}{n} \times \sum_{n} \frac{1 - e^{-nki}}{ki}$$

However, if the TWA interval is no multiple of the application interval, which is most often the case, a weighted average of the individual  $MAF_m \times TWA$  factors after each application must be calculated, considering their different contributions to the overall MAF  $\times$  TWA factor. No generic equation is given for that. However, in practice, Excel-type spreadsheets or computer programs are available for such calculations. By varying the start of the time window in the spreadsheet or computer program, the highest MAF<sub>m</sub>  $\times$  TWA must be identified and used in the risk assessment.



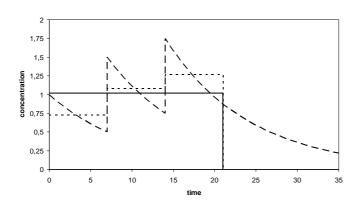
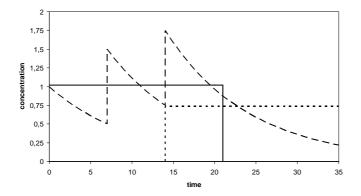


Figure 4. Combining  $MAF_m$  and several TWA exposure concentrations into an overall  $MAF_m \times TWA$  factor.



**Figure 5.** Appropriate selection of time window for  $MAF_m \times TWA$  factor.

# Background for the selection of a pseudo- $DT_{50}$ of 10 d for describing residue dynamics in arthropod food items

To enable the calculation of daily dietary doses at the Tier-1 level for insectivorous and mixed diets of generic focal species, it is proposed to apply the same methodology to arthropod food items as for food items of plant origin, i.e. multiple application (MAF) and time-weighted average (TWA) factors based on a first-order pseudo- $DT_{50}$  of 10 d for residue decline. Residue decline over time will occur on arthropods and in certain circumstances accumulation will occur. Outlined below is the rationale behind the selection of the  $DT_{50}$  and associated MAF and TWA factors. It should be noted that this approach does not imply that respective residue dynamics are most appropriately described by first-order degradation kinetics. Instead, the factors should be understood as generic descriptors for the possible extent of residue decline and accumulation, which can and should be refined by more appropriate data when these are available.

In order to check the appropriateness of using a first-order pseudo- $DT_{50}$  of 10 d for describing residue decline in arthropod food items, the time course of residues as reported in 90 datasets from field trials conducted by industry was analysed. These data comprise measured residues of insecticides, fungicides and herbicides on the three strata ground-dwelling, leaf-dwelling and flying insects during intervals of 0 to 7 days after spray application. For various reasons (insufficient sample mass, non-representative sample composition, etc.), nine datasets were excluded from quantitative assessment.

First inspection of the data revealed that in about 50 % of the cases, highest residues did not occur on the day of application, but up to 7 days later. This is probably due to the uptake of residues by arthropods from contaminated soil and plant surfaces and confirms, in principle, the more complex nature of residue dynamics on arthropod food items as compared to plant food items. Therefore, a twofold approach was followed for quantitative analysis of the data.

In one approach, average normalised residue concentrations per sampling date for all categories (n = 81), for ground and leaf dwellers (n = 70), for ground dwellers alone (n = 39) and for leaf dwellers alone (n = 31) were assessed according to the methodology of FOCUS degradation kinetics (FOCUS, 2006). Using a non-linear regression method, single first order (SFO) kinetics and the biphasic first-order multiple-compartment (FOMC) model were fitted to the data.

	n		SFO	)	FOMC			
Category		DT <sub>50</sub>	DT <sub>90</sub>	χ2 (5 % err. lvl.)	DT <sub>50</sub>	DT <sub>90</sub>	χ2 (5 % err. lvl.)	
All	81	2.1	6.8	24.1	0.9	23.4	15.3	
Ground and leaf dwellers	70	2.1	6.9	25.6	0.8	27.0	16.6	
Ground dwellers	39	3.5	11.7	19.5	1.6	173.8	14.4	
Leaf dwellers	31	2.6	8.5	23.0	1.1	94.5	14.8	

**Table 3:** Fitting of kinetical models to residues on arthropods

As visible from the  $\chi^2$  values, only poor fits were achieved for SFO kinetics, whereas the FOMC model yielded slightly better fits for all categories. Thus, assessment should be focused on FOMC DT<sub>90</sub> values, which can be used to derive conservative estimates for surrogate first-order DT<sub>50</sub> values (needed for MAF and TWA estimation) by division by (ln 10/ln 2) = 3.32. It is obvious from the data that exclusion of the category flying insects did not have a great impact on the results, whereas splitting the datasets between ground- and leaf-dwelling arthropods resulted in much higher DT<sub>90</sub> values than for the aggregated data. However, taking into account the knowledge on mechanisms that will drive residue decline in arthropod food items, these extremely high DT<sub>90</sub> values for the split datasets are considered not reliable. Hence, surrogate first-order DT<sub>50</sub> values according to this kinetical assessment will amount to about 7.0 to 8.1 d.

Following the second approach, a simple comparison was made between the highest residue levels in the 0-7 d interval ( $c_{max}$ ) and the last measured value ( $c_{final}$ ). Trials with only one measurement and trials where the maximum residue level occurred at the final sampling date were excluded. Using the quotient  $c_{final}/c_{max}$  and the time interval *t* between the two corresponding sampling dates, an estimate DT<sub>50</sub> can be calculated according to the following equation.

$$DT_{50} = -\frac{t \times \ln 2}{\ln \frac{c_{\text{final}}}{c_{\text{max}}}}$$

This type of calculation was performed for all categories using the average, the median and the 90<sup>th</sup> percentile of  $c_{\text{final}}/c_{\text{max}}$  and *t*, respectively.



	average			median			90 <sup>th</sup> %-ile		
Category	c <sub>final</sub> / c <sub>max</sub>	t	DT <sub>50</sub>	c <sub>final</sub> / c <sub>max</sub>	t	DT <sub>50</sub>	c <sub>final</sub> / c <sub>max</sub>	t	DT <sub>50</sub>
All	0.30	5.10	2.9	0.22	5	2.3	0.61	7	9.9
Ground and leaf dwellers	0.32	5.04	3.1	0.26	5	2.6	0.61	7	9.9
Ground dwellers	0.35	5.07	3.4	0.31	5.5	3.2	0.63	7	10.3
Leaf dwellers	0.28	5.00	2.7	0.20	4.5	1.9	0.61	7	9.9

**Table 4:** DT<sub>50</sub> estimates based on the ratio of maximum and final measured residues on arthropods

No significant differences are visible between the four categories. The results for average and median parameters are well in line with the SFO-DT<sub>50</sub> according to the kinetical analysis of average RUDs, while the results for 90<sup>th</sup> percentile parameters are in the same range (numerically slightly above) as the relevant surrogate first-order DT<sub>50</sub> values derived from FOMC-DT<sub>90</sub> values.

Overall, it can be concluded that a first-order pseudo- $DT_{50}$  of 10 d constitutes an appropriate basis for estimating MAF and TWA factors for arthropod food items in the context of a Tier 1 exposure assessment for generic focal species.

# Consequences of using MAF and TWA for arthropod food items and important aspects to consider for refinements

Exposure calculations for insectivorous birds or mammals according to EC (2002) were based on the assumption that each treatment in a multi-application scenario could be considered an independent event with respect to residues on arthropod food items. No accumulation of residues (i.e. no MAF) and no residue decline (i.e. no TWA) were considered. This will result in a higher level of protection for single-application scenarios (potential overestimation of exposure due to non-consideration of residue decline) than for multiple-application scenarios (potential underestimation of exposure due to non-consideration of potential for accumulation of residues).

Consequently, inclusion of MAF and TWA in exposure calculations will have different impacts on the scenarios with single and multiple applications compared to previous assessments carried out under EC (2002). As regards calculated peak exposure levels, these will not change compared to previous assessments for single applications, but will be higher due to the use of a MAF factor for multiple applications. If time-weighted averaging is considered, the actual factor by which calculated exposure will be lower or higher as compared to EC (2002) will depend on the number of applications, the interval between applications and the relevant TWA interval. An overview for four typical scenarios is provided in Table 5.

It should be kept in mind that using the default pseudo- $DT_{50}$  of 10 d for Tier 1 calculations does not imply that respective residue dynamics are most appropriately described by first-order degradation kinetics. Instead, the factors should be understood as generic descriptors for the possible extent of residue accumulation and decline. If refinement is intended, attempts should be made to realistically describe the expected time course of residues under conditions of use (see Appendix N for further information on how to carry out a residue study).



TWA- inter- val	1 applic.	2 appli	ic., interval 14 d	3 appli	ic., interval 10 d	5 applic., interval 7 d		
	TWA only	MAF <sub>90</sub>	MAF <sub>m</sub> × TWA (start of interval)	MAF <sub>90</sub>	MAF <sub>m</sub> × TWA (start of interval)	MAF90	MAF <sub>m</sub> × TWA (start of interval)	
2	0.934		1.288 (d 14)		1.634 (d 20)		2.214 (d 28)	
3	0.903		1.245 (d 14)		1.580 (d 20)		2.141 (d 28)	
10	0.721	1.234	0.995 (d 14)	1.467	1.262 (d 20)	1.852	1.878 (d 21)	
21	0.527		0.791 (d 0)		1.157 (d 10)		1.741 (d 14)	
28	0.441		0.761 (d 0)		1.029 (d 10)		1.626 (d 7)	
60	0.237		0.467 (d 0)		0.695 (d 0)		1.140 (d 0)	
90	0.160		0.319 (d 0)		0.479 (d 0)		0.796 (d 0)	

Table 5:Modification of calculated exposure as compared to EC (2002), due to consideration of<br/>MAF and TWA, for a default  $DT_{50}$  of 10 d.

For example, if a multi-application scenario is appropriately reflected in a test, then both the  $MAF_{90}$  (highest peak measured) and  $MAF_m \times TWA$  (area under residue versus. time curve) could be replaced with 'real' data. Another option could be to justify with data that multiple applications can be treated as single individual events, due to fast and quantitative decline of residue levels after each application. In case of broad-spectrum insecticides, the lethal effect on in-field arthropods might contribute to such fast decline.

However, any argumentation must account for aspects like the potential of residue increase in arthropod after application due to uptake from contaminated surfaces. Thus, refinement should not aim at simply replacing the default pseudo- $DT_{50}$  of 10 d by a different value, but should always include a detailed justification for the appropriateness of this value as discussed above in the explanation for the default pseudo- $DT_{50}$ .

## References

- FOCUS (Forum for the Co-ordination of pesticide fate models and their use), 2006. Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.
- EC (European Commission DG Health and Consumer Protection), 2002. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000 final 25 September 2002, pp 74.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Available at: <u>http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc19\_en.pdf</u>



## APPENDIX J

## PHASE-SPECIFIC APPROACH FOR REPRODUCTIVE RISK ASSESSMENT

This Appendix provides detailed information regarding the phase-specific approach for reproductive risk assessment for birds and mammals. The phase-specific approach was proposed by EFSA (2008) for use in first-tier assessments, but a Joint Working Group of representatives from DG Health and Consumers and nominated Member States (assisted by technical experts from EFSA) decided that it should instead be introduced as an option for use at higher tiers (EC, 2009). A detailed account of the reasons for developing a new approach is provided in Appendix 16 to the PPR Panel Opinion (EFSA, 2008).

## TOXICITY

Outlined in section 2.2 and 2.3 of the Guidance Document is information regarding the toxicity studies that are considered along with issues such as determining the appropriate endpoint, how to deal with data from more than one study or on more than one species, etc.

### EXPOSURE

The reproductive risk to both birds and mammals is assessed using the same process as outlined for the first tier reproductive risk assessment. Details regarding the indicator species and generic focal species and the relevant 'shortcut values' can be found in the Guidance Document.

### Use of a time-weighted average approach

The use of a 21-day time window in EC (2002) and in the first tier reproductive assessment (section 4 of this Guidance Document) is arbitrary. In the phase-specific methodology a different approach is proposed, that aims towards a more refined assignment of exposure periods. However, because the exposure periods are generally uncertain, each assessment is done twice, once assuming short-term effects and once assuming long-term effects. Guidance on how to use the results of these parallel assessments is provided later in this Appendix.

For birds it is proposed to run two parallel assessments, one assumes that the effects observed in the toxicity study are the result of short-term exposure (1-3 days depending on endpoint), whilst the other assessment assumes that the effects are the result of long-term exposure (21 days, again chosen arbitrarily). When better information is available to determine what time window is relevant, the assessment should be modified accordingly. As regards the mammalian assessment, use is made of whether an acute reference dose (ARfD) is required for the substance. If one is deemed to be necessary, then it is initially assumed that the reproductive effects may be the result of short-term exposure (1 day); if however an ARfD is not considered necessary, it is assumed that reproductive effects are the result of long-term exposure (up to 90 days, see below).

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix J. EFSA Journal 2009; 7(12):1438. [16 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu



#### **PHASE-SPECIFIC ASSESSMENT FOR BIRDS**

#### Selection of the toxicity endpoints for the phase-specific approach

According to Bennett et al. (2005) a phase-specific approach makes greater use of information on specific reproductive and other toxicological endpoints. This information is used as a potential indication of the types of effects that could occur during the reproductive cycle. Bennett et al. (2005) divided the breeding cycle of birds into five phases, namely:

Phase 1 = pair formation and establishing site selection;

Phase 2 = copulation and egg laying ranging from 5 days pre-laying through to the end of the egg-laying period;

Phase 3 = incubation and hatching;

Phase 4 = juvenile growth and survival until fledging; and

Phase 5 = post-fledging

It is strongly recommended that Bennett et al. (2005) and the accompanying papers be consulted for a fuller explanation behind the phase specific approach and the selection of endpoints.

Some of the phases are further divided to reflect possible effects from extrinsic (pesticide exposure from the environment occurring coincidentally with the phase) and intrinsic (pesticide residues contained in the egg affecting a later stage of the breeding cycle) exposure. For precocial species (i.e. those species that are able to fend for themselves soon after hatching, e.g. ducks) phase 4 refers to the period when chicks are dependent on parents for brooding and protection and phase 5 refers to the older, more independent chicks. Full details regarding these five phases and their further breakdown into extrinsic and intrinsic exposure are provided in Bennett et al. (2005).

Further details regarding the selection of toxicity endpoints are provided below. It should be noted that if more than one study has been presented then it is necessary to extract all the following endpoints from all studies submitted. Section 2.3 of the Guidance Document should be consulted as to how to incorporate data from more than one study in to the risk assessment.

### Phase one

For phase one, i.e. pair formation and establishing site selection, it is assumed that pair formation and breeding site selection is essential for successful mating. This could be adversely affected by the behaviour of adults, for example, if their exposure is such that they are prevented from defending a territory. Unfortunately this effect is not measured directly in any of the available toxicity studies. A review of  $LD_{50}$  studies shows that severe signs of toxicity likely to lead to deficits interfering with a bird's normal activities tend to be recorded at dosing levels greater than 1/10 of the  $LD_{50}$  (Callaghan and Mineau, 2000; Appendix 11 of EFSA, 2008). On the basis of this work, it is proposed that 1/10 of the  $LD_{50}$  be used. If the  $LD_{50}$  is a limit dose and hence the endpoint is a 'greater' than value it is proposed to use the methodology outlined in section 2.1.2 of the Guidance Document to determine an  $LD_{50}$ .

It should be noted that for pesticides where the mode of action and/or results from mammalian studies indicate a potential for the  $LD_{50}$  measured by a short term dietary study to be lower than the  $LD_{50}$  based on an acute oral study then it may be more appropriate to use information from an avian dietary study. Bennett et al. (2005) recommend the use of bodyweight and food consumption endpoints from the avian reproduction study. EFSA (2008, Appendix 16) considered this approach to be too precautionary in the majority of cases because of the prolonged exposure period in the test – typically ten weeks. A shorter dietary dosing test with sub-adult birds has been proposed by an OECD committee (OECD 1986) but this protocol has never been formally accepted.

### Phase two

For phase two, i.e. copulation and egg-laying, it is assumed that adult behavioural effects that lead to reduced clutch size or abandonment of a nesting attempt could impact upon the success of copulation and



hence fertility, egg-laying or, possibly, eggshell quality. Unfortunately not all of these parameters are measured in the standard study and therefore it is proposed to use the lower of either:

- The NOAEL for the number of eggs laid per hen or
- The NOAEL for mean eggshell thickness.

Based on the work of Mineau et al. (1994a), it was determined that the number of eggs laid has a strong component of 'parental' toxicity and clusters with measures of weight loss or food intake in the currently-designed avian reproduction study. The number of eggs laid per hen was a measurement that was found to have the lowest NOAEL in a sample of studies analysed for the York workshop (see Mineau (2005) for further consideration of this issue).

## Phase three

Phase three deals with the incubation of the clutch and hatching of young. Changes in the behaviour of the adult may adversely affect nest care and incubation ability and hence the same endpoint (i.e. 1/10 of the LD<sub>50</sub> from the acute oral study) used above in phase one is used again here. There may also be an impact on the fertility of the adult and hence the hatchability of eggs; this is indicated by the proportion of fertile eggs per eggs set per hen. (This endpoint may not be presented in the study; if this is the case then the most relevant endpoint is 'percent viable embryos over number of eggs set'). As regards toxicity to the embryo itself, the concern here is direct toxicity to the embryo and an indication of this can be obtained from the NOAEL for the proportion of hatching per fertile eggs set per hen. (This endpoint may not be presented in the study; if this endpoint may not be presented in the study; if this endpoint may not be presented in the study; if this endpoint may not be presented in the study; if this endpoint may not be presented in the study; if this endpoint may not be presented in the study; if this endpoint may not be presented in the study; if this endpoint may not be presented in the study; if this endpoint may not be presented in the study; if this is the case then the most relevant endpoint is 'percent hatching of viable embryos'.)

The endpoints required for phase 3 are:

- NOAEL for the proportion of fertile eggs per eggs set per hen; this endpoint may not be presented in the study, if this is the case then the most relevant endpoint is viability or 'percent viable embryos and number of eggs set'.
- NOAEL for the proportion of hatching per fertile eggs per hen; this endpoint may not be presented in the study, if this is the case, then the most relevant endpoint is hatchability or 'percent hatching of viable embryos' and
- 1/10 of the LD<sub>50</sub> for adult birds.

## Phase four

Phase four deals with the growth and survival of the juvenile. There may be an adverse effect from exposure of the embryo in the egg (an intrinsic effect), so the NOAEL for the proportion of 14-day old juveniles per number of hatchlings is used. As regards extrinsic impacts on juvenile survival, Bennett et al. (2005) proposed to use an endpoint from the dietary ( $LC_{50}$ ) study. However this study is problematic and difficult to interpret, for example it is difficult to determine a daily dose if food avoidance has occurred (see Mineau et al., 1994b). Therefore, it is proposed to use 1/10 of the adult  $LD_{50}$  to assess the ability of juveniles to grow and develop. This is based on the assumption that for precocial young at least, there is no systematic difference between the relative sensitivity of young and adult (Hudson et al., 1972). There may be differences on a substance by substance basis but no systematic correction factor is possible. It should be noted that this may not be the case for altricial young (i.e. species where the young are tended by their parents, e.g. passerines) where, for cholinesterase-inhibiting chemicals at least, young are known to be more sensitive (Wolfe and Kendall, 1998). However, it is not known whether this difference applies to pesticides with other modes of action. In the absence of any further information, it is proposed that the 1/10LD<sub>50</sub> toxicity endpoint should be matched to a specific chick exposure scenario. For further details on this issue see Appendix 5 of EFSA (2008).

## Phase five

Finally, phase five assesses post-fledging survival therefore 1/10 of the LD50 adjusted for chick food intake rate is required as well as the NOAEL for 14-day old juvenile weights per hen from the reproduction study.



## Summary of toxicity endpoints required for the phase-specific approach

The measured endpoints used in this approach fall into the three general categories (i.e., parental toxicity, developmental toxicity, and eggshell effects) as described by Mineau et al. (1994a) and Mineau (2005). In total, seven endpoints are required to carry out a phase-specific risk assessment in birds:

- 1/10 of the measured adult LD<sub>50</sub>. If this value is a limit value (e.g. > 2000 mg/kg) see section 2.1.2 (phases 1, 3, 4 and 5)
- NOAEL for the number of eggs laid per hen (phase 2)
- NOAEL for mean eggshell thickness (phase 2)
- NOAEL for the proportion of fertile eggs per eggs set per hen; this endpoint may not be presented in the study, if this is the case then the most relevant endpoint is 'percent viable embryos and number of eggs set' (phase 3)
- NOAEL for the proportion of hatching per fertile eggs per hen; this endpoint may not be presented in the study, if this is the case, then the most relevant endpoint is 'percent hatching of viable embryos' (phase 3)
- NOAEL for the proportion of 14-day old juveniles per number of hatchlings (phase 4)
- NOAEL for 14-day juvenile weights per hen (phase 5)

If there is more than one study available, then endpoints should be extracted from all available studies. It should be noted that it may be possible to merge the studies (see section 2.3 of the Guidance Document for further details).

## Selection of exposure scenarios and associated risk assessment

In order to address uncertainty about the appropriate exposure scenario for the phase-specific approach, two exposure scenarios are assessed, namely:

- 1. A scenario where the residue on treated food is assumed to be based on a 1- to 3-day period.
- 2. A scenario where the residue on treated food is assumed to be based on a 21-day period.

For the first scenario, it is assumed that a short exposure *could* lead to reproductive effects, whereas in the second scenario it is assumed that prolonged or long-term exposure *could* lead to reproductive effects. Each of the phase-specific endpoints outlined above is compared to a 21-day time-weighted average. It should be noted that this time window is used for all phases and that it is **arbitrary** and does not imply any biological relevance. This step is simply to try to determine, by comparing the two scenarios, what the potential effect on the risk assessment could be if the effects were the result of prolonged exposure.

# Determination of the daily dietary dose (DDD) estimates based on the assumption that reproductive effects are due to short-term exposure

If the resulting TER produced as a result of the screening step breaches the Annex VI trigger of 5, then further refinement is required. In the first instance, it is assumed that the timing of application may overlap with breeding such that applications always occur on the first day of each phase. Therefore, each of the phase-specific toxicity endpoints outlined above should be compared to an exposure estimate that is pertinent to the endpoint (e.g. either single day maximum estimates or a biologically-appropriate time-weighted average). The DDD should initially be for a **generic focal species** (see Annex I of the Guidance Document, and the shortcut values for the mean RUD). Where more than one generic focal species is highlighted, the one that is relevant in terms of time of application or growth stage should be selected. Where there is more than one generic focal species in terms of timing, then it is proposed that risk assessment should be carried out with **all** relevant generic focal species and then refined as necessary.

## Daily dietary dose

Once an appropriate generic focal species has been selected, then DDD based on 1-, 2-, and 3-day exposure should be determined. In order to calculate the DDD, it is necessary to select the appropriate generic focal species and the corresponding shortcut value based on mean RUD, then multiply this figure by the application rate in kg a.s./ha and if appropriate a time-weighted average or TWA figure (see below for further details). This then gives the DDD that can be compared to the appropriate toxicity endpoint.

The one-day DDD uses the initial exposure estimate. In order to calculate the 2 and 3-day DDD it is necessary to apply a TWA factor to the initial exposure estimate. For 2 days, the factor is 0.93 and 0.9 for 3 days. It is proposed that these values be used for both arthropods and vegetation (see Appendix H of the Guidance Document for details).

As regards the chick scenario it is proposed that a chick shortcut value of 3.8 and 22.7 should be used. These values are based on residues on ground and foliar dwelling arthropods (i.e. mean RUD of 3.5 and 21 respectively, see Appendix F of the Guidance Document) and food intake rate of chicks (see Appendix R of the Guidance Document). In the first instance both scenarios should be assessed. If either or both of the scenarios fail then refinement should include consideration of the dietary composition of chicks of relevant species. The following equation should be used:

# $DDD = application \ rate \times shortcut \ value \times TWA \times MAF_{m}$

These DDD should then be compared to the appropriate toxicity endpoint relevant for the exposure period; this is summarised below in Table 1.

DL	D	TT	Track and state and some	DDD
Phase	Breeding phase	Type of effect	Test endpoint used as surrogate	
1	Pair formation/ breeding site selection <sup>2</sup>	Extrinsic adult	1/10 of LD <sub>50</sub>	1-day maximum DDD for relevant generic focal species.
2	Copulation and egg laying (5	Extrinsic adult	NOAEL for the number of eggs laid per hen	1-day maximum DDD for relevant generic focal species.
	days pre-laying through end of laying)	Extrinsic adult	NOAEL for mean eggshell thickness	1-day maximum DDD for relevant generic focal species.
3	Incubation and hatching	Extrinsic adult	1/10 of LD <sub>50</sub>	1-day maximum DDD for relevant generic focal species.
		Extrinsic adult	NOAEL for proportion of viable eggs per eggs set per hen	1-day maximum DDD for relevant generic focal species.
		Intrinsic juvenile	NOAEL for proportion hatchling per viable eggs per hen	Ovum development 3-day time- weighted average (TWA).
4	Juvenile growth	Extrinsic adult	1/10 of LD <sub>50</sub>	2-day TWA DDD <sup>3</sup> .
	and survival until fledging <sup>2</sup>	Extrinsic juvenile	1/10 of LD <sub>50</sub>	1-day DDD based on chick shortcut value of 3.8 and 22.7
		Intrinsic juvenile	NOAEL for proportion of 14-day-old juveniles per number of hatchlings per hen	Ovum development 3-day TWA DDD <sup>4</sup> .
5	Post-fledging survival <sup>2</sup>	Extrinsic juvenile	1/10 of LD <sub>50</sub>	1-day DDD based on chick shortcut value of 3.8 and 22.7
		Intrinsic juvenile	NOAEL for 14-day-old juvenile weights per hen	Ovum development 3-day TWA $DDD^4$ .

**Table 1**Summary of the relevant DDD that need to be generated for each phase.

1. DDD is based on the application rate in kg a.s./ha, multiplied by the 'shortcut value' based on mean RUD (see Annex I of the Guidance Document) and any appropriate TWA factor. If multiple applications are made then multiple application factors (MAF) as outlined in table 2 are used.

2. The types of behavioural effects on territorial defence and pairing can occur very rapidly after exposure, so the toxicity endpoint should be compared with the maximum exposure concentration estimated for any single day. If pesticide application occurs during this phase, the exposure based on the short-term is appropriate. This will also be the case for extrinsically-affected juvenile survival and post-fledging survival.

3. Nestlings that are still in the process of yolk absorption are capable of withstanding temporary abandonment by the adult. Bennett et al. (2005) proposed that a 2-day time-weighted average (TWA) be used to reflect the fact that a nesting attempt may not necessarily fail if the parents are temporarily prevented from caring for the young by a fast-disappearing substance.



4. The endpoint for embryo toxicity is compared to the TWA for an exposure period equivalent to length of time for an ovum to develop in the species or range of species of concern. This assumes that the primary in ovo exposure is from material deposited in the yolk during the formation of an ovum or by maternal transfer from feathers to the eggshell and subsequent absorption into the egg. Based on the rapid follicular development period in small passerines, it is proposed to use a 3-day window for calculating the TWA.

(Further details regarding the rationale behind the selection of time windows are provided in Bennett et al., 2005.)

# Determination of daily dietary dose based on the assumption that reproductive effects are due to long-term exposure

Having determined appropriate toxicity endpoints for each phase and then compared them to DDD based on the assumption that the effects seen were due to *short-term* exposure, it is now necessary to repeat the exercise, however this time it is assumed that the effects seen were the result of **long-term exposure**. It should be noted that this step is only necessary if the TER from the above assessment are less than 5.

Each of the phase-specific endpoints outlined above is compared to a 21-day time-weighted average. This time-window is used for all phases. The selection of this time window is **arbitrary** and does not imply any biological relevance, this step is simply to try to determine, along with the above assessment, what the potential effect on the risk assessment could be if the effects were the result of prolonged exposure.

In order to determine the exposure estimates, or DDD, the same procedure regarding selection of generic focal species should be followed. In calculating the 21-day time weighted average DDD it is assumed that the  $DT_{50}$  for pesticides on vegetation is 10 days (see EC, 2002). As regards arthropods, there is no standard default value based on measured values as there is for vegetation; however it is considered that in the first instance it is possible to use the same data as for vegetation and hence a  $DT_{50}$  of 10 days is proposed (see Appendix H of the Guidance Document for further details). Using these assumptions the 21-day TWA factor is 0.53. For single applications, this factor, along with the application rate, should be combined with the shortcut value based on mean RUD. For multiple applications, the relevant MAF from the Guidance Document should be used.

The following equation should be used:

## $DDD = application \ rate \times shortcut \ value \times TWA \times MAF_{m}$

Presented in Table 2 is a summary of the relevant toxicity endpoints as well as the DDD that need to be generated for each phase.



Phase	Breeding phase	Type of effect	Test endpoint used as surrogate	<b>DDD</b> <sup>1</sup>
1	Pair formation/ breeding site selection	Extrinsic adult	1/10 of LD <sub>50</sub>	21-day TWA DDD <sup>2, 3</sup>
2	Copulation and egg laying (5	Extrinsic adult	NOAEL for the number of eggs laid per hen	21-day TWA DDD <sup>2</sup>
	days pre-laying through end of laying) <sup>4</sup>	Extrinsic adult	NOAEL for mean eggshell thickness	21-day TWA DDD <sup>2</sup>
3	Incubation and	Extrinsic adult	1/10 of LD <sub>50</sub>	21-day TWA DDD <sup>2</sup>
	hatching	Extrinsic adult	NOAEL for proportion of viable eggs per eggs set per hen	21-day TWA DDD <sup>2</sup>
		Intrinsic juvenile	NOAEL for proportion hatchling per viable eggs per hen	21-day TWA DDD <sup>2</sup>
4	Juvenile growth	Extrinsic adult	1/10 of LD <sub>50</sub>	21-day TWA DDD <sup>2</sup>
	and survival until fledging <sup>3</sup>	Extrinsic juvenile	1/10 of LD <sub>50</sub>	21-day TWA DDD <sup>2</sup> based on chick shortcut value of 3.8 and 22.7
		Intrinsic juvenile	NOAEL for proportion of 14-day-old juveniles per number of hatchlings per hen	21-day TWA DDD <sup>2</sup>
5	Post-fledging survival <sup>3</sup>	Extrinsic juvenile	1/10 of LD <sub>50</sub>	21-day TWA DDD <sup>2</sup> based on chick shortcut value of 3.8 and 22.7
		Intrinsic juvenile	NOAEL for 14-day-old juvenile weights per hen	21-day TWA DDD <sup>2</sup>

Table 2	Summary of the relevant DDD that need to be generated for each phase.
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- 1. DDD is based on the application rate in kg a.s./ha, multiplied by the 'shortcut value' based on mean RUD (see Annex I) and any appropriate TWA factor. If multiple applications are made then multiple application factors (MAF) as outlined in table 2 are used.
- 2. The selection of a 21-day time window is arbitrary and arbitrary and does not imply any biological relevance, this step is simply to try to determine, along with the above assessment what the potential effect on the risk assessment could be if the effects were the result of prolonged exposure. The use of the output of this risk assessment should be considered alongside the output from the assessment assuming that effects are the result of short-term exposure.
- 3. Although derived from an acute study, using  $1/10 \text{ LD}_{50}$  is considered to make the long-term assessment sufficiently conservative overall (see section 3.5 of Guidance Document). Using parental endpoints from the reproduction study would be likely to over-estimate risk as they are measured over longer time scales of constant exposure than is ecologically relevant.
- 4. The types of behavioural effects on territorial defence and pairing can occur very rapidly after exposure, so the toxicity endpoint should be compared with the maximum exposure concentration estimated for any single day. If pesticide application occurs during this phase, the exposure based on the short-term is appropriate. This will also be the case for extrinsically-affected juvenile survival and post-fledging survival.

#### Interpretation and use of the TER for the phase-specific approach

Following the above procedure, it is possible that there could be two TER per toxicity endpoint – one assuming that the effects are the result of short-term exposure and the other assuming that the effects are the result of long-term exposure. Outlined in Table 3 below is guidance on how to interpret and hence use the outputs from the above assessment.



Scenario	Assessment outcomes		
1 to 3-day DDD (i.e. effects are based on short- term exposure)	TER≥5	TER<5	TER<5
21-day DDD scenarios (i.e. effects are based on long- term exposure.)	TER≥5	TER≥5	TER<5
<u>Next Steps</u>	No further refinement required	Further refinement is required. The outcome of the risk assessment indicates that one possible refinement step is to try to determine if the effects are the result of short-term exposure.	Further refinement is required, however, the outcome of the risk assessment indicates that little will be gained by additional effects data and hence trying to determine if the effects are the result of short-term exposure, it is recommended that refinements should concentrate on effects, and the potential consequences of effects.

 Table 3
 Summary table on how to interpret the outcome from the phase-specific risk assessment

#### Further refinement of the phase-specific approach for birds

If the substance and associated use under consideration has 'passed' the assessment assuming that the effects are the result of long-term exposure, but 'failed' when it is assumed that exposure is the result of short-term exposure, then it may be possible to carry out further toxicity studies to determine if effects are due to short or long-term exposure (see below for further details). It should be noted that due to animal welfare reasons, refining the risk by using modified toxicity studies should not be the first option; refinements to the exposure estimates should be considered first, as well as the potential consequences of effects before additional toxicity studies are contemplated.

<u>Refine the residue element of the initial DDD</u> – in the above assessment default residue information has been used; and it has also been assumed that the  $DT_{50}$  on vegetation and arthropods is 10 days. It is feasible that initial residues as well as the speed of residue decline may differ from these initial default assumptions; therefore, it is possible to refine the residue element of the DDD calculation.

If a more realistic indication of the initial residues for the substance and use under consideration is required then residue studies should be carried out as outlined in the Guidance Document. Once substance specific residue data have been obtained, it will be necessary to re-run the scheme.

<u>Refine ecological parameters</u> – In the above assessment a generic focal species has been used; in using this it is assumed that the bird obtains all of its food from the treated areas and that its diet is realistically worst case. It is possible to refine these ecological elements of the exposure estimate by first determining the appropriate focal species (FS) for the crop under consideration (see section 6.1.3 of Guidance Document). It should be noted that the focal species selected should represent species breeding in and around the crop of concern, and hence should be worst case in terms of food intake, use of crop and breeding behaviour. It should further be noted that the FS selected may not be the same as used to refine the acute risk assessment.

Having selected a suitable FS, it is possible to determine the composition of diet obtained from the treated area (PD); the methodology for doing this is outlined in section 6.1.6 of the Guidance Document. It is also possible to determine the proportion of food that the bird or mammal obtains from the treated crop (PT), and details of how to do this are presented in section 6.1.5 of the Guidance Document. Section 6 of the Guidance Document provides details on how to combine the refinement steps as well as issues to consider when combining them.

<u>Assess the broods at risk</u> – the above phase-specific approach assumes that every phase of every reproductive attempt is maximally exposed. In reality, only a proportion of birds will be exposed and



furthermore, for those which are exposed, the peak exposure may not occur during the most sensitive reproductive phase.

In order to assess the number of broods at risk, it is essential to identify a suitable focal species. Once a suitable focal species has been identified, information on the possible start dates and durations for each phase of reproduction is required. Information is also required on the proportion of the population of the focal species that visit treated fields, i.e. consumers, as well as a scale of interest to the risk manager (i.e. local, national, international population scale). This information can then be combined with information on the timing of pesticide applications. Once this information is available, the exposure can be assessed and then compared to the relevant toxicological endpoint for each reproductive phase. The final output should be an estimate of the proportion of broods at risk, i.e. the proportion of reproductive attempts where exposure in one or more phases exceeds the relevant toxicological endpoint (including the appropriate uncertainty factor). Examples of this approach were provided by Shore et al. (2005) and Roelofs et al. (2005). User-friendly population models able to integrate timing of application with breeding cycle information for a number of generic species are currently being developed and tested by the US EPA (Rick Bennett, pers. comm.). It is expected that they will be available shortly, making this approach potentially attractive.

<u>Field trials</u> – Theoretically it is possible to carry out a field study to assess the potential effects on reproduction, however from a practical point of view, this refinement step is not really practical. It has long been suggested (OECD 1996) that residue levels in eggs should be measured in the current protocol in order to allow a comparison with residue levels in eggs taken from focal species in the field. This may provide some possibility for refinement where the effects are the result of intrinsic exposure, i.e. material transferred into the egg influencing embryo development and survival. (Further details are presented in Section 6.4 of the Guidance Document)

<u>Population modelling</u> – if despite the above refinements, there is still concern regarding the risk to birds, then one option would be to assess the risk at the population level. Unfortunately there are no population models that can be readily used or adapted for use in pesticide risk assessment. This should not, however, preclude their use, possible examples of population models are presented in Topping et al. (2005), Sibly et al. (2005), Roelofs et al. (2005) and Wang and Grimm (2007).

<u>Refine the risk assessment via the use of modified toxicity studies</u> – As stated above, it may be possible to refine the risk assessment by carrying out a modified toxicity study. Due to animal welfare reasons, this should not be first option and it is recommended that the exposure refinements as well as an assessment of the consequences of effects should be considered first.



#### **PHASE-SPECIFIC ASSESSMENT FOR MAMMALS**

Provided below is a detailed explanation of the proposed risk assessment process for mammals. This scheme is based on EFSA (2006) and Bennett et al. (2005) and it is recommended that these documents are consulted to provide further explanation behind the following scheme.

In the following section the text is laid out with information on how to select toxicity endpoints, how to determine the daily dietary dose, and then how to refine the risk assessment.

#### Selection of the toxicity endpoints for the phase-specific approach

According to the PPR opinion (EFSA, 2006a) a phase-specific approach makes greater use of information on specific reproductive and other toxicological endpoints. This information is used as a potential indication of the types of effects that could occur during the reproductive cycle. The PPR divided the breeding cycle of mammals into four phases, namely:

Phase 1 – establishing a breeding site, pairing and mating

Phase 2 – pregnancy

Phase 3 – pup growth and survival until weaning

Phase 4 – post-weaning survival until maturity

Full details regarding these four phases are provided in EFSA (2006a) as well as Bennett et al. (2005). Further details regarding the toxicity endpoints required are provided below. Details regarding the studies and determination of endpoints is presented in section 2.2 of the Guidance Document.

#### Phase one

For phase one, i.e. establishing a breeding site, pairing and mating, it is assumed that pair formation and breeding site selection is essential for successful mating. This could be adversely affected by the behaviour of adults leading to territory abandonment or delayed or abnormal mating, or systemic effect leading to reduced fertility. In order to try to assess this risk, it is proposed that effects on body weight, indices of mating, indices of fertility and systemic toxicity are required and information on these endpoints is obtained from either a single dose (e.g. modified  $LD_{50}$  type or acute neurotoxicity study if performed), 28 (if available) or 90-day toxicity test and two-generation tests.

An evaluation of the single dose toxicity study can be found at B.6.2.1 of the draft assessment report (DAR), the acute neurotoxicity study (if performed) can be found at B.6.7.1 of the DAR, whilst the twogeneration study can be found at B.6.6.1. It should be noted that the 28-day study, if performed, can be found at B.6.3.1 of the DAR along with the 90-day study.

It is proposed that the four studies listed above should be examined for the following toxicological endpoints – body weight, indices of mating, indices of fertility and systemic toxicity. In the first instance the lowest overall NOAEL should be selected.

#### Phase two

For phase two, i.e. pregnancy, effects on pup and litter parameters developmental abnormalities and maternal effects are of concern. According to the PPR opinion, in order to try to assess the effects on pup and litter parameters, the two-generation study should be consulted and NOAEL for the indices of gestation, litter size, pup and litter weight, indices of viability and pre- and post-implantation loss should be obtained. The two-generation reproduction study can be found in Section B.6.6.1 of the DAR. The lowest NOAEL from this study(ies) should be obtained for the above parameters.

As regards abnormalities, it is proposed that the pre-natal developmental toxicity test and/or the twogeneration reproduction study are consulted. The NOAEL for the embryo/foetal toxicity including teratological effects should be obtained. The pre-natal development toxicity test - this should be in Section B.6.6.2 of the DAR



As regards the maternal effects, the prenatal development toxicity test should be consulted and the NOAEL for the number aborting and the number delivering early should be obtained.

## Phase three

As regards phase three, this deals with pup growth and survival until weaning. In order to try to assess the risk re-adult behavioural effects leading to abnormal litter care, it is proposed that information on systemic toxicity and effects on adult body weight should be considered. This information may be obtained from single dose, 28 (if available) or 90-day toxicity test and two-generation tests and hence the lowest NOAEL for systemic toxicity and effects on body weight should be obtained.

As regards effects on post-natal litter and pup parameters, it is proposed that the two-generation test should be considered and the NOAEL for indices of post-natal growth, indices of lactation and data on physical landmarks be obtained.

## Phase four

Phase four deals with the post-weaning survival until maturity. In order to try to assess the risk, it is proposed that information on juvenile survival, growth and development be obtained from either the single dose studies or the two-generation reproduction study. The use of the single dose studies may be useful if there are no effects at the top concentration tested in the two generation study. It should be noted that if this approach is followed then the endpoint will be based on survival or overt signs of toxicity. Other studies might also provide useful information but are not always available for many substances, e.g. acute neurotoxicity study or developmental neurotoxicity study. It is proposed that in the first instance the lowest overall NOAEL should be selected.

Note - it is possible that there may be more than one study to address a specific endpoint, if this is the case, see the refinement section at the end of this Appendix for further details.

#### Conclusion

In conclusion the endpoints presented in Table 4 are required to carry out a phase-specific risk assessment.



## **Table 4.**Source of information for the different mammalian reproductive phases.

(Establishing a breeding site, pairing and mating)as the two-generation study should also be consulted for information on body weigh change/behavioural effects and systemic toxicity!. As regards indices of mating and fertility the two-generation study should be consulted. In the first instance the lowest NOAEL should be used. There should be one endpoint for this phase.Two (Pregnancy)For effects on pup and litter parameters, the two-generation reproduction study should be consulted and the NOAEL regarding the indices of gestation, litter size, pup and litter weight' indices of viability, pre- and post-implantation loss should be selected. (NB some information on these endpoints may be obtained from developmental studies.) For developmental abnormalities, the prenatal development toxicity test and/or the two generation reproduction study should be consulted for embryo/foetal toxicity including teratological effects and lowest NOAEL should be selected. For maternal toxicity, the prenatal development toxicity test should be consulted for the number aborting and number delivering early and the lowest NOAEL selected. There should be a total of three NOAEL for this phase.Three (pup growth and survival until weaning)This phase deals with the potential effects on parents bringing up young as well as on the young themselves. In order to try to assess the risk re-adult behavioural effects leading to abnormal litter card (e.g. reducing feeding of young etc which would not be seen in laboratory studies, e.g. due to readily available food supply), information on systemic toxicity and effects on adult body weight should be consulted for endpoints for indices of post-natal growth <sup>3</sup> , indices of lactation and data on physical landmarks and the lowest overall NOAEL obtained. There should be two NOAEL for this phase.Four <t< th=""><th>Phase</th><th>Source of information</th></t<>	Phase	Source of information
Two (Pregnancy)For effects on pup and litter parameters, the two-generation reproduction study should be consulted and the NOAEL regarding the indices of gestation, litter size, pup and litter weight² indices of viability, pre- and post-implantation loss should be selected. (NB some information on these endpoints may be obtained from developmental studies.)For developmental abnormalities, the prenatal development toxicity test and/or the two generation reproduction study should be consulted for embryo/foetal toxicity including teratological effects and lowest NOAEL should be selected.For maternal toxicity, the prenatal development toxicity test should be consulted for the number aborting and number delivering early and the lowest NOAEL selected. There should be a total of three NOAEL for this phase.Three (pup growth and survival until weaning)This phase deals with the potential effects on parents bringing up young as well as on the young themselves. In order to try to assess the risk re-adult behavioural effects leading to abnormal litter card (e.g. reducing feeding of young etc which would not be seen in laboratory studies, e.g. due to readily available food supply), information on systemic toxicity and effects on adult body weight should be considered and the lowest overall NOAEL be obtained from either the single dose, 28 (if available) or 90-day toxicity test and two-generation tests. The results or the 2-generation study should be consulted for endpoints for indices of post-natal growth³, indices of lactation and data on physical landmarks and the lowest overall NOAEL be bained. There should be two NOAEL for this phase.FourThe single dose studies and the two-generation study should be consulted for endpoints for indices of post-natal growth³, indices of lactation and data on physical landmarks and the lowest ov	(Establishing a breeding site, pairing and	Data from single dose studies and the 90-day study and if available the 28-day study as well as the two-generation study should also be consulted for information on body weight change/behavioural effects and systemic toxicity <sup>1</sup> . As regards indices of mating and fertility the two-generation study should be consulted. In the first instance the lowest NOAEL should be used.
(Pregnancy)consulted and the NOAEL regarding the indices of gestation, litter size, pup and litter weight indices of viability, pre- and post-implantation loss should be selected. (NB some information on these endpoints may be obtained from developmental studies.)For developmental abnormalities, the prenatal development toxicity test and/or the two generation reproduction study should be consulted for embryo/foetal toxicity including teratological effects and lowest NOAEL should be selected.For maternal toxicity, the prenatal development toxicity test should be consulted for the number aborting and number delivering early and the lowest NOAEL selected.Three (pup growth and survival until weaning)This phase deals with the potential effects on parents bringing up young as well as on the young themselves.In order to try to assess the risk re-adult behavioural effects leading to abnormal litter carr (e.g. reducing feeding of young etc which would not be seen in laboratory studies, e.g. due to readily available food supply), information on systemic toxicity and effects on adult body weight should be considered and the lowest overall NOAEL be obtained from either the single dose, 28 (if available) or 90-day toxicity test and two-generation tests. The results or the 2-generation study would generally take precedence over the effects seen in the 28 or 90 day study.As regards effects on the young themselves, i.e. post-natal litter and pup parameters, the 2 generation study should be consulted for endpoints for indices of post-natal growth <sup>3</sup> , indices of lactation and data on physical landmarks and the lowest overall NOAEL obtained. There should be two NOAEL for this phase.FourThe single dose studies and the two-generation study should be assessed to determine in the to a study should be two NOAEL		There should be one endpoint for this phase.
generation reproduction study should be consulted for embryo/foetal toxicity including teratological effects and lowest NOAEL should be selected.For maternal toxicity, the prenatal development toxicity test should be consulted for the number aborting and number delivering early and the lowest NOAEL selected.Three (pup growth and survival until weaning)This phase deals with the potential effects on parents bringing up young as well as on the young themselves.In order to try to assess the risk re-adult behavioural effects leading to abnormal litter card (e.g. reducing feeding of young etc which would not be seen in laboratory studies, e.g. due to readily available food supply), information on systemic toxicity and effects on adult body weight should be considered and the lowest overall NOAEL be obtained from either the single dose, 28 (if available) or 90-day toxicity test and two-generation tests. The results o the 2-generation study would generally take precedence over the effects seen in the 28 or 90 day study.As regards effects on the young themselves, i.e. post-natal litter and pup parameters, the 2 generation study should be consulted for endpoints for indices of post-natal growth <sup>3</sup> , indices of lactation and data on physical landmarks and the lowest overall NOAEL obtained. There should be two NOAEL for this phase.FourThe single dose studies and the two-generation study should be assessed to determine in the for the single dose studies and the two-generation study should be assessed to determine in the for the single dose studies and the two-generation study should be assessed to determine in the for the single dose studies and the two-generation study should be assessed to determine in the for the single dose studies and the two-generation study should be assessed to determine in the for the single dose st		For effects on pup and litter parameters, the two-generation reproduction study should be consulted and the NOAEL regarding the indices of gestation, litter size, pup and litter weight <sup>2</sup> , indices of viability, pre- and post-implantation loss should be selected. (NB some information on these endpoints may be obtained from developmental studies.)
number aborting and number delivering early and the lowest NOAEL selected. There should be a total of three NOAEL for this phase.Three (pup growth and survival until weaning)This phase deals with the potential effects on parents bringing up young as well as on the young themselves. In order to try to assess the risk re-adult behavioural effects leading to abnormal litter card (e.g. reducing feeding of young etc which would not be seen in laboratory studies, e.g. due to readily available food supply), information on systemic toxicity and effects on adult body weight should be considered and the lowest overall NOAEL be obtained from either the single dose, 28 (if available) or 90-day toxicity test and two-generation tests. The results o the 2-generation study would generally take precedence over the effects seen in the 28 or 90 day study.As regards effects on the young themselves, i.e. post-natal litter and pup parameters, the 2 generation study should be consulted for endpoints for indices of post-natal growth³, indices of lactation and data on physical landmarks and the lowest overall NOAEL obtained. There should be two NOAEL for this phase.FourThe single dose studies and the two-generation study should be assessed to determine in the for the lowest NOAEL for this phase.		For developmental abnormalities, the prenatal development toxicity test and/or the two- generation reproduction study should be consulted for embryo/foetal toxicity including teratological effects and lowest NOAEL should be selected.
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<ul> <li>(pup growth and survival until weaning)</li> <li>(e.g. reducing feeding of young etc which would not be seen in laboratory studies, e.g. due to readily available food supply), information on systemic toxicity and effects on adult body weight should be considered and the lowest overall NOAEL be obtained from either the single dose, 28 (if available) or 90-day toxicity test and two-generation tests. The results of the 2-generation study would generally take precedence over the effects seen in the 28 or 90 day study.</li> <li>As regards effects on the young themselves, i.e. post-natal litter and pup parameters, the 2-generation study should be consulted for endpoints for indices of post-natal growth<sup>3</sup>, indices of lactation and data on physical landmarks and the lowest overall NOAEL obtained. There should be two NOAEL for this phase.</li> <li>Four</li> </ul>		There should be a total of three NOAEL for this phase.
survival until weaning)In order to try to assess the risk re-adult behavioural effects leading to abnormal litter card (e.g. reducing feeding of young etc which would not be seen in laboratory studies, e.g. due to readily available food supply), information on systemic toxicity and effects on adult body weight should be considered and the lowest overall NOAEL be obtained from either the single dose, 28 (if available) or 90-day toxicity test and two-generation tests. The results o the 2-generation study would generally take precedence over the effects seen in the 28 or 90 day study.As regards effects on the young themselves, i.e. post-natal litter and pup parameters, the 2 generation study should be consulted for endpoints for indices of post-natal growth <sup>3</sup> , indices of lactation and data on physical landmarks and the lowest overall NOAEL obtained. There should be two NOAEL for this phase.FourThe single dose studies and the two-generation study should be assessed to determine in the up of the two parameters.		This phase deals with the potential effects on parents bringing up young as well as on the young themselves.
generation study should be consulted for endpoints for indices of post-natal growth <sup>3</sup> , indices of lactation and data on physical landmarks and the lowest overall NOAEL obtained. There should be two NOAEL for this phase.         Four       The single dose studies and the two-generation study should be assessed to determine in the fourth of the single dose studies and the two-generation study should be assessed to determine in the fourth of the single dose studies and the two-generation study should be assessed to determine in the fourth of the single dose studies and the two-generation study should be assessed to determine in the fourth of the single dose studies and the single dose studies are should be assessed to determine in the single dose studies and the two-generation study should be assessed to determine in the single dose studies and the single dose studies are should be assessed to determine in the single dose studies and the single dose studies are should be assessed to determine in the single dose studies are should be assessed to determine in the single dose studies and the single dose studies are should be assessed to determine in the single dose studies are should be assessed to determine in the single dose studies are should be assessed to determine in the single dose studies are should be assessed to determine in the single dose studies are should be assessed to determine in the single dose studies are should be assessed to determine in the single dose studies are should be assessed to determine are should	survival until	In order to try to assess the risk re-adult behavioural effects leading to abnormal litter care (e.g. reducing feeding of young etc which would not be seen in laboratory studies, e.g. due to readily available food supply), information on systemic toxicity and effects on adult body weight should be considered and the lowest overall NOAEL be obtained from either the single dose, 28 (if available) or 90-day toxicity test and two-generation tests. The results of the 2-generation study would generally take precedence over the effects seen in the 28 or 90 day study.
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		There should be two NOAEL for this phase.
	(Post-weaning	
survival and maturity)       There should be one NOAEL for this phase.         1       Effects derived from absorption of the substance that causes modification of an organ or an apparate	maturity)	-

- 1. Effects derived from absorption of the substance that causes modification of an organ or an apparatus (biochemical, physiological and/or morphological). Examples include behavioural or physiological impairment (e.g. reduced locomotive activity, altered reflexes)
- 2. Any effects in foetal body weight should be evaluated in the context of all pertinent data including other developmental effects as well as maternal toxicity.
- 3. For example body weight gain, ear and eye opening, tooth eruption, hair growth and effects on sexual maturation such as age and body weight at vaginal opening or balano-preputial separation.
- 4. NB Please note for points 2 and 3 above a slight, e.g. 1 day, delay in obtaining a particular endpoint or developmental milestone can be ignored, however longer delays could be considered as adverse. This is based on a frequency of measuring and hence is a pragmatic approach. Please note that a 1 d delay may be of importance for certain substances and it should be checked that it is not treatment related before discounting it.

#### **Determination of daily dietary doses**

In order to carry out a risk assessment it is necessary to have information on the toxicity of the substance and then compare this to the likely exposure levels. In trying to determine likely exposure levels, it is proposed to use the mammalian toxicity assessment and in particular whether an 'acute reference dose' (ARfD) has been determined. An ARfD is determined for those substances that are considered to cause effects following short-term exposure. It is usual that an ARfD is based on just oral routes of exposure and hence normally only reflects this route of exposure. It should also be noted that the ARfD is dose dependant, i.e. if an extremely high dose of any substance were tested, then it would it could be possible to set an ARfD, however it is being used in this context to highlight those substances likely to cause effects with long-term consequences following short-term exposure and hence are most concern. It should be further noted that for solid formulations the ARfD may not be totally appropriate due to concerns regarding the concentrations tested in relation to the potential DDD, in these circumstances it is proposed that the assessor should determine if the product is classified in terms of acute oral toxicity; if it is then it can be assumed, in the first instance, that effects with long-term consequences may be the result of short-term exposure. For further information on ARfD see Solecki et al. (2005)<sup>1</sup>.

Where an ARfD has been determined it can be concluded that effects in the reproduction repeat dose or developmental studies *may* have been the result of single or short-term exposures. In these cases, it is proposed that estimated theoretical exposure estimate or DDD are based, in the first instance, on a short time window.

It should be noted that it is **<u>not</u>** proposed to use the ARfD itself, but merely use it as an indicator as to whether the effects seen are the result of short or long-term exposure.

If, as a result of the mammalian toxicology assessment, no ARfD is considered necessary then it can be assumed that any effects seen are the result of long-term or continuous exposure. If this is the case it is proposed that the following time windows can be used:

- If the endpoint from a two-generation study is being used and an ARfD is not considered necessary, then it is assumed that the effects are the result of the 60 day pre-mating period, therefore a 60-day TWA is proposed.
- If the 90-day study is being used and an ARfD is not considered necessary, then it is assumed that the effects are the result of 90 days exposure, therefore, a 90-day TWA is proposed.
- If the 28-day study is being used and an ARfD is not considered necessary, then it is assumed that the effects are the result of 28 days exposure, therefore a 28-day TWA is proposed.
- If the prenatal study has been used and an ARfD is not considered necessary, this it is assumed that the effects are the result of 10 days exposure as the animals are dosed generally from day 6 to 16, therefore a 10-day TWA is proposed.
- If an endpoint from a single-dose study is providing the lowest NOAEL, it is proposed that a 1-day DDD is used.

It should be noted that shorter time windows should be used if there is any indication in these studies of adverse effects occurring during the study, for example if in the 90-day study there were effects at 20 days, then a 20-day TWA should be used.

It is accepted that in certain circumstances the lowest NOAEL may come from the longest study, and hence when combined with a TWA calculated over a long period, will result in a high TER; whereas the next highest NOAEL may come from a shorter study, and hence when combined with a TWA calculated over a short time period may produce a lower TER. Whilst this is possible it is considered that this is unlikely to be a serious issue due to the influence of dose spacing and arbitrary selection of doses in the above studies.

Outlined in Table 5 is a summary of the relevant DDD that need to be generated for each phase. The rationale behind the time-windows proposed for those substances where an ARfD is not considered necessary is outlined above. The rationale for those where there is an ARfD is provided in EFSA (2006), however, it can be summed up that there is the potential for the effects to be the result of a one off or a short-term exposure and hence a 1-day DDD is used.

<sup>&</sup>lt;sup>1</sup> Solecki R., Davies L., Dellarco V., Dewhurst I., van Raaij M., and Tritscher A. (2005) Guidance on setting of acute reference dose (ARfD) for pesticides. Food and Chemical toxicology 43 (2005) 1569 – 1593.



Phas e	Breeding phase	Endpoint	DDD – assuming ARfD is necessary	DDD – assuming ARfD is not considered necessary
1	Establish breeding site, pairing and mating	NOAEL to reflect body weight change/behaviour effects. NOAEL for systemic toxicity <sup>1</sup> NOAEL for mating NOAEL for fertility	1-day DDD <sup>4</sup> 1-day DDD 1-day DDD 1-day DDD	
2	Pregnancy	NOAEL for gestation, litter size, pup and litter weight <sup>2</sup> , indices of viability, pre- and post-implantation loss	1-day DDD	
		NOAEL for embryo/foetal toxicity including teratological effects	1-day DDD	TWA will depend on the study used, but
		NOAEL for number aborting NOAEL for number delivering early	1-day DDD 1-day DDD	could range from 1 day to 90 day – see above for details
3	Pup growth and survival until weaning	NOAELforsystemictoxicity/bodyweightchange/behavioureffectsNOAELforindicesof	1-day DDD 1-day DDD	
		lactation/post-natal growth/for physical landmarks <sup>3</sup>	1-day DDD 1-day DDD	
4	Post-weaning survival until maturity	NOAEL for survival or general toxicity up to 4 weeks of age.	1-day DDD	

#### **Table 5.**Summary of relevant DDD that need to be generated for each phase.

1. Effects derived from absorption of the substance that causes modification of an organ or an apparatus (biochemical, physiological and/or morphological). Examples include behavioural or physiological impairment (e.g. reduced locomotor activity, altered reflexes)

2. Any effects in foetal body weight should be evaluated in the context of all pertinent data including other developmental effects as well as maternal toxicity.

3. For example body weight gain, ear and eye opening, tooth eruption, hair growth and on sexual maturation such as age and body weight at vaginal opening or balano-preputial separation. (Please note that for points 2 and 3 above a slight, e.g. 1 day, delay in obtaining a particular endpoint or developmental milestone can be ignored, however longer delay of greater than 1 day could be considered as adverse. This is based on a frequency of measuring and hence is a pragmatic approach. Please note that a 1 day delay may be of importance for certain substances and it should be checked that it is not treatment related before discounting it.)

4. 1-day DDD is the initial exposure estimate.

The DDD should be based, in the first instance, on a **generic focal species** and the shortcut value based on the mean RUD should be used. Where more than one generic focal species is highlighted, the one that is relevant in terms of time of application or growth stage should be selected. Where there is more than one generic focal species in terms of timing etc, then it is proposed that risk assessment should be carried out with all relevant generic focal species and then refined as necessary.

In determining the above DDD it is necessary to use the shortcut value based on the mean RUD (see Annex I of the Guidance Document and shortcut values based on the mean RUD), the application rate in kg a.s./ha and the appropriate TWA value. For the one-day DDD the initial exposure estimate should be used, and hence no TWA factor should be applied. In order to calculate the 10, 28, 60 and 90 days DDD outline above it is necessary to apply a TWA factor to the initial exposure. For 10 days, the factor is 0.72, for 28 days, the factor is 0.44; for 60 days the factor is 0.24 and for 90 days the factor is 0.16. It is

proposed that these TWA factors and related MAF factors are applicable to both arthropods and vegetation (see Appendix H of the Guidance Document for further details). (Please note that it is possible that, depending upon the effects seen and the studies used to derive the endpoints, other TWA factors may be required. If this is the case, please see Appendix H of the Guidance Document for details.)

The following equation should be used:

# $DDD = application \ rate \times shortcut \ value \times TWA \times MAF_{m}$

In order to calculate the TER it is necessary to combine the information on the toxicity at each phase with the potential exposure at each phase. If the substance under consideration has an ARfD then DDD based on the information in column 4 in the Table 5 should be used; however if an ARfD is not considered necessary then the information in Column 5 should be used.

## Calculation of TER for phase-specific approach using generic focal species for the average scenario

Having determined the various NOAEL as well as the various exposure estimates as outlined above, they should be compared to obtain TER. Each TER should be compared to the Annex VI trigger value of 5. If the  $TER_{repro}$  is greater than 5 then it can be assumed that the risk to this particular stage is 'acceptable', however if the TER is less than 5, then further work is required.

## Further refinement of the phase-specific approach for mammals

Outlined below is a selection of possible refinement steps, these can be used individually or combined together. Before considering any of the following refinement steps it is important to read section 6 of the Guidance Document on refinement options, and in particular ensure that the likely level of protection that will result from the refined risk assessment is the level wanted by the risk manager.

<u>Re-examination of the mammalian toxicity dataset</u> – In the above assessment the lowest relevant NOAEL has been selected for each phase. It may be valid to re-examine the mammalian toxicity dataset and confirm that the NOAEL used is also the lowest biologically relevant NOAEL (see section 2.2.1 of Guidance Document). It is not proposed for this step to use the geometric mean approach due to difficulties regarding the determination of an appropriate time window for the time-weighted average calculation.

<u>Re-assessment of the exposure period relevant to the toxicity endpoints</u> – If the substance under consideration has an ARfD, it has initially been assumed that all the effects seen were the result of a single- or short-term exposure. However, this may not have been the case and hence there is scope to refine the toxicity endpoint. Therefore, it may be worthwhile revisiting the toxicity endpoints to determine if they are totally appropriate. If this refinement step is chosen, it is recommended to discuss with a mammalian toxicologist.

<u>Refine the residue element of the initial DDD</u> – It is possible to refine the residue element of the DDD calculation. To do this, data are required on either the initial residue values or/and the residue decline. Details regarding refining the risk using specific residue data are provided in section 6.1.4 of the Guidance Document.

<u>Refine ecological parameters</u> – Focal species (FS), composition of diet obtained from treated area (PD) and proportion of an animal's daily diet obtained in habitat treated with pesticide (PT). – It is possible to refine the DDD by using more relevant data on the ecological components of the risk assessment, i.e. FS, PT and PD (see sections 6.1.3, 6.1.5 and 6.1.6 of the Guidance Document).

<u>Assess the litters at risk</u> – The above phase-specific approach assumes that every phase of every reproductive attempt is maximally exposed. In reality, only a proportion of mammals will be exposed and furthermore, for those that are exposed, the peak exposure may not occur during the most sensitive reproductive phase. Assessing the risk by comparing the exposure to the relevant reproductive phase is the primary advantage of the phase-specific approach. However, concerns regarding the availability of data (e.g. time of application of the pesticide, time of breeding phases for focal species etc) exist. Despite these concerns, refining the risk to breeding mammals is still considered a viable alternative if the data are available.



In order to assess the number of litters at risk, it is essential to identify a suitable focal species (see section 6.1.3 of the Guidance Document). Once a suitable focal species has been identified, information on the possible starting dates and durations for each phase of reproduction is required.

<u>Field trials</u> – Effects on reproduction for small mammals may be studied by using capture-mark-release-recapture techniques to monitor population density and age structure (see section 6.4 of the Guidance Document).

<u>Population modelling</u> – If, despite the above refinements, there is still concern regarding the risk to mammals, then one option would be to assess the risk at the population level. Unfortunately, there are no population models that can be readily used or adapted for use in pesticide risk assessment. Existing possible examples of population models are presented in Topping et al. (2005), Sibly et al. (2005), Roelofs et al. (2005) and Wang and Grimm (2007). It should be noted that the models included in these references are not endorsed but are provided as an indication of the types of studies that are available. Due to the complexity of this issue, it is envisaged that each assessment would be on a case-by-case basis.

## REFERENCES

See reference list in Guidance Document.



# APPENDIX K

# BACKGROUND INFORMATION ON THE ASSESSMENT OF UPTAKE VIA DRINKING WATER

## Relevant crops for the leaf scenario and calculation of PEC<sub>pool</sub>

The leaf scenario, i.e. the uptake of contaminated water collected in leaf whorls, reflects specific concerns that were raised by incidents reported in Germany. Cole crops were treated with highly acute pesticides during a long dry period and irrigated shortly thereafter. Birds were attracted by the water collected in the leaf whorls of the crop plants, which resulted in a great number of observed mortalities due to the action of the pesticide dissolved in the water (Schietinger and Hoffmann, 1984; Hommes et al., 1990).

With regard to the risk to birds, the leaf scenario clearly reflects a worst-case situation. It is relevant for spray applications only. Formation of pools that would serve as drinking water supply for birds requires a certain plant morphology. Leaves must point upwards and at the same time must be closely pressed against other leaves or the stem at their basis to form cavities that could hold water over a considerable amount of time. Also, these structures must be accessible to birds, i.e. they must be able to sit on the plant for drinking. Considering these criteria, the following crop categories are proposed to be relevant for an assessment according to the leaf scenario:

- Leaf vegetables (forming heads) at principal growth stage 4 until harvest (classification according to BBCH<sup>1</sup>).
- Other leaf vegetables (e.g. cauliflower) at principal growth stage 4 or later, with a morphology that facilitates collection of rain/irrigation water in reservoirs that are large enough and easily accessible to attract birds and sufficiently stable over some hours.

The leaf scenario is not deemed relevant for small mammals as no concurrent poisoning of mammals was reported for the sites with bird incidents.

Based on measurements conducted at the sites of incidents, it was concluded that the worstcase concentration in water would correspond to the concentration in the spray solution (i.e. the product already diluted in the required amount of water), diluted by a factor of 5.

<sup>&</sup>lt;sup>1</sup> Biologische Bundesanstalt, Bundessortenamt und CHemische Industrie

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix K. EFSA Journal 2009; 7(12):1438. [6 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

<sup>©</sup> European Food Safety Authority, 2009



$$\text{PEC}_{\text{pool}} = \frac{\text{C}_{\text{spray}}}{5}$$

With:

PEC<sub>pool</sub> = Predicted environmental concentration in the pool of the leaf whorl

# Calculation of PEC<sub>puddle</sub> for the puddle scenario

The puddle scenario accounts for the uptake of contaminated water collected in puddles on soil. To obtain an estimate for pesticide concentrations in puddles formed on a field after rainfall (PEC<sub>puddle</sub>), it may be assumed that this concentration would be the same as the concentration in runoff water as calculated for the assessment of surface water exposure. The FOCUS<sup>2</sup> surface water model employs the PRZM<sup>3</sup> for estimating these runoff contributions to PEC<sub>sw</sub>, which could thus in principle be used for estimating PEC<sub>puddle</sub> under appropriate worst case conditions.

However, runoff entries in surface water as calculated in FOCUS Step 3 reflect the effect of all precipitation events after pesticide application in the modelled time period, whereas puddles on the field are deemed to be related to one precipitation event only. Also, many input parameters are required to run the model. Nevertheless, closer inspection of the intended scenario reveals the potential for using a simplified model. In first instance, concentrations in runoff water are identical to concentrations in the pore water diluted by rainfall. While the subsequent calculation of actual runoff entries in surface water bodies requires complex calculations of water outflow from the field, this is not necessary for estimating  $PEC_{puddle}$ . Thus, a simplified model without water outflow routines can be proposed to calculate  $PEC_{puddle}$  as a function of application rate and the organic carbon adsorption coefficient ( $K_{OC}$ ) of a substance. As long as the full application rate is considered, this approach assumes applications. Where appropriate, crop interception may be considered in the same way as for calculation of PEC<sub>soil</sub>, PEC<sub>gw</sub> and PEC<sub>sw</sub>, in order to increase realism.

The standard assumptions for  $PEC_{soil}$  calculations from the Fate section are applied, i.e. a field soil layer with a depth of 5 cm and a density of 1.5 kg/L. For pesticides incorporated into the soil, a soil layer of 5 cm or deeper (reflecting actual incorporation depth) is relevant. Depending on the distribution coefficient  $K_d$  of the substance, a part of it is sorbed to the soil matrix and the remaining part is dissolved in the pore water. Only the latter part is of interest for further considerations.

$$\mathbf{X}_{pw} = \frac{\mathbf{V}_{pw}}{\mathbf{V}_{pw} + \mathbf{V}_{s} \times \mathbf{d} \times \mathbf{K}_{d}}$$

With:

 $X_{pw} =$  fraction of substance in pore water  $V_{pw} =$  volume of pore water

 $V_s =$  volume of soil – here per field area: 0.05 m<sup>3</sup>/m<sup>2</sup> (at 5 cm depth)

<sup>&</sup>lt;sup>2</sup> Forum for the Co-ordination of pesticide fate models and their use

<sup>&</sup>lt;sup>3</sup> Pesticide Root Zone Model



d = soil density - 1.5 kg/L (default)

 $K_{d=}$  distribution coefficient of the substance

To achieve  $V_{pw}$  after rainfall, the amount of precipitation per m<sup>2</sup> is added to the pore water volume before rainfall. A realistic estimate for the latter considers a moisture level of 50 % of field capacity with field capacity 0.4 m<sup>3</sup>/m<sup>3</sup>. Multiplication of the figures for 50 % field capacity and soil depth yields 0.01 m<sup>3</sup>/m<sup>2</sup> as pore water volume before rainfall.

The amount of precipitation must be fixed at a level high enough to ensure production of runoff water, but all precipitation above this threshold will lead to dilution of concentrations in runoff water. In FOCUS surface water, the pesticide application timer (PAT) is used for setting the application date due to the requirement that at least 10 mm of precipitation be received within ten days following application (FOCUS, 2001). Therefore, a value of  $10 \text{ mm} = 10 \text{ L/m}^2$  is assumed in this model. So, with a K<sub>d</sub> of 1, the fraction in pore water would be:

$$X_{pw} = \frac{0.02}{(0.02 + 0.05 \times 1 \times 1.5)} = 0.21$$

The pesticide concentration in the pore water is then calculated as follows:

$$C_{pw} = \frac{X_{pw} \times AR/10}{V_{pw}}$$

With:

AR = application rate in g/ha; divisor of 10 to achieve rate in mg/m<sup>2</sup>

For  $K_d = 1$  and an application rate of 1 kg/ha (100 mg/m<sup>2</sup>), the concentration, taking into account a divisor of 1000 for recalculation from m<sup>3</sup> to L, would thus amount to:

$$C_{_{pw}} = \frac{0.21 \times 100}{0.02 \times 1000} = 1.05 \text{mg/L}$$

As stated above, only a part of this diluted pore water will leave the field as runoff, while the concentration of the water remaining in puddles on the field will not change; only the actual volume of water in puddles would be affected. So, it can be concluded that  $PEC_{puddle} = C_{pw}$ .

For use in the context of the bird and mammal risk assessment, the  $K_d$  parameter is replaced by the more likely available  $K_{OC}$  (ie.  $K_d$  normalised to the organic carbon content  $frac_{OC}$  of the soil,  $K_{OC} = K_d / frac_{OC}$ ). This requires introducing a standard factor for  $frac_{OC}$  in the calculation where 2 % is proposed as a typical value for field soils. The equations can then be combined and rearranged to give  $PEC_{puddle}$  in mg/L as a function of application rate and  $K_{OC}$ , taking into account a divisor of 1000 for recalculation from m<sup>3</sup> to L.



$$\text{PEC}_{\text{puddle}} = \frac{\text{AR}/10}{1000(w + \text{Koc} \times s)}$$

With:

AR = application rate [g/ha]; divisor of 10 to achieve rate in mg/m<sup>2</sup>

 $w = V_{pw} = 0.02$  (pore water term)

 $s = V_s \times d \times frac_{OC} = 0.0015$  (soil term)

When multiple spray applications are considered, a multiple application factor (MAF) based on the  $DT_{50}$  in soil (single first order kinetics, geometric mean as used for  $PEC_{gw}$  and  $PEC_{sw}$ ) may be applied to achieve the effective application rate  $AR_{eff}$ .

$$AR_{eff} = AR \times MAF_{m} = AR \times \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

With:

 $k = \ln(2)/\mathrm{DT}_{50}$  (rate constant)

n = number of applications

i = application interval (d)

### Drinking water rates (DWR) for indicator bird species (potential use in refined RA)

New data on water demand and water balance of birds have recently been made available as drinking water rates (DWR) by Defra4 (2007). Conceptually, these are based on the work of Nagy and Peterson (1988) who provided allometric equations for total water fluxes for birds as well as for mammals. Drinking water rates can be calculated from these values by subtracting the water amounts contained in food items and metabolic water formed during food digestion. For calculation of the latter, data on the daily energy expenditure (DEE) of animals as well as on food water content and metabolic water production are required, which can be either found in Appendices G and L or in the report by Defra (2007). DWRs for selected generic focal species representing different dietary guilds are presented in Table 1 and Table 2 below, together with further information on how they were derived. In principle, such values may also be used for assessing the risk from combined dietary and drinking water uptake of a pesticide for a focal species. However, it should be noted that no robust and reliable model for assessing such combined exposure can currently be proposed.

<sup>&</sup>lt;sup>4</sup> Department for Environment, Food and Rural Affairs



Generic FS	BW	Food type	FIR (fresh mat.)	Moist.	Food water	Water flux		Metabolic water	DWR	DWR/ BW
	(g)		(g/d)	(%)	(mL)	Equation	Flux (mL/d)	(mL)	(mL/d)	
Granivorous bird 'finch'	15.3	Cereal seeds	5.4	14.7	0.8	Passerine <sup>1</sup>	9.8	$2.0^{3}$	7.0	0.46
Insectivorous bird 'warbler'	9.5	Arthropods	9.2	68.8	6.3	Passerine <sup>1</sup>	6.1	1.44	-1.6	-0.17
Large herbivorous bird 'goose'	3108	Grasses, cereal shoots	782.9	76.4	598.1	All birds <sup>2</sup>	490.5	68.7 <sup>5</sup>	-176.3	-0.06
Medium herbivorous bird 'partridge'	390	Non-grass herbs	214.2	88.1	188.7	All birds <sup>2</sup>	110.5	10.4 <sup>5</sup>	-88.6	-0.23

Table 1. Drinking water rates (DWR) for selected generic focal bird species after Defra (2007).

1 log WF = log a + b × log BW; with log a = -0.195, b = 1.003

2 log WF = log a + b × log BW; with log a = 0.183, b = 0.718

3 factor for seeds from bird studies: 0.0294 mL/kJ

4 factor for insects from bird studies: 0.0257 mL/kJ

5 mean factor: 0.0278 mL/kJ

Table 2.	Drinking water rates (DWR) for selected generic focal mammal species after Nagy and
	Peterson (1998) and Defra (2007).

Generic FS	BW	Food type	FIR (fresh mat.)	Moist.	Food water	Water flux		Metabolic DWR water		DWR/ BW
	(g)		(g/d)	(%)	(mL)	Equation	Flux (mL/d)	(mL)	(mL/d)	
Granivorous mammal 'mouse'	21.7	Cereal seeds	4.5	14.7	0.7	Non- desert species <sup>1</sup>	7.4	1.6 <sup>2</sup>	5.1	0.24
Insectivorous mammal 'shrew'	9.7	Arthropods	5.3	68.8	3.6	Non- desert species <sup>1</sup>	4.1	0.9 <sup>2</sup>	-0.4	-0.04
Small herbivorous mammal 'vole'	25.0	Grasses, cereal shoots	34.1	76.4	26,0	Non- desert species <sup>1</sup>	8.3	1.8 <sup>2</sup>	-19,5	-0.78
Medium herbivorous mammal 'rabbit'	1543	Non-grass herbs	791.6	88.1	697.4	Non- desert species <sup>1</sup>	169.9	34.5 <sup>2</sup>	-562,0	-0.36

log WF = log a + b × log BW; with log a = -0.110, b = 0.7342

mean factor: 0.0278 mL/kJ

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# APPENDIX L

# ENERGY, MOISTURE CONTENT AND ASSIMILATION EFFICIENCY OF BIRD AND MAMMAL FOOD

This Appendix contains the document

# "Energy, moisture content and assimilation efficiency of bird and mammal food"

by C.E. Smit.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> In: Factsheets for the (eco)toxicological risk assessment strategy of the National Institute for Public Health and the Environment, Part V, eds. J.W.A. Scheepmaker, C.E. Smit, M.T.M. van Raaij, RIVM report 601516013/2005, Bilthoven, The Netherlands.

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"Energy, moisture content and assimilation efficiency of bird and mammal food".

Author: C.E. Smit

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# 1. Introduction

The risk assessment for birds and mammals as performed within the framework of EU Directive 91/414/EC is based on a comparison of the estimated daily uptake of a pesticide with the toxic dose for that compound. The principles of the risk assessment are laid down in a guidance document (EC, 2002). The main exposure route is assumed to be ingestion of food items containing spray residues. Additional exposure may take place by secondary poisoning via eating of contaminated earthworms or fish.

For the exposure via sprayed food, the daily pesticide uptake for a given species is determined by the daily intake of a specific food type (Food Intake Rate, FIR), the concentration of the pesticide in that food, the fraction of the diet that is contaminated, the fraction of a specific food type in the total diet and the potential to avoid contaminated food. The FIR is equal to the daily energy expenditure divided by the energy content of the food with a correction for assimilation efficiency expressed per day. For the standard risk assessment, four typical bird and mammal species are distinguished, in combination with four different food types. In order to establish the FIR for these four indicator species, data on DEE, energy and moisture content and assimilation efficiency have been collected at the Central Science Laboratory in York, United Kingdom (Crocker *et al.*, 2002).

For caloric values, the CSL dataset contains about 2000 data, which are grouped into 15 different food categories. A summary of the data as presented in the CSL report is given in Table 1.

Group	Energy content [kJ/g DW]	Moisture content [%]
Dicot. crop leaves	11.2	88.6
Grasses and cereal shoots	18.0	76.4
Non-grass herbs	18.0	82.1
Tree leaves	20.7	51.4
Orchard topfruit	11.6	83.7
Cereal seeds	16.7	13.3
Weed seeds	21.0	11.9
Small mammals	21.7	68.6
Bird and mammal carrion	22.6	68.8
Arthropods	21.9	70.5
Caterpillars	21.7	79.4
Soil invertebrates (earthworms and slugs)	19.3	84.6
Fish	20.7	71.1
Aquatic invertebrates	19.6	77.3
Aquatic vegetation	15.0	81.4

Table 1. Energy and moisture content of several food sources (Crocker et al., 2002).

For assimilation efficiency of *birds*, the average data as presented by Bairlein (1998) are used by CSL. For assimilation efficiency of *mammals*, the dataset contains 91 individual records. Resulting values are given in Tables 2 and 3 below.



# **Table 2.** Assimilation efficiency [%] of different food types for birds (Crocker *et al.*,<br/>2002; taken from Bairlein, 1998)

Bird order	Representatives	Food type						n	n
	_	animals	fruits	herbage	seeds	sugars	artificial	species	cases
Struthioniformes	Ostriches			36				2	6
Gruiformes	Cranes, coots, rails	34	45	59			69	1	5
Ralliformes	Coots, rails							1	1
Charadriiformes	Gulls, waders	69					74	7	19
Lariformes	Gulls, terns	79						1	3
Alciformes	Auks	76						1	2
Sphenisiciformes	Penguins	75						7	26
Procellariformes	Petrels	87						2	3
Pelecaniformes	Pelicans, gannets, cormorants	80	76					4	8
Columbiformes	Pigeons						76	4	36
Psittaciiformes	Parrots					96		1	4
Strigiformes	Owls	77						6	45
Falconiformes	Eagles, falcons	84						4	12
Accipitriformes	Hawks	82						11	22
Ciconiiformes	Herons, storks	80						4	8
Anseriformes	Ducks, geese	87		41	83		74	22	98
Galliformes	Fowl	70	57	42	65		67	18	184
Opisthocomiformes	Hoatzin (S. America)						74	1	2
Trochiliformes	Hummingbirds					98		7	16
Coliiformes	Mousebirds (Africa)		56				73	4	14
Piciformes	Woodpeckers	64		61			80	1	14
Passerriformes	Passerines	76	67	76	80	09	72	67	441

**Table 3.** Assimilation efficiency [%] of different food types for mammals (Crocker *et al.*, 2002).

Mammal species	Food type	mean	SD	n
shrews and bats	insects	88	5.9	8
Carnivores	vertebrates	85	5.8	16
Squirrels	nuts	85	7.5	10
small mammals	seeds and nuts	83	8.5	11
small mammals	grasses	46	10.7	15
small mammals	crops, forbs, mixed vegetation	74	12.3	17
Lagomorphs	general vegetation	74	13.5	4
white tailed deer	tree tissue	32	8.4	7
Ruminants	hay and browse	80	2.8	3

About 10 years ago, a similar dataset has been established at the RIVM to be used in a food chain model for birds and mammals. The data were published in an RIVM report (Jongbloed *et al.*, 1994) and referred to by Traas *et al.* (1996). The purpose of the current project was to combine both datasets to obtain a more complete database which in the future can be used to refine the existing exposure scenarios and to establish scenarios for new indicator species.

# 2. Methods

## 2.1 Caloric values, moisture and ash content

## 2.1.1 Data arrangement

A first comparison the two datasets with respect to caloric value and moisture content indicated that there was little overlap in literature sources. This can be explained by the



fact that these data are often published as part of a different type of research, and are thus not found with a keyword based literature search.

Both datasets were available as Excel-spreadsheets in which data for different organism groups were ordered, but not to the same taxonomic level. After combining both files, data were therefore first sorted by scientific species names. Obvious duplicates with the same literature reference were removed. For suspected duplicates, those values that were (nearly) the same but originated from different sources, the original reference was retrieved where possible and the numbers were checked. It appeared that a number of references in both the CSL and the RIVM file were review papers and in addition, various data originated from different papers by the same author(s). Duplicate values could therefore often be attributed to citations or self-citations.

After removal of duplicates, taxonomic position of the species was checked and/or completed using the Integrated Taxonomic Information System on-line database, <u>http://www.itis.usda.gov</u>, an internet database containing authoritative taxonomic information on plants, animals, fungi and microbes. Data were then ordered into the following main groups: fungi, annelids, molluscs, fish, arthropods, seeds, tree and plant tissue, fruit, birds, mammals, fodder and other. Additional information on life form or habitat was also obtained from the internet.

# 2.1.2 Data treatment and statistical methods

The CSL dataset contained information on caloric content on a dry weight basis (kJ/g DW) and % moisture, the RIVM dataset has additional values for caloric content on the basis of fresh weight (kJ/g FW) and ash-free dry weight (kJ/g AFDW), and for % ash content. After re-arranging the dataset, missing variables were calculated from the other parameters where possible, if kJ/g DW and % ash were available, kJ/g AFDW was calculated, kJ/g FW was calculated from kJ/g DW and % moisture and so on.

Data within each main group were subdivided on the basis of taxonomic level, habitat and/or life stage or because it is anticipated that birds or mammals forage on a specific type of food. Statistical analyses were performed with GraphPad Prism 4.0. Significant differences in caloric content between sub-groups were identified using the dry weight data, because this parameter had the highest number of observations and the smallest variation within subgroups. In case of a comparison between two sub-groups, an unpaired two-sided t-test was used; three or more groups were compared using one-way ANOVA with Tukey's multiple comparison of means. Non-parametric variants were used in case data were not normally distributed and/or variances were not homogeneous. P was 0.05 in all cases.

# 2.2 Assimilation efficiency

# 2.2.1 Birds

For assimilation efficiency of *birds*, Dr. Franz Bairlein of the Institute of Avian Research in Wilhelmshaven, Germany, kindly supplied the underlying data on which the CSL overview was based. It appeared that this dataset, with over 1200 entries, completely covers the RIVM data. This means that for birds, the values as presented in the CSL report (see Table 2) remain unchanged.



# 2.2.2 Mammals

For assimilation efficiency of *mammals*, the CSL and RIVM database relied partly on different literature sources. A comparable strategy as presented above was followed, except that food was not classified to the species level but only sorted by category. The following food types were distinguished: fodder, vertebrates, insects, nuts and seeds, grasses, non-grass herbs/crops and mixed plants, and tree tissue. The different food sources were compared taking all mammals together. Where possible, differences between mammal groups for one type of food were analysed.

# 3. Results

# 3.1 Caloric values, moisture and ash content

For each of the main groups, the average, standard deviation, minimum and maximum and number of observations for the respective parameters are given in the summary tables below. The Coefficient of Variation (CV) is the standard deviation expressed as percentage of the mean (= [SD/mean] x 100 %). The results of the statistical analysis of the kJ/g DW data are given in separate tables.

# 3.1.1 Annelids

The annelids were divided into terrestrial and aquatic species. No further division in life stage or habitat (freshwater or marine) was made because too few data were available. Terrestrial and aquatic annelids did not significantly differ in caloric content (two-sided t-test, P > 0.05).

Parameter	Subgroup	mean	SD	CV [%]	min	max	n
kJ/g FW	all values	3.1	1.5	49	0.6	9.4	31
	terrestrial	3.2	0.3	8	2.7	3.5	8
	aquatic	3.1	1.8	57	0.6	9.4	23
kJ/g DW	all values	18.7	4.7	25	8.9	31.5	48
_	terrestrial	18.7	3.0	16	13.0	22.2	16
	aquatic	18.6	5.4	29	8.9	31.5	32
kJ/g AFDW	all values	21.6	2.8	13	19.7	23.6	2
	terrestrial	23.6	-	-	-	-	1
	aquatic	19.7	-	-	-	-	1
% H2O	all values	82.8	5.9	7	62.0	97.6	31
	terrestrial	83.3	1.4	2	80.0	85.0	10
	aquatic	82.5	7.2	9	62.0	97.6	21
% ash	all values	0.8	-	-	-	-	1
	terrestrial	0.8	-	-	-	-	1
	aquatic	-	-	-	-	-	

Table 4. Caloric values, moisture and ash content of annelids.



# 3.1.2 Molluscs

A sub-division was made between terrestrial gastropods and aquatic gastropods, bivalves and cephalopods. Only few data were available for the latter group and they were not included in the statistical analysis. There was a significant difference in caloric content between terrestrial and aquatic gastropods and between aquatic gastropods and bivalves. Bivalves and terrestrial gastropods did not significantly differ, and terrestrial gastropods were not significantly different from terrestrial annelids (see above).

Parameter	Subgroup	mean	SD	CV [%]	min	max	n
kJ/g FW	all values terrestrial gastropods	2.2	1.5 -	69	0.6	6.9	68
	aquatic gastropods	2.1	1.6	73	0.8	6.9	34
	bivalves	1.9	1.1	61	0.6	4.9	29
	cephalopods	4.7	0.8	17	3.6	5.6	5
kJ/g DW	all values	18.2	3.6	20	3.8	27.7	95
	terrestrial gastropods	20.0	1.3	7	17.2	21.9	9
	aquatic gastropods	16.8	4.2	25	3.8	27.7	49
	bivalves	19.3	2.0	10	14.3	25.5	35
	cephalopods	23.8	0.4	2	23.5	24.0	2
kJ/g AFDW	all values	25.2	7.5	30	14.6	54.6	24
-	terrestrial gastropods	22.5	2.6	12	19.8	25.0	3
	aquatic gastropods	26.8	7.9	30	20.7	54.6	18
	bivalves	18.6	3.5	19	14.6	21.3	3
	cephalopods	-	-	-	-	-	-
% H₂O	all values	86.8	10.7	12	42.8	96.9	77
	terrestrial gastropods	85.7	3.2	4	80.2	90.6	17
	aquatic gastropods	84.5	14.5	17	42.8	96.0	34
	bivalves	91.7	5.5	6	75.6	96.9	24
	cephalopods	78.9	4.0	5	76.0	81.7	2
% ash	all values	35.0	19.5	56	1.0	74.6	21
	terrestrial	22.8	-	-	-	-	1
	aquatic	37.3	20.0	54	1.0	74.6	18
	bivalves	19.8	10.7	54	12.2	27.3	2
	cephalopods	-	-	-	-	-	-

 Table 5.
 Caloric values, moisture and ash content of molluscs.

## Table 6. Comparison of mean caloric content (kJ/g DW) for molluscs.

all valu	sentex rile served serv							
	ial gastropods			*	n.s.			
aquatio	gastropods		*		**			
Bivalve	es		n.s.	**				
cephal	opods							
**	significant, one-way ANC	DVA wit	h Tuke	y's, P <	0.01			
*	significant, one-way ANC	DVA wit	h Tuke	y's, P <	0.05			
n.s.	not significant, one-way	ANOVA	۱.					
	not tested							



# 3.1.3 Arthropods

The arthropods were divided into aquatic and terrestrial species and for each group a subdivision was made between larvae or sub-adults on the one hand, and adults, mixed or non-specified life-stages on the other hand. The aquatic species were also divided into marine and freshwater species. It should be noted that for most of the freshwater species only the larval stage is truly aquatic. The adults often have a wet habitat, but do not actually live in the water. Caloric values are presented in Table 7, moisture and ashcontent in Table 8.

	Table 7.	Caloric values of arthropods.
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Parameter	Subgroup	mean	SD	CV	min	max	n
	- •			[%]			
kJ/g FW	all values	5.6	2.8	50	0.9	22.5	166
-	aquatic and terrestrial, larvae	6.3	3.2	51	1.9	14.7	28
	aquatic and terrestrial, adults	5.4	2.7	50	0.9	22.5	138
	aquatic, freshwater and marine	4.9	2.6	52	0.9	22.5	113
	aquatic, freshwater	5.1	2.7	53	0.9	22.5	98
	aquatic, freshwater, larvae	3.6	0.8	22	2.9	4.7	4
	aquatic, freshwater, adults	5.1	2.7	53	0.9	22.5	94
	aquatic, marine, adults	4.0	1.3	32	1.6	5.5	14
	terrestrial	7.0	2.7	39	1.9	14.7	53
	terrestrial, larvae	6.8	3.2	47	1.9	14.7	23
	terrestrial, adults	7.1	2.4	34	3.1	14.0	30
kJ/g DW	all values	21.7	3.8	17	7.4	31.0	582
•	aguatic and terrestrial, larvae	22.4	3.2	14	10.3	31.0	185
	aquatic and terrestrial, adults	21.4	4.0	19	7.4	30.9	397
	aquatic, freshwater and marine	20.1	4.3	21	7.4	29.2	232
	aquatic, freshwater	20.9	3.5	17	9.0	29.2	202
	aquatic, freshwater, larvae	20.9	3.7	18	10.3	29.2	49
	aquatic, freshwater, adults	20.9	3.5	17	9.0	28.0	153
	aquatic, marine, adults	15.3	5.5	36	7.4	25.2	29
	terrestrial	22.7	3.0	13	10.3	31.0	350
	terrestrial, larvae	23.0	2.8	12	11.8	31.0	135
	terrestrial, adults	22.6	3.2	14	10.3	30.9	215
kJ/g AFDW	all values	23.7	2.5	10	16.0	31.6	257
	aquatic and terrestrial, larvae	23.5	2.1	9	18.3	29.8	80
	aquatic and terrestrial, adults	23.7	2.6	11	16.0	31.6	177
	aquatic, freshwater and marine	22.9	2.6	12	16.0	31.1	118
	aquatic, freshwater	23.0	2.7	12	16.0	31.1	110
	aquatic, freshwater, larvae	23.3	2.4	10	19.1	29.8	34
	aquatic, freshwater, adults	22.8	2.8	12	16.0	31.1	76
	aquatic, marine, adults	21.6	1.9	9	19.1	24.4	
	terrestrial	24.4	2.1	9	18.3	31.6	139
	terrestrial, larvae	23.7	1.9	8	18.3	29.2	46
	terrestrial, adults	24.7	2.1	9	19.2	31.6	93

The relatively low dry weight based value for marine arthropods (15.3 kJ/g DW) is caused by the inclusion of crabs in this dataset, which all had a lower energy content as compared to the other groups (mainly shrimps). The most probable explanation for this is that the exoskeleton was included in the analysis. The dataset for ash free dry weight energy content only contained shrimps and the resulting mean value is comparable with that of the other arthropod groups.



Parameter	Subgroup	mean	SD	CV [%]	min	max	n
% H₂O	all values	71.5	9.4	13	38.1	96.0	265
	aquatic and terrestrial, larvae	72.7	10.0	14	46.6	92.0	57
	aquatic and terrestrial, adults	71.1	9.2	13	38.1	96.0	206
	aquatic, freshwater and marine	75.9	8.8	12	38.1	96.0	99
	aquatic, freshwater	76.3	8.0	10	61.0	96.0	83
	aquatic, freshwater, larvae	79.9	8.3	10	74.0	85.8	2
	aquatic, freshwater, adults	76.2	8.0	11	61.0	96.0	81
	aquatic, marine, adults	74.0	12.7	17	38.1	89.8	15
	terrestrial	68.8	8.7	13	44.2	92.0	166
	terrestrial, larvae	72.4	10.1	14	46.6	92.0	54
	terrestrial, adults	67.0	7.4	11	44.2	82.8	110
% ash	all values	7.6	9.4	124	0.0	56.0	219
	aquatic and terrestrial, larvae	8.8	10.1	114	0.0	48.0	65
	aquatic and terrestrial, adults	7.1	9.1	129	0.1	56.0	154
	aquatic, freshwater and marine	11.9	11.1	93	0.0	56.0	96
	aquatic, freshwater	11.1	10.4	94	0.0	48.0	88
	aquatic, freshwater, larvae	13.7	12.8	93	0.0	48.0	31
	aquatic, freshwater, adults	9.6	8.5	89	0.8	31.7	57
	aquatic, marine, adults	21.0	15.0	71	7.0	56.0	8
	terrestrial	4.2	6.1	145	0.1	55.0	123
	terrestrial, larvae	4.4	2.2	50	0.5	8.9	34
	terrestrial, adults	4.2	7.1	169	0.1	55.0	89

## **Table 8.** Moisture and ash content of arthropods.

There was no significant difference in caloric content of adults and larvae within the terrestrial and freshwater groups, the marine group contained only one value for the larval stage. There was a significant difference between the caloric content of marine and freshwater adults, the same was found for the grouped means of freshwater and terrestrial arthropods (Table 9).

**Table 9.** Comparison of mean caloric content (kJ/g DW) for arthropods.

	aq. + terr. all	aq. + terr. larvae	aq. + terr. adults	freshwater, all	freshwater, larvae	freshwater, adults	marine, adults	terrestrial, all	terrestrial, larvae	terrestrial, adults
aquatic + terrestrial, all										
aquatic + terrestrial, larvae			n.s.							
aquatic + terrestrial, adults		n.s.								
Freshwater, all								***		
Freshwater, larvae						n.s.				
Freshwater, adults					n.s.		***			
marine, adults						***				
terrestrial, all				***						
terrestrial, larvae										n.s.
terrestrial, adults									n.s.	
*** significant, t-test, P < 0.0	significant, t-test, P < 0.001									
n.s. not significant, t-test, P >	0.05									
not tested										

# 3.1.4 Tree and plant tissue

Tree and plant tissue data were divided on the basis of life form (trees or plants) and taxonomy (*Poaceae* and other plants) and for plants, a subdivision was made on the basis of the plant parts analysed. Caloric content of various plant parts was not significantly



different, as was the case for the difference between cereals and other grasses. Caloric content is given in Table 10, moisture and ash content of tree and plant tissue is given in Table 11.

Parameter	Subgroup	mean	SD	CV [%]	min	max	n
kJ/g FW	tree tissue	9.9	0.8	8	9.0	11.1	5
	conifer needles	9.5	0.0	Õ	9.5	9.6	2
	crop leaves (incl. pods)	1.1	0.6	53	0.5	2.3	20
	cereals and grasses	3.9	1.7	43	2.3	6.1	6
	cereals	2.4	0.1	4	2.3	2.4	2
	other grasses	4.	1.6	34	2.5	6.1	4
	plants, all values	1.9	1.1	56	0.8	3.5	8
	plants, leaves	-	-	-	-	-	-
	plants, roots	1.9	1.0	55	0.8	3.0	4
	plants, stems and branches	-	-	-	-	-	-
	plants, miscellaneous	2.6	1.1	41	1.2	3.5	4
kJ/g DW	tree tissue	20.2	0.9	4	18.9	21.9	16
•	conifer needles	21.2	0.8	4	20.0	22.3	13
	crop leaves (incl. pods)	11.4	3.0	26	6.3	16.7	21
	cereals and grasses	17.6	1.5	8	12.7	20.9	68
	cereals	16.9	2.1	13	12.7	19.6	11
	other grasses	17.8	1.3	7	13.5	20.9	57
	plants, all values	17.8	1.9	11	11.7	23.2	146
	plants, leaves	17.8	1.6	9	14.0	20.0	24
	plants, roots	17.1	1.5	9	13.0	19.8	15
	plants, stems and branches	17.4	1.1	6	16.1	19.4	10
	plants, miscellaneous	18.0	2.1	12	11.7	23.2	98
kJ/g AFDW	tree tissue	-	-	-	-	-	-
-	conifer needles	56.2	1.1	2	21.4	43.3	5
	crop leaves (incl. pods)	-	-	-	-	-	-
	cereals and grasses	19.1	0.9	5	17.6	20.3	10
	cereals	-	-	-	-	-	-
	other grasses	19.1	0.9	5	17.6	20.3	10
	plants, all values	20.1	1.1	6	18.1	23.6	26
	plants, leaves	20.1	0.8	4	19.3	21.4	7
	plants, roots	19.4	-	-	-	-	1
	plants, stems and branches	-	-	-	-	-	-
	plants, miscellaneous	20.1	1.3	6	18.1	23.6	17

## Table 10. Caloric values of tree and plant tissue.



Parameter	Subgroup	mean	SD	CV [%]	min	max	n
% H₂O	tree tissue	49.5	4.4	9	42.7	54.7	5
	conifer needles	56.2	1.1	2	55.4	56.9	2
	crop leaves (incl. pods)	88.5	4.6	5	79.7	95.3	31
	cereals and grasses	76.4	5.7	7	68.5	87.6	11
	cereals	82.2	5.3	6	77.0	87.6	3
	other grasses	74.2	4.3	6	68.5	81.5	8
	plants, all values	88.1	5.4	6	80.0	95.0	8
	plants, leaves	-	-	-	-	-	-
	plants, roots	88.4	5.8	7	81.9	95.0	4
	plants, stems and branches	-	-	-	-	-	-
	plants, miscellaneous	84.7	4.4	5	80.0	90.0	4
% ash	tree tissue	-	-	-	-	-	-
	conifer needles	18.2	26.7	147	2.3	49.0	3
	crop leaves (incl. pods)	-	-	-	-	-	-
	cereals and grasses	4.2	1.6	38	1.6	6.1	9
	cereals	-	-	-	-	-	-
	other grasses	4.2	1.6	38	1.6	6.1	9
	plants, all values	7.2	4.0	57	0.5	18.0	21
	plants, leaves	8.8	0.6		8.2	10.0	7
	plants, roots	1.4	-	-	-	-	1
	plants, stems and branches	-	-	-	-	-	-
	plants, miscellaneous	7.1	4.7	67	0.5	18.0	12

## Table 11. Moisture and ash content of tree and plant tissue.

Pooled means for plants and for cereals and other grasses were not significantly different from each other. There was also no significant difference between tree tissue and conifer needles. Other groups differed significantly (Table 12).

Table 12. Comparison of mean caloric content (kJ/g DW) for tree	e and plant tissue.
---	---------------------

tree tissue conifer needles conifer needles crop leaves plants, roots plants, roots plants, stems									plants, misc.		
tree tissue		n.s.	***	***							
conifer needles	n.s.		***	***							
crop leaves	***	***		***							
cereals/grasses	***	***	***								
cereals						n.s.					
other grasses					n.s.						
plants, all values	***	***	***	n.s.							
plants, leaves									n.s.	n.s.	n.s.
plants, roots								n.s.		n.s.	n.s.
plants, stems and branches								n.s.	n.s.		n.s.
plants, miscellaneous								n.s.	n.s.	n.s.	
*** significant, one-way ANC	OVA with	n Tukey'	's test o	r Kruska	al-Wallis	s with D	unn's te	est, P <	0.001		
n.s. not significant, one-way	not significant, one-way ANOVA with Tukey's test or Kruskal-Wallis with Dunn's test, P > 0.05										
n.s. not significant, Mann-Wh	itney te	st, P > 0	0.05								
not tested	-										

## 3.1.5 Seeds

For seeds, a similar division was made as for tree and plant tissue, and a distinction was made between kernels and whole seeds. Non-specified values were added to the dataset



for whole seeds. Caloric content is given in Table 13, moisture and ash content in Table 14.

Table 13. Caloric v	alues of tree	and plant seeds.
---------------------	---------------	------------------

Parameter	Subgroup	mean	SD	CV [%]	min	max	n
kJ/g FW	all seeds	18.8	6.3	33	2.4	31.8	57
	kernels	22.3	6.4	29	6.9	31.8	20
	whole/not specified	16.9	5.3	32	2.4	31.0	37
	cereals	13.2	3.7	28	2.4	17.1	14
	grasses (incl. sedges)	16.8	0.6	3	16.4	17.2	2
	grasses, kernels						
	grasses, whole/not specified	16.4	17.2	105	16.8	0.6	2
	non-grass plants	18.6	5.8	31	12.4	29.4	6
	non-grass plants, kernels						
	non-grass plants, whole/not specified	18.6	5.8	31	12.4	29.4	6
	non-conifer trees	20.5	6.2	30	6.9	31.8	30
	non-conifer trees, kernels	21.5	7.2	33	6.9	31.8	15
	non-conifer trees, whole/not specified	19.6	5.0	26	12.1	31.0	15
	conifers	24.8	2.2	9	22.8	28.4	5
	conifers, kernels	24.8	2.2	9	22.8	28.4	5
	conifers, whole/not specified						
J/g DW	all seeds	21.6	4.1	19	9.5	33.6	292
-	kernels	24.8	4.8	19	15.0	33.6	66
cere gras gras gras non- non- non-	whole/not specified	20.7	3.5	17	9.5	32.8	226
	cereals, whole/not specified	17.6	1.8	10	12.8	19.7	41
	grasses (incl. sedges)	19.1	1.0	5	16.8	21.8	42
	grasses, kernels	19.7	1.0	5	18.5	21.2	6
	grasses, whole/not specified	19.0	1.0	5	16.8	21.8	36
	non-grass plants	21.7	3.3	15	9.5	31.4	109
	non-grass plants, kernels	23.3	3.4	14	19.0	30.8	11
	non-grass plants, whole/not specified	21.5	3.2	15	9.5	31.4	98
	non-conifer trees	22.9	4.5	19	15.0	33.6	67
	non-conifer trees, kernels	24.1	5.0	21	15.0	33.6	31
	non-conifer trees, whole/not specified	21.9	3.7	17	15.9	32.8	36
	conifers	27.2	3.1	11	18.6	32.4	33
	conifers, kernels	28.4	3.1	11	18.6	32.4	5
	conifers, whole/not specified	25.7	2.4	9	19.7	29.8	15
J/g AFDW	all seeds	25.6	4.8	19	17.4	34.0	51
5	kernels	28.1	4.3	15	18.7	34.0	25
	whole/not specified	23.2	3.9	17	17.4	33.6	26
	cereals	19.4	1.3	7	18.4	20.3	2
	grasses (incl. sedges)			•		2010	-
	grasses, kernels						
	grasses, whole/not specified	11.6	1.8	16	10.3	12.9	2
	non-grass plants	22.7	2.8	12	20.7	24.7	2
	non-grass plants, kernels	22.1	2.0	12	20.7	27.1	2
	non-grass plants, whole/not specified						
	non-conifer trees	23.9	4.3	18	17.4	34.0	28
	non-conifer trees, kernels	25.3	4.5	18	18.7	34.0	11
	non-conifer trees, whole/not specified	23.0	4.0	17	17.4	33.6	17
	conifers	23.0	4.0 2.7	9	23.6	33.3	18
	conifers, kernels	30.7	2.1	7	26.1	33.3	13
	conifers, whole/not specified	26.7	2.1	8	23.6	28.8	5



## Table 14. Moisture and ash content of seeds.

Parameter	Subgroup	mean	SD	CV [%]	min	max	n
% H₂O	all seeds	14.6	12.0	82	2.8	87.6	70
	kernels	15.5	11.7	76	5.0	54.0	21
	whole/not specified	14.3	12.2	85	2.8	87.6	49
	cereals	17.7	18.1	102	5.8	87.6	17
	grasses (incl. sedges) grasses, kernels grasses, whole/not specified	11.6	1.8	16	10.3	12.9	2
	non-grass plants non-grass plants, kernels	9.9	2.8	29	6.0	13.0	7
	non-grass plants, whole/not specified	9.6	2.9	31	6.0	13.0	6
	non-conifer trees	15.0	11.0	74	2.8	54.0	34
	non-conifer trees, kernels	16.8	13.6	81	5.0	54.0	15
	non-conifer trees, whole/not specified	13.5	8.6	64	2.8	34.6	19
	conifers	12.2	4.5	37	6.9	19.0	5
	conifers, kernels conifers, whole/not specified	12.2	4.5	37	6.9	19.0	5
% ash	all seeds	4.2	2.8	68	0.4	19.4	47
	kernels	4.2	1.4	34	1.6	6.9	24
	whole/not specified	4.1	3.8	93	0.4	19.4	23
	cereals grasses (incl. sedges) grasses, kernels grasses, whole/not specified non-grass plants non-grass plants, kernels	1.0	0.8	82	0.4	1.5	2
	non-grass plants, whole/not specified non-conifer trees	3.9	1.8	46	1.6	7.1	25
	non-conifer trees, kernels	3.9	1.8	40	1.6	6.9	25
	non-conifer trees, whole/not specified	3.9	1.7	44 49	1.6	7.1	14
	conifers	3.9 4.0	1.9	49 37	0.9	6.1	14
	conifers, kernels	4.0 4.5	1.5	26	2.3	6.1	13
	conifers, whole/not specified	2.8	1.6	20 59	0.9	4.9	5

It was first tested whether kernels and whole seeds were different, this was the case when all seeds were combined, for conifers and trees, but not for grasses and non-grass plants (t-test). Thereafter, differences in caloric content of kernels and whole seeds between groups were tested (one-way ANOVA). Results are summarised in Table 15.



	all seeds	kernels	whole/not spec.	cereals, whole	grasses	grasses, kernels	grasses, whole	non-grass plants	non-grass plants, kernels	non-grass plants, whole	non-conifer trees	non-conifer trees, kernels	non-conifer trees, whole	conifers	conifers, kernels	conifers, whole
all seeds																
kernels			***													
whole/not specified		***														
cereals (only whole/not spec.)					n.s.		n.s.	***		***	***		***	***		***
grasses				n.s.				***			***			***	***	
grasses, kernels							n.s.		n.s.	***		n.s.	***		***	***
grasses, whole				n.s.	***	n.s.								***		
non-grass plants non-grass plants, kernels						<b>n</b> 0				n.s.	n.s.	<b>n</b> 0			**	
non-grass plants, whole				***		n.s.	***		n.s.	11.5.		n.s.	***			***
non-conifer trees				***	***			n.s.	11.5.					***		
non-conifer trees, kernels						n.s.		11.5.	n.s.				n.s.		**	
non-conifer trees, whole				***		11.3.	***		11.3.	***		n.s.	11.3.			***
conifers				***	***			***			***	11.0.				
conifers, kernels						***			**			**				**
conifers, whole				***			***			***			***		**	
*** significant, one-way ANOV	A with	n Tuke	y's tes	st or K	ruskal	Wallis	with I	Dunn's	s test,	P < 0.	001					
n.s. not significant, one-way Al			•													
*** significant, Mann Whitney			-													
** significant, t-test, P < 0.01																
n.s. not significant, t-test or Ma	nn \//ł	hitney	tast D	< 0 0	5											
<b>u</b>		пању	1031, F	- 0.0	0											
not tested																

## Table 15. Comparison of mean caloric content (kJ/g DW) for seeds.

# 3.1.6 Vertebrates

A summary of vertebrate food sources fish, birds and mammals (including meat) is given in Table 16. Dry weight caloric content of birds and mammals and of mammals and fish did not significantly differ; the difference between fish and birds was significant (Kruskal-Wallis with Dunn's test, P < 0.001).



Parameter	Subgroup	mean	SD	Cv [%]	min	max	n
kJ/g FW	fish	6.1	2.1	35	2.9	11.2	66
-	birds	7.7	2.4	31	3.5	17.7	57
	mammals	7.1	1.8	25	3.2	11.5	64
kJ/g DW	fish	21.0	3.7	18	12.0	30.5	60
	birds	24.2	5.2	21	16.8	38.6	141
	mammals	22.2	2.9	13	16.5	28.3	109
kJ/g AFDW	fish	-	-	-	-	-	-
0	birds	27.2	5.4	20	19.1	38.8	68
	mammals	25.8	2.9	11	20.9	30.9	39
% H₂O	fish	73.7	5.4	7	62.3	81.8	43
-	birds	67.2	7.7	11	44.0	84.6	54
	mammals	69.6	5.7	8	58.8	84.5	66
% ash	fish	-	-	-	-	-	
	birds	8.5	5.0	59	0.3	16.2	64
	mammals	9.0	4.0	44	1.2	13.4	23

**Table 16.** Caloric values of vertebrate food and fodder.

# 3.1.7 Fruit and fodder

The last group contains data of fruit and of commercial fodder. The data for fodder are mainly for bird fodder (22) with only two for mammal fodder (2). Data are summarised in Table 17.

Parameter	Subgroup	mean	SD	CV [%]	min	max	n
kJ/g FW	fruit	2.2	1.3	57	1.0	5.8	19
	fodder	15.7	3.9	25	11.8	22.8	7
kJ/g DW	fruit	14.8	4.9	33	7.2	22.2	24
	fodder	15.1	2.5	17	12.6	19.7	21
kJ/g AFDW	fruit fodder	- 20.3	- 1.2	-	- 19.4	- 21.1	2
% H₂O	fruit	83.9	4.1	5	74.0	88.0	19
	fodder	8.0	1.7	22	6.0	9.3	3
% ash	fruit fodder	-	-	-	-	-	-

Table 17. Caloric values of fodder.

# **3.2** Assimilation efficiency of mammals

In Table 18, summary statistics are given for the different food types. Assimilation efficiency of grasses and tree-tissue are significantly lower as compared to other food types (one-way ANOVA with Dunnett's test, P < 0.005). For tree tissue, this may be caused by deer having lower efficiencies than other ruminants. The number of data for the latter group, however, is too small to draw conclusions on this. For mammals eating seeds and nuts, there was no difference between squirrels and mice. The same goes for the assimilation efficiency of non-grass herbs/crops and mixed plants by either small mammals or hares and rabbits.

Mammal species	Food type	mean	SD	CV	min	max	n
				[%]			
mouse, rabbit, squirrel, badger	fodder	85.5	10.2	12.0	71.2	95.0	6
shrew, bat	insects	87.4	6.3	7.2	78.0	94.9	8
shrew, otter, bobcat, fox, weasel	vertebrates	80.8	7.3	9.1	62.7	91.0	21
mouse, vole, squirrel	seeds and nuts						
	all mammals	84.3	7.6	9.1	65.2	94.0	23
	squirrels	85.2	7.5	8.8	72.0	94.0	10
	mice	83.6	8.0	9.6	65.2	91.0	13
vole, lemming	grasses	46.8	12.8	27.3	19.0	79.0	35
mouse, vole, hare	non-grass herbs <sup>1</sup>						
	all mammals	75.5	11.0	14.5	50.7	91.4	26
	lagomorphs	74.3	13.5	18.2	60.0	91.3	4
	small mammals	75.7	10.8	14.3	50.7	91.4	22
deer, ruminants	tree tissue						
	all mammals	42.1	21.9	52.1	24.0	80.6	9
	deer	31.7	8.4	26.4	24.0	45.9	7
	other ruminants	78.5	-	-	76.4	80.6	2

## Table 18. Assimilation efficiency [%] of different food types for mammals.

1: including crops and mixed vegetation

# 4. Discussion and conclusions

## 4.1 Caloric values, moisture and ash content

From the above presented tables it appears that variation in energy content within subgroups is reduced when values are expressed on the basis of dry weight or ash free dry weight. As for the latter far less data are available, dry weight data are preferred. For most groups, the greater variation in caloric content expressed on a fresh weight basis cannot be explained by a variation in moisture content. The variation in moisture content is remarkably low, with CV almost always < 15 %. Only for seeds, a large variation in moisture content is found, indicating that the usually applied drying period of 24 hours at 80 or 105 °C may not be sufficient for this type of material. It is suggested by Cummins and Wuycheck (1971) that freeze drying followed by desiccation over  $P_2O_5$  should be used for material with a high lipid content.

From the statistical comparison, it appeared that for a number of subgroups data can be pooled, and that for other groups a subdivision should be applied.

Based on the division in food sources as made by Crocker *et al.* (2002), which is presented in Table 1, the values as proposed on the basis of the combined dataset are given in Table 19.





Group	Energy content [kJ/g DW]	Moisture content [%]
Dicot. crops	11.4	88.5
Grasses and cereal shoots	17.6	76.4
Non-grass herbs	17.8	88.1
Tree and conifer tissue	20.7	52.9
Fruit	14.8	83.9
Grass and cereal seeds	18.4	14.7
Weed seeds	21.7	9.9
Tree seeds	22.9	15.0
Conifer seeds	27.2	12.2
Terrestrial vertebrates	23.2	68.4
Fish	21.0	73.7
Bivalves	19.3	91.7
Freshwater arthropods	20.9	76.3
Terrestrial arthropods	22.7	68.8
Soil invertebrates (earthworms and slugs)	19.4	84.3
Aquatic vegetation <sup>1</sup>	15.0	81.4

**Table 19.** Energy and moisture content of several food sources (combined dataset).

1: value taken from Crocker et al. (2002), no new data available

#### 4.2 Assimilation efficiency

#### 4.2.1 Mammals

Relatively few data on assimilation efficiency by mammals are available. Especially for insects and tree tissue, the dataset is limited. For the latter group, this is not considered problematic, as the intake of contaminated tree tissue is not assumed to be a major exposure route. Contaminated insects, however, are considered to represent a major uptake route. The present dataset consists of only eight values, seven of which are for shrews, and of those seven, four values are obtained with the sawfly as prey species. To obtain a more reliable estimate, more data on other insect species and arthropods in general should become available. The assimilation efficiencies as proposed on the basis of the combined dataset are given in Table 20.

Table 20. Assimilation efficiency	y [%]	of different	food types	for mammals

Mammal species	Food type	mean	SD	n
small and medium mammals	fodder	85.5	10.2	6
shrews and bats	insects	87.4	6.3	8
carnivores	vertebrates	80.8	7.3	21
small mammals	seeds and nuts	84.3	7.6	23
small mammals	grasses	46.8	12.8	35
small and medium mammals	non-grass herbs <sup>1</sup>	75.5	11.0	26
deer, ruminants	tree tissue	42.1	21.9	9

1: including crops and mixed vegetation

#### 4.2.2 Birds

As already stated in section 2.2.1, the values for birds as presented by Crocker *et al.* (2002) and summarised in Table 2, remain unchanged.



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## **APPENDIX M**

## HOW TO DETERMINE A FOCAL SPECIES

If an active substance, and its associated product and use, fails Tier 1, it is possible to further refine the exposure element of risk via the use of a <u>'focal species'</u>. A 'focal species' is a real species that actually occurs in the crop when the pesticide is being used. The aim of using a 'focal species' is to add realism to the risk assessment insofar as the assessment is based on a real species that uses the crop. It is essential that the species actually occurs in the crop at a time when the pesticide is being applied. It is also essential that this species is considered to be representative of all other species from the feeding guild highlighted at the screening level and at Tier 1 that may occur in the crop at that time. As a 'focal species' needs to cover all species present in the crop, it is possible that there may be more than one 'focal species' per crop representing more than one feeding guild.

#### Determining a focal species

In order to determine a suitable 'focal species' it is necessary to carry out field work and presented below is a brief outline of the key issues to consider:

**Selection of field sites**: As for any field work it is necessary to select appropriate fields, in order to ascertain what species occur in the crop of concern. The crop studied should be the same as the one used in the risk assessment at the screening level and at Tier 1, it should also be at the same growth stage. It is also necessary to have a range of fields that are representative of where the pesticide is used or is intended to be used. This may be across relevant geographical and climatic regions or zone, within a Member State (MS) if the pesticide is to be used in one MS, or if the pesticide is used across a range of MS, then it may be appropriate to have a selection of fields across MS. The key point is that the focal species selected should be appropriate for the risk assessment.

Experience has shown that the fields surveyed should be separated by at least 250 m so as to avoid any potential double counting. Cropping details of the fields studied as well as their surrounding habitats (e.g. what crops were being grown, presence of woodlands, hedgerows etc) should be included in the final report.

If data are only available from either one MS or a small selection of sites and the Notifier wishes to extrapolate to another, then it is necessary to justify its use. Justification can be based on a comparison of the agricultural landscape including size of fields, presences of hedgerows, field boundaries as well as climatic conditions. Likewise, if a Notifier wishes to extrapolate from one crop to a closely related crop, justification is required.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix M. EFSA Journal 2009; 7(12):1438. [3 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

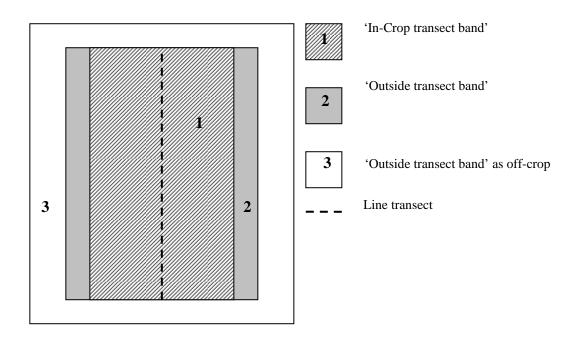


**Survey techniques**: Basically there are two techniques for birds – namely the transect method and the field survey method. These are described in more detail below:

**The 'transect method':** All bird species are recorded in the field by walking slowly along a defined longitudinal line transect, allowing for a clear view between the rows of crop plants. Birds are recorded only within the ,in-crop transect band' as individual birds visually or acoustically registered (see Figure 1 for details).

**'In-crop transect band':** birds are recorded within a wide band, for example 50 m either side of the observer where the crop field was at least 100 m wide. For narrower fields the band considered could be narrowed and contain only the in-crop area (i.e. width of the crop field).

**'Outside transect area/band:** no birds are recorded beyond the in-crop transect band. Depending on the width of the field the 'outside transect band' may include in-crop and off-crop habitat.



**Figure 1**. Graduation of different areas within defined crop fields as applied by this focal species studies

**The 'point count method':** With this method the observers survey the part of a field from a single location to avoid disturbing the birds. Both methods, i.e. field survey and transect methods, are complimentary to obtain unbiased census. It should be noted that this technique may be more appropriate for fields in the winter, freshly drilled fields or bare soil. This method is further described in Crocker and Irving (1999) or Bibby *et al.* (2000).

**Analysing the data**: the survey data may be analysed in a variety of ways, however in trying to determine 'focal species' the following information is considered to be most relevant:



**FOfield or frequency of observation in the field** – denotes the number of fields in which a defined species was recorded as percentage of the total number of fields regardless of the number of individuals observed. This approach serves as a measure for the <u>spatial</u> frequency of occurrence, or the proportion of fields a species is present on. A FOfield of 100% for one species indicates that this species was observed in all fields during at least one survey.

**FOsurvey or frequency of observation per survey** – denotes the number of surveys in which a defined species was recorded given as percentage of the total number of surveys. This approach gives an approximation for the <u>temporal</u> evenness of occurrence throughout the complete study period. This gives an indication of how widespread a species is and is considered to be an indication of 'prevalence'. A FOsurvey of 100% means the species was recorded during each survey in every field with at least one individual.

**Selection of Focal Species:** The above gives an indication of what potential focal species may occur in the crop. Those species with a frequency of occurrence >20% might be considered to be of high priority especially if they have high dominance. However before deciding which species 'covers' all other species present on the field, it is necessary to consider issues such as feeding strata, food intake rate, body weight of potential focal species and diet to ensure that species with the highest potential exposure are considered. It should be noted that a focal species is not automatically the species that was most frequently seen in FOfield and/or FOsurvey.

The above is illustrated by an example where a swallow was recorded as being both prevalent and abundant in a certain crop at a certain time of year. But whilst is has a high intake to body weight ratio, and consumes small invertebrates it is not consuming invertebrates with residues on and hence is not protective of other species that may occur in the crop at the same time. Similarly, wood pigeons are potential focal species in sugar beet in the summer (see Crocker and Irving, 1999); however on the basis of its low food intake rate it is clear that the wood pigeon is not protective of other species, e.g. the skylark.

#### References

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<sup>&</sup>lt;sup>1</sup> Available at: <u>http://www.pesticides.gov.uk/uploadedfiles/Surveys\_short1.pdf</u>



# APPENDIX N

## RECOMMENDATIONS ON ARTHROPOD RESIDUE FIELD STUDIES TO REFINE FOOD RESIDUES IN HIGHER TIERED BIRD AND MAMMAL RISK ASSESSMENTS<sup>1</sup>

## STUDY CONDUCTION AND INTERPRETATION

#### Introduction

The aim of this document is to provide guidance on how to carry out an arthropod residue field study and considerations on how to interpret the results of a study for a higher tiered risk assessment. This guidance given in this document should not be seen as fixed as it may be more appropriate to design a specific study to address a specific issue highlighted during the initial risk assessment. In situations where there have been deviations from the recommendations made here a full justification and explanation should be given to explain why and how a study was conducted in a specific way and why the data can be used to refine the exposure different from Tier 2 scenarios in the Guidance Document (GD).

#### Laboratory versus field studies

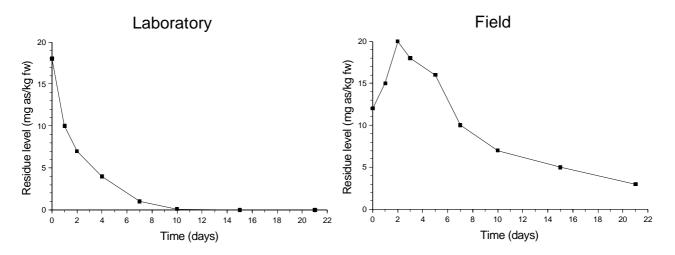
As in many other areas of ecotoxicology it might be helpful to start with simpler laboratory studies, followed by semi-field approaches, before scheduling a field study as the highest tiered approach. However, it should be emphasised that it might be very difficult to simulate the processes relevant for residue levels in arthropods under laboratory conditions, especially if the time courses of residues are to be examined. Furthermore, laboratory studies are limited to a single species whereas field studies investigate the whole arthropod community, which together represents the potential food of insectivorous birds and mammals. The figures below show how the residue curves can differ for a compound which is non-toxic to arthropods. Results demonstrate the residue decline after over-spraying a single species in the laboratory compared to the data obtained from a field experiment, considering the whole arthropod community in the respective crop (NB: the curves shown below are hypothetical (generic) curves derived from a number of real studies; those studies normal contain protected data owned by specific companies). Due to food web interactions and environmental conditions

<sup>&</sup>lt;sup>1</sup> Acknowledgement: EFSA wishes to thank Christian Wolf and Katja Schneider, RIFCon GmbH, Germany, for the elaboration of this Appendix.

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the residue pattern obtained from the whole arthropod community in the field shows a higher maximum (accumulation) and a slower decline. However, in field studies where single species of arthropods were artificially exposed to applications, e.g. in cages, exposure conditions are normally not comparable to those experienced by free-living arthropods under natural circumstances. Absolute residue levels (peak values) in single species tests tend to be lower (no accumulation in a food web) and residue decline can be faster (no consideration of inter-species interaction, different feeding strategies and metabolic processes). Thus a single species test is less representative compared to data obtained from the whole fauna and therefore, field studies should be preferred to laboratory and semi-field studies.



**Figure 1.** Hypothetical (generic) residue levels plotted as a function of time for a compound which is non-toxic to arthropods, (based on real studies). Due to confidentially and data protection rules claimed with studies conducted by applicants no specific reference can be given.

#### General remarks on the use of field residue data in refined exposure assessments

Concerns are often raised over whether data from field studies where sample size is often limited can be used to replace worst case Tier 2 data. In principle, field data obtained under practical use conditions add a further level of realism to a risk evaluation. Furthermore, the replacement of RUDs for maximum residue levels is reasonable if data are more focussed on a particular application regimen, crop stage or geographical area. Also, as noted above, data from field studies may be suitable to describe residue declines over time under natural conditions, which are very difficult to obtain from laboratory studies. Both the definition of Tier 3 maximum residue values and as well data of residue decline under natural conditions could be derived from the same field study.

#### Number of study sites and site selection

When planning a residue field study it is clear that the number of study sites and the number of replicates within the study sites are the decisive factors for the significance of the data, i.e. the more test sites and replicates the more reliable the data. But this is often limited by several factors including the availability of suitable study sites and cooperative farmers, analytical capacities and available resources, so normally a study will be conducted at one test site.



Each test site will represent an individual residue value/time course, i.e. an individual study. Nevertheless, within each site it is desirable to have at least three replicates available to have information on intra-site variability of the residue values. The minimum size of each replicate within the test site should be approximately 1 ha, otherwise effects of immigration and emigration may have an unrealistically high impact on the residue dynamics within the monitored arthropod community (i.e. sampling should be avoided in the border structures of a crop, e.g. the outer tree rows from an orchard).

The abundance of arthropods is one of the most important factors for the selection of suitable study sites. Since an orchard plot which has been intensively farmed for several decades, surrounded by other high production commercial orchards, may contain a very small arthropod community and will therefore be unsuitable for an arthropod residue study even if it is a typical site where several pesticides are used throughout the season. Conversely, a small orchard out of production, surrounded by a diverse woodland habitat may hold an enormous amount of arthropods but exchange with the surrounding source habitat may lead to an unrepresentatively fast dilution of individuals with a residue loading- so this is not a suitable situation for residue decline studies. Therefore it is absolutely critical to describe the orchard use history (e.g. planting or age, prior crop, treatments before study start, pesticides used) and also the surrounding landscape in detail (e.g. kind of crop or vegetation of the bordering areas, current aerial photos) to justify the selection of the study site and also to facilitate the discussion of observed residue decline patterns.

To ensure the maximum abundance of arthropods, no insecticides should be used during the study year and up to the termination of the study. Fungicides, which will not affect arthropod communities, can be used according to the usual application schedule. To prevent major habitat changes, no herbicides should be used during the trial unless it is necessary to assure a proper application of the test substance or the survival of the crop itself. Hence a balance between commercial practice and detrimental effects for the arthropod community should be achieved for the study site.

## Application of the test item

The application(s) should be performed according to the recommendations of the product label and to good agricultural practice. Special attention should be given to the adjustment of the volume of the spray liquid towards the dimension of the crop, especially in orchards (tree size, tree spacing, row spacing etc.). All exact data and details of the application technique should be described in the study report. The water volume used for spray applications in the study should be justified and represent a typical commercial application.

## Test organisms

Attention should focus on organisms likely to be consumed by the potential focal species. Therefore it is necessary to have information about the prey selection of the bird (and/or mammal) community inhabiting the study site from a study on 'portion of diet' (PD). If this information is available the division of sampled arthropods into classes, e.g. 'beetles', 'caterpillars', 'spiders' etc, can be useful. It is important that the fresh weight of the total of each of these groups should be recorded. Without this information it is not possible to reconstitute in the correct proportions the total residue for a bird which may feed on all these groups. The specific residue level and decline information for a suitable focal species. However, detailed information about the composition of the diet are rarely available and often

the amount of sample matrix necessary for a proper residue analysis limiting the ability to divide arthropods into specific classes. If no information on dietary preferences of focal wildlife species are available it is recommended to collect sub samples of arthropods of the different foraging strata in a crop, e.g. foliage dwellers and ground dwellers, to have more information on residue levels of specific food groups. Since an insectivorous bird collecting arthropods from the tree canopy may receive a different exposure level in an orchard when compared to a nocturnal shrew collecting ground dwelling arthropods in predominantly dense vegetation cover.

The division of arthropods into 'large' and 'small' classes is unnecessary, because the ecology of specific arthropod groups and the feeding ecology of the bird and mammal species concerned are the most significant factors.

#### Methodological considerations for sample methods in field studies

A main point always to be taken into consideration is the loss or increase of residues in the sample matrix based on methodological shortcomings. Desiccation of the sample matrix should be avoided by fast handling times and storage of the samples as soon as possible in a deep freezer or on dry ice. Another problem which can severely influence residue levels of the sample is cross contamination with other (non-arthropod) materials like soil particles or plant material. This will be discussed in more detail in the section on specific sample techniques below. Nevertheless it should be noted that so far no real comparative assessment of different sampling techniques with respect to their influence on the resulting residue levels is available. Only for suction sampling techniques (i.e. D-VAC sampling) it was proved that the residue data will be significantly biased by cross contamination from dust particles (SETAC, 2007)<sup>2</sup>. Accurate recording of the composition of each sample, e.g. the number of individuals in each of the various taxonomic groups present, is very important to explain specific data points. For example, if a sample consists of one large beetle and a few tiny spiders only, the residue level analysed very much describes the residue loadings only of the single large beetle.

#### Ground dwelling arthropods

The most practical method to collect ground dwelling arthropods is the use of pitfall traps. They have of course the disadvantage of collecting only active and moving individuals, but, on the other hand, pitfall traps are the only method to selectively collect only arthropods. Other methods, like suction sampling (e.g. with a D-Vac) have the huge disadvantage of severe cross contamination with soil-, plant- and other dust-particles potentially carrying often high residue loadings. Pitfall traps should be used without a preservation liquid (which would dissolve/wash off residues from arthropods) and should be emptied once at least every 24 hours. If the sample container of a pitfall trap is contaminated with water or soil material, e.g. during rainfall events samples should be discarded.

Arthropods should be killed with an ether-soaked paper after being recovered from the traps. Following the determination of suitable sub-fractions (if intended, see above) and weighing, the sample should be stored on dry ice or in a deep freezer. The number of pitfall traps used per sample site should be adjusted to the matrix mass necessary for residue determination in the analytical part of the study.

<sup>&</sup>lt;sup>2</sup> S. Moreno, J. Pascual, A. Drexler & J.-D. Ludwigs (2007). Unsuitability of a suction sampling method for the collection of arthropods for residue analysis of plant protection products. SETAC Poster 2007.



#### Foliage dwelling arthropods

Methods to collect foliage dwelling arthropods are most relevant in high crops like orchards, vineyards, hops. Field crops with sufficient plant material and arthropods inhabiting the plant layer may also be sampled successfully (e.g. in potatoes, cereals, some vegetables). In principle, the two most established methods for sampling foliage-dwelling arthropods are beating and inventory spray.

With **beating**, the leaves/plants/branches are beaten with a stick and the arthropods dropping down are captured in a large funnel. The disadvantage of this method is that some species (like flying ones) may escape instead of falling into the funnel. Other materials such as leaves, petals, bark, dust etc. will also fall into the sample container of the funnel. Thus, some sorting between arthropods and undesired material is necessary after the sampling event. This may prolong the handling time before the sample is stored in a freezer and the problem of desiccation of the arthropods arises (see above). The problem can, at least partly, be overcome by direct freezing of the samples and sorting under frozen conditions. Beating is however, only able to sample the parts of the plant readily accessible by hand. For example, it is not possible to sample the upper parts of fruit trees.

A more sophisticated method for sampling foliage dwelling arthropods is inventory spraying. Using this method, a number of plants are treated with a fast acting knock-down insecticide. The most common knock-down insecticides in current use are pyrethroids. Formerly, compounds such as Dichlorvos were also often used. Depending on the knock-down insecticide used this method has also a certain selectivity and not every arthropod inhabiting the respective plant foliage will fall down on the collection sheet. It is important to apply the knock down insecticide very gently and when there is no wind, to avoid disrupting the unsampled parts of the study. After spraying the arthropods which have fallen from the leaf layer will be collected from sheets placed underneath the plants or trees. Dense cotton sheets acting like a sponge for the pesticide and the knock down substance when dripping from the treated foliage and avoid puddles in which arthropods can fall (resulting in changes of the residue loadings like with pitfall traps when preserve liquids are used), hence they are an optimal underlay. However, care must be taken when collecting the arthropods from the cotton sheet, because claws of beetles might get entangled and legs get pulled off - both resulting in an underestimation of residue levels. The best way is to collect the individual arthropods selectively from the sheets using tweezers or a small suction device, in order to avoid contamination with other material like leaves or pieces of bark. For some small-bodied arthropods such as aphids individual sampling with tweezers or a suction device is inappropriate and too slow resulting in desiccation; these can be carefully collected using a soft brush. Those samples should be kept and analysed separately if possible. The number of plants/trees used for one inventory spray sampling event should be also adjusted to the amount of sample matrix needed for residue determination. The plants should be randomly spread throughout each sample site and each plant/tree should be sampled only once during the study. The method requires some waiting time between inventory spray and collection of the arthropods until the spray liquid has dried. It is important to ensure that as much individuals as possible are knocked down and dropped on the collection device. The waiting time must be kept reasonably short (1-2 hours) and meanwhile, the arthropods should not be exposed to direct sunshine on the collection device to minimise the effect of desiccation. Subsequent sorting, partition into sub-samples and weighing must also be done immediately after the collection in order to transfer the samples as soon as possible into a freezer or on dry ice.



Sampling methods which differ from the two methods mentioned above may be used in some circumstances and for certain crops. However, for all these methods, clear descriptions are necessary to allow any possible influence of the methodology on residue levels to be assessed (e.g. cross contamination).

#### Knock down samples during application

It can be assumed for insecticides (and other pesticides with insecticidal side effects like some fungicides) the highest initial residue loading occurs on those arthropods which are killed during or immediately after application of the product. These individuals are normally missed during the sample events for foliage dwelling arthropods (because they are already dead and have fallen on the ground) and will not be found in pitfall traps (because they can no longer move). It is unclear to what extent those arthropods are used as food items by birds and mammals. At least some reports can be found in the scientific literature describing the uptake of dead and/or moribund arthropods by birds<sup>3</sup>. Thus, in principle this scenario should not be overlooked and a respective sample of those arthropods affected directly from the product application should be obtained whenever possible. In high crops (e.g. orchards) this can be easily achieved with a method similar to the inventory spray method used to collect foliage dwelling arthropods. The sampling devices (e.g. sheets) should be placed before the application and arthropods can be collected in a suitable time after the spraying, normally when the spray liquid has dried. Note that these collecting sheets should be covered at the time of spraying itself and the covers removed immediately afterwards to prevent the specimens being contaminated with further residues of the test item.

#### Number of samples and sample intervals

The number of samples analysed in parallel depends on the study site (size, structure, abundance of arthropods) and available capacities within the respective analytical facility. In order to get some information on intra-site variability of the residue levels at least three samples from each strata/sample method should be planned for each sampling date ( $n \ge 3$ ). Nevertheless, unexpected low masses of arthropods may force the pooling of samples to obtain sufficient matrix for residue analysis.

The general sampling scheme should be adjusted to the properties of the test substance and should be performed in such a way that the aims of the study can be achieved. In general, at least for spray applications, more sampling events should take place within the first three to six days after application, in order to obtain the maximum residue levels after application. If more than one application is being investigated then a sampling should also take place on the day before the next application. Some samples should also be obtained before the first application to adjust the sampling effort required for each method intended and to obtain reference matrix for the analytical laboratory.

<sup>&</sup>lt;sup>3</sup> J. Schabacker, B. Giessing (2006). Pesticide Kills, Easy Prey for Insectivores? Poster on SETAC-Europe 16<sup>th</sup> Annual Meeting, The Hague, The Netherlands.



DAT (Day Af	ter Treatment)		Numb	er of sa	mples	
DAT (Day AI	ter Treatment)			Plot	-	
First application	Second application	1	2	3	4	
-1		1	1	1	1	
0 (before application)		1	1	1	1	
+1		1	1	1	1	
+2		1	1	1	1	
+3		1	1	1	1	
+4		-	-	-	-	
+5		1	1	1	1	
+6	-1	-	-	-	-	
+7	0 (before application)	1	1	1	1	
+8	+1	1	1	1	1	
+9	+2	1	1	1	1	
+10	+3	1	1	1	1	
+11	+4	-	-	-	-	
+12	+5	1	1	1	1	
+13	+6	-	-	-	-	
+14	+7	1	1	1	1	
+15	+8	-	-	-	-	
+16	+9	1	1	1	1	
+17	+10	-	-	-	-	
+18	+11	1	1	1	1	
+19	+12	-	-	-	-	
+20	+13	-	-	-	-	
+21	+14	1	1	1	1	
+22	+15	-	-	-	-	
+23	+16	-	-	-	-	
+24	+17	-	-	-	-	
+25	+18	-	-	-	-	
+26	+19	-	-	-	-	
+27	+20	-	-	-	-	
+28	+21	1	1	1	1	
Su	ım	16	16	16	16	1

## **Table 1.**Example for a sampling schedule for a field study with two spray applications:

#### **Reporting and data interpretation**

As every arthropod residue field study for the submission to a regulatory authority should be performed according to GLP the respective report must be comprehensible and should describe clearly the aim, all methods, deviations, encountered problems and results of the study. As the main results are normally initial residue values and / or time course of residues these data should be explicitly expressed in the study, if possible, including data on their variance. It should be considered that, regarding initial (maximum) residue values, the maximum is often found some time later - not immediately after application of the test substance (especially for substances non-toxic to arthropods may accumulate within the first few days after application). For a proper elucidation of the time courses of residues it is important to use an appropriate model to describe the residue decline. Normally it is not a first order kinetic, because several processes are interfering (e.g. a rapid decline of surface



residues by abrasion / renewal of the wax layer of the cuticula of individuals with direct contamination during the application vs. systemic uptake via food and residue decline via metabolisation and excretion, which is often much slower as well as immigration and emigration and population turnover). Thus, often a time weighted average approach (TWA), summarising the area under the curve is the most suitable method to describe longer-term residue patterns for arthropods. Nevertheless, for what ever method is chosen as most appropriate, clear evidence should be provided that this particular way of providing data for a refined exposure calculation is representing a realistic but sufficiently conservative approach to be suitable for a risk assessment.



# **APPENDIX P**

# HOW TO ESTIMATE PT<sup>1</sup>

PT is defined as the proportion of an animal's daily diet obtained in habitat treated with pesticide. As a worst-case (first tier assessment) it is assumed that individuals find all their food in the treated area and that PT = 1. In reality, birds and mammals in the agricultural landscape may visit a variety of habitats within a single day, and not all of them may be treated with plant protection products. Therefore, in higher tier risk assessment it is recommended that more realistic estimates of PT be obtained for relevant species and crop scenarios.

It has not been possible so far to make direct measurements of the amount of treated food ingested by individual birds and mammals in the farming landscape. However, by radio-tracking, it is possible to make indirect estimates of PT. Radio-tracking can deliver data on how much time an individual spends in different habitats. Assuming a) that the amount of time spent by an animals in a given crop is directly proportional to the food eaten there, and b) that the crop has been recently treated with pesticide, then it may be followed that a bird, which spends e.g. 50 % of its day in a given crop is likely to have 50 % of its daily food intake contaminated with pesticide.

When considering how to use radio-tracking data to estimate PT, the risk assessor should be aware of some methodological and analytical questions:

- 1. Using radio-tracking contact time as an estimate of foraging time.
- 2. Selection of which individuals to radio-track and which to include in the estimate of PT.
- 3. How long to follow individuals?
- 4. How to use PT in deterministic worst-case calculations?

#### 1. Radio-tracking contact time as an estimate of foraging time.

PT is intended to be a measure of exposure to pesticides through the consumption of contaminated food. Radio-tracking data are more likely to be a good estimate of PT if they distinguish between time spent in crop where the animal is active and potentially foraging and time spent where the animal is inactive or engaged in non-foraging activity (e.g. singing, nest building, burrowing). For example, a blackbird may spend a large part of its day in a hedgerow but be relatively inactive there, using it principally as a refuge and only leaving it for short periods when searching intensively within a crop for food items. Ideally, PT should be expressed as the amount of (potential) foraging time in the crop expressed as a proportion of the total time spent (potentially) foraging in the day.

<sup>&</sup>lt;sup>1</sup> Acknowledgement: EFSA wishes to thank Joe Crocker and Magnus Wang for the elaboration of this Appendix.

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#### 2. Selection of which animals to radio-track and which to include in the estimate of PT

This is essentially a question for the risk manager. Pesticide risk assessments usually concern a particular pesticide used on a particular crop and the possible dangers presented to a particular wildlife species.

In choosing which individuals to radio-track one might:

- a) Focus on the crop and radio-track only those individuals that were caught in the target crop.
- b) Focus on the species and radio-track individuals captured in local farmland habitats where they are most abundant.

In estimating PT from radio-tracking data, one might:

- c) Include only those individuals that foraged in the target crop ("consumers only" group).
- d) Include all individuals with sufficient radio-tracking data.

PT estimated from group (a) (crop caught individuals) is likely to be higher (more conservative) than that from group (b) where individuals may visit a variety of habitats. For example the woodpigeon is a very common bird on UK arable land and may often be seen on fields of wheat in summer. But it is much more frequently seen on oilseed rape. Estimating cereal PT for woodpigeons by including only those caught on cereal fields will focus the risk to that sub-group of woodpigeons that use cereals but may be a rather unrepresentative sample of the broader woodpigeon population on arable land. On the other hand, estimating PT from the radio-tracking data obtained from all individuals in the general locality may give a better description of the exposure for a typical woodpigeon on arable land, (if the pattern of agriculture in the locality is also representative of the general pattern) but by including animals whose normal home range may not actually include the target crop, the risk assessment will be less conservative.

Having decided to focus on the particular group around the target crop (a) or the more general population in the locality (b), one needs to determine whether the interest is primarily in the exposure of those birds that actually foraged in the target crop (i.e. group (c) excluding individuals where PT = 0) or whether birds that ignored or avoided the crop (i.e. group (d) including individuals where PT = 0) should be included as well. For birds or mammals that were actually caught in the crop (a) it could be argued that PT must necessarily be greater than zero, and that all radio-tracked individuals are therefore legitimate subjects. However, some animals may have been caught in crop margins as they moved along the (non-crop) hedgerow and the crop itself may have played no significant part in their foraging routine.

In general it would seem reasonable that for focal species caught in the crop, PT can be estimated from all individuals (whether they used the crop or not) whereas for the population caught in the general locality, PT should be estimated from only those individuals shown by radio-tracking to have used the crop (PT > 0). The inclusion or exclusion of individuals with PT = 0 is a trivial calculation so it may be advisable to compare the risk for both groups (c and d), regardless of whether the animals were caught in the target crop or outside it.

In addition to the different sampling bias on PT from focusing on wildlife species caught in particular target crops or species in a variety of farmland habitat, there may be practical issues to consider. Restricting the sample to those caught in the target crop has the advantage that it gives a focused sample but it may increase the effort required to capture a large enough sample size and each crop will need a new radio-tracking sample. For wildlife caught in the general locality, some individuals may visit a variety of crops and may legitimately be used to estimate PT for each of those crops.



#### **3.** How long to follow individuals

In acute pesticide risk assessments, possible dangers to wildlife are assessed over a presumed exposure of 1 day. Therefore the most appropriate time course for collecting radio-tracking data is a set of continuous observations covering all the hours in a single day that the species may be potentially foraging. Observations of less than one day can exaggerate extremes in animals' choices of foraging habitats. For example, in an extreme case where an animal was observed for only a second then PT is likely to be either 0 or 1 and is unlikely to be an intermediate value because 1 second is not enough time for an individual to visit more than 1 habitat. Similarly, as crop maturity changes and food sources vary, individuals followed for days or weeks will tend to show some drift in habitat use with time: some habitat averaging will occur and PT will be less likely to be 0 or 1. Therefore the ideal radio-tracking record will last all of a single day.

However, the behaviour of some species in some seasons may make it particularly difficult to obtain a continuous record of behaviour lasting a day. Linnets for example can make rapid flight of more than a kilometre staying only briefly at new sites and making it difficult for radio-trackers to keep track of their movements. Another reason why continuous observation for a single day may not be available for analysis is that the experimenter chose to sample individuals' behaviour. For example the radio-tracking data collected by CSL and reported in Finch *et al.* (2006) aimed to collect observations for 1 hour in 2 of a typical day's behaviour. This made it easier for the data to be collected by a single observer and enabled more than 1 individual bird or mammal to be tracked during the course of a day. However, it will push estimates of PT closer to 0 or 1.

The degree to which an observation time of less than a full day will exaggerate the extreme value of PT will depend on the length of typical observation time in relation to the frequency with the subject moves between habitats. For example if a blue tit moved between cropland and woodland every few minutes and this was a constant feature of its behaviour throughout the day, then an observation time of an hour or so may be more than sufficient to estimate its PT. But if the individual spent the morning in a crop and the afternoon in woodland then a single hour's observation would most likely give a PT of 0 or 1, when the true value is 0.5. For radio-tracking reports covering less than a full day's observations it is recommended that the experimenter should:

- Show that the general sampling regime is unlikely to introduce biases into the estimation of PT e.g. will not lead to greater sampling of the animal when it is in the crop, and does not favour particular times of day when the animal is engaged in particular behaviours.
- Show that the shorter observation time is unlikely to have a significant bias on estimates of PT; or estimate the likely bias that shorter observation may have on the estimation of PT and correct it; or at least indicate whether the bias will have conservative or non-conservative effects on the risk assessment and allow the risk manager to decide if this is acceptable.

#### 4. How to use PT in deterministic worst-case calculations

Having obtained estimates of PT for all individuals in the sample, the default value of 1 in the first tier need to be replaced. If the PT of 1 was replaced by a median or mean then this would suggest, in the absence of other safety factors, that the estimation of risk would be protective for only half the target population. The risk manager needs to decide what proportion of the population should be protected. In other words the risk manager should decide whether a reasonable worst-case is represented by a specific percentile of the population at risk.

#### How to estimate relevant percentiles and confidence bounds.

The simplest (non-parametric) way of estimating any centile is to rank the individuals in increasing order of PT and to choose the value of PT corresponding to e.g. the 90<sup>th</sup> centile individual. Where there is no precise identity between an individual and the percentile of interest, an interpolate between values of neighbouring individuals in the sequence can be made. A problem of this approach is that, with small sample sizes (which is the case for many radio-tracking scenarios), the value of any given



centile may be very variable between samples. A better (parametric) estimate of the 90<sup>th</sup> percentile may be obtained by assuming that the data represent a random sample from a parent distribution with known mathematical properties. For many real-world measurements, statisticians assume that a sample comes from a normal distribution with parameters  $\mu$  and  $\sigma$  estimated by the mean and standard deviation of the sample. However, the normal distribution (with infinite upper and lower bounds) does not often provide a good fit for proportional data (limited between 0 and 1). Therefore, the Beta distribution is considered as the most appropriate one for describing PT.

For the calculation of confidence intervals, bootstrap methods are commonly applied (Efron and Tibshirani, 1993; Manly, 2001, Davison and Hinkley, 2003). They can be categorised as *parametric* or *non-parametric* bootstraps. Non-parametric bootstraps repeatedly resample from the same dataset and the results of such a procedure will be critically dependent on how representative the underlying dataset is. Small datasets are less likely to be representative and the confidence limits obtained by non-parametric bootstraps are likely to be underestimated. Therefore parametric bootstrapping may be preferable for small radio-tracking datasets. For the analysis of PT data the following approach is proposed<sup>2</sup>:

- 1) From a field study n PT values are obtained, where n is the number of birds observed during one tracking session.
- 2) A beta distribution is fitted (distribution A) to all *n* PT values.
- 3) A random sample of sample size *n* is taken from distribution A.
- 4) Again, a beta distribution (B) is fitted to the new random sample.
- 5) From distribution B the 90<sup>th</sup> centile (or other estimate) of PT is calculated and recorded.
- 6) Steps 3 to 5 are repeated many times (e.g. 1000 times), each time a random sample of size n is taken from distribution A, a new beta distribution is fitted and the 90<sup>th</sup> centile is recorded.
- 7) Finally, the upper 95<sup>th</sup> (or other) one-sided confidence bound is calculated by ordering all 1000 estimates of the 90<sup>th</sup> centile from low to high and picking the value of the 95<sup>th</sup> place (or other) in the sequence.

#### **Example protocol**

Detailed protocols of how to fit radio-transmitters and appropriate field practice for radio-tracking birds are given in Appendixes 1 and 2 of Crocker *et al.* 1998, and RifCon (2006). Examples of how the data may be analysed can be found in Appendices 1-3 of Finch *et al.*, 2006, RifCon 2006, and Crocker *et al.*, 1998. The following summarises the essential points.

#### Telemetry

There are two purposes of the radio-tracking technique: (i) To locate a bird in order to observe its behaviour ('radio surveillance', Kenward, 2001) and (ii) to follow the bird continuously over a defined period (see below) in order to determine its exact location and any behavioural changes ('continuous monitoring', Kenward, 2001).

During the tracking session birds should be tracked continuously, i.e. a bird should be followed nonstop by car or by walking. Every change in behaviour (according to the categories in Table 1) and

<sup>&</sup>lt;sup>2</sup> This is a simplified explanation that omits important assumptions about the most appropriate distribution to fit (e.g. Beta, Binomial, Uniform, or some mixture of distributions), what method of fitting to use, and how to decide what is a good fit. For fitting a beta distribution to specific data different statistical method are available (e.g. maximum likelihood estimation, method of moments). These methods can give quite different results depending on the mature of the underlying data. Therefore the goodness of fit should be checked either graphically by comparing plots of the data and fit as cumulative distribution functions and/or by calculating appropriate goodness of fit statistics (e.g. chi Square, Kolmogorov-Smirov, Anderson-Darling) (See appendix 3 of Finch *et al.* (2006), Frey *et al.*, 1999, Efron & Tibshirani 1993, Skylar & Smith 2003).



location (habitat and position) should be accurately recorded to the minute. If the tracking session lasts a whole day, an exchange of observers may take place every few hours to ensure full attention of the persons tracking the birds. When monitoring bird activity, the sampling regime should be designed to capture activity throughout the day, and trackers should follow the sampling regime irrespective of "bird's compliance", i.e. sampling sessions should not be cut short because the bird has moved away or extended because the birds is easy to monitor (see Crocker *et al.*, 1998, Appendix 1).

With the use of unidirectional Yagi-antennas it is possible to determine the location of the tracked bird. The signal strength also allows an estimation of the distance to the bird. In order to describe the behaviour of the tracked bird as accurately as possible and to verify its location the tracker always endeavours (if the bird is not hidden by vegetation) to observe the bird by visual contact and with optical devices (scope, binoculars). Moreover, during visual contact it is possible to connect the signal quality of the radio tag to the observed behaviour of the bird. Hence, it may sometimes be possible to deduce the behaviour of the bird from the signal quality. Use of colour rings enables the observer to identify each bird with certainty. To ensure that the observer does not affect the behaviour of the bird, an appropriate 'safe distance' has to be maintained. Different species in different habitats may call for different safety distances. The idea is to follow the bird's habitual movements rather than chase it about the landscape.

As a general rule, the aim should be to obtain data from at least 20 individuals for any given scenario in order to get an appropriate sample size. For acute risk assessments the data should reflect a single typical day in the life of a focal species under conditions when the target crop might be treated with a given pesticide. For long-term assessments observation of more than one day may be considered.

#### Calculation of PT in a specific crop

The calculation of PT assumes a correlation between the time spent by a bird in a particular habitat and the amount of food it ingested in that habitat. In other words, it is assumed that the amount of food taken by a bird in a certain time span will be the same in any habitat or crop within its home range. The 'proportion of time foraging' is thus assumed to be equivalent to the 'proportion of diet obtained'.

At each telemetry session the proportion of diet obtained by an individual bird in a specific crop (PT) is calculated as the proportion of time the bird spent 'potentially foraging' in that crop. **'Potential foraging time'** is thus the sum of the time intervals during which a bird showed any of the behaviour categories, 'foraging', or 'active unknown'. All instances when the animal is known to be performing definitely non-foraging activities (e.g. singing, nest building) or when it is considered to be inactive are excluded from the calculation of PT. For each tracking session the 'time potentially foraging' within the crop of concern is compared with the total 'time potentially foraging' in any habitat (see below).

To provide further behavioural details, e.g. to assess whether a bird is active but not foraging (see text below for details on behaviour categories), all recorded visual observations of radio-tracked birds are included in the evaluation.

During some of the telemetry sessions it may not always be possible to determine a bird's location throughout the whole tracking session (i.e. whether it is in a specific crop or not). In such cases, the habitat should be recorded as 'unknown'. In most cases, the corresponding time periods during which the habitat is unknown are rather short and may therefore be excluded from the data analysis. This approach is justified when assuming that there is an equal likelihood of determining a bird's position in all habitat types in an agrarian landscape.



Potentially foraging All instances when the bird was foraging for sure, or might have been foraging.	Foraging Active: unknown	Bird is foraging (e.g. fluctuating radio-tracking signal, supported by visual sightings of bird searching for food) Bird is active (e.g. fluctuating radio-tracking signal strength) but more definite information cannot be obtained
<u>Not Foraging</u> All instances where bird was inactive or clearly engaged in non-foraging activity	Breeding Active: other non-foraging Inactive	Bird is engaged in behaviours that are part of reproduction (e.g. singing of males, song flight), copulation, mate guarding, territory defence, incubating (if nest site is known) etc., thus foraging can be excluded Bird is carrying out activities other than foraging and reproduction (e.g. seen preening, bathing, drinking, sunbathing) Bird classified as inactive (not moving) by radio- tracking signal and/or by visual contact (thus, foraging can be excluded)

#### **Table 1.** Definition of behaviour categories (used for calculation of PT)

#### **Example of PT calculation**

Total time a bird is present in all known habitats including the 'crop in focus' during an individual tracking session:

Behavioural category	Duration [h]	Sum
Foraging	1.5	potentially foraging: 9 h
Active: unknown	7.5	
Breeding	2	time when foraging behaviour can be excluded: 7 h
Active: other non-foraging	1	
Inactive	4	
Total time in all known habitats	16	

This results in a 'potential foraging time' for the 'crop in focus' of 4 h.

The individual PT is then calculated as:

 $\frac{Potentially for aging time in the crop in focus}{Potentially for aging time in all known habitats} = \frac{4 h}{9 h} = 0.44$ 



#### **Example justification for using < 1 day of observation data<sup>3</sup>**

It was noted earlier that where individuals had been observed for less than a continuous full day, then it should be shown that this does not significantly affect the estimate of PT, or the bias arising should be quantified. For the data obtained by example Finch *et al.* (2006) for a variety of arable and orchard scenarios typically tracked radio-tagged birds for 1 hour in 2 throughout the day. In the case of 17 yellowhammers monitored on cereal fields in summer this amounted to an average of 9.1 hours radio-tracking observation. The shortest observation time lasted 5.6 hours. It might be expected that PT estimated from very short observation times would be significantly different from PT estimated from longer observation times.

Based on the first 1 to 9 hours radio-tracking data for each bird the 90<sup>th</sup> centile PT and its 95<sup>th</sup> centile upper bound as calculated by the method described above. It may be seen that the 90<sup>th</sup> centile PT changes noticeably over the first couple of hours of monitoring but then stabilises to a fairly constant value. Similarly the upper 95<sup>th</sup> confidence bound appears stable even when observation times are short. With the shortest yellowhammer observation time lasting 5.6 hours, it would seem that the sampling protocol does not, in this scenario, seriously affect the estimation of 90<sup>th</sup> centile PT and its upper confidence bound.

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<sup>&</sup>lt;sup>3</sup> Where possible it is preferable to collect a full day's observations. But if less than this is available the data may still be useful in estimating PT provided they meet the criteria detailed in section 3a and 3b.



# APPENDIX Q

# HOW TO DETERMINE BIRD AND MAMMAL DIETS

#### 1. Introduction

At Tier 1, a worst case diet is used along with an indicator species to produce a screening step. If a pesticide fails Tier 1, then, in a higher tier it is possible to refine the risk assessment by using a more realistic scenario in terms of bird or mammal occurring in a treated crop, along with a more realistic diet. The diet used at higher tiers is based on publicly available data. Therefore if a compound fails Tier 1, it may be possible to refine the exposure component via revising the diet in two ways.

Firstly, it may be possible to revisit the publicly available data, providing that the studies on the diet of focal species are conducted in an appropriate landscape (crop of agricultural mosaic) and to a methodology considered to be equivalent to that outlined below. Alternatively, the diet of focal species can be determined via field work as outlined below.

#### 2. How to determine a bird diet

An analysis of the diet of a bird can help to estimate the exposure of a bird to a plant protection product after application. Different food sources of birds may contain different residue levels. For example, when seeds are dressed with a fungicide and sown in a field they may contain higher residue levels than the arthropods living in that field. The risk for seed eating birds may then be greater than that for omnivores. Therefore, for a realistic estimation of the actual exposure to birds the respective proportion of these food items in the diet of a bird species must be examined.

Several methods for measuring the composition of the diet of birds are used. Direct monitoring of the birds' food selection is often hindered by vegetation or the observation distance. Therefore, alternative methods have to be considered. Video recordings at bird nests can offer an insight in the nestlings' diet. However, the diet of nestlings may differ considerably from the diet of the adults. Another method is the application of neck collars to chicks in order to prevent food items to be swallowed. This method restricts the view to the analysis of the nestlings' diet and is therefore not an ideal method for determining the diet of adult birds.

The investigation of faeces or stomach contents obtained via gastric lavage (stomach flushing) of adult birds is not subject to these constraints. For these approaches it is essential to be able to identify food items on the basis of diminutive remains found in faeces or stomach flushing samples. A considerable difficulty is the differential digestibility of different food types. Few remains may be found either because few items were eaten or because food items were almost completely digested. Calibration trials with captive birds can help to overcome this difficulty. Also, in some cases it may be possible to apply correction factors taken from the literature.

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If radio-tracking is applied simultaneously to the collection of diet samples, the source (e.g. a specific crop) of the food items found in the sample can be identified.

## 2.1 Test procedure

#### 2.1.1 Bird trapping and sample collecting

In order to obtain an estimate of the diet of a focal species, it is necessary to trap birds using accepted methods (e.g. mist nets, whoosh nets, perch traps, spring traps), when they have access to the crop of concern. The study should also be done at the appropriate time of year. Nets and/or traps should be placed within or at least in close proximity to the target crop. The sites should be representative of where the pesticide is used or is intended to be used. This may be across relevant geographical and climatic regions, within a MS if the pesticide is to be used in one MS, within a zone, or if the pesticide is used across a range of MS, then it may be appropriate to have a selection of fields across MS.

Once caught, it is possible to obtain a diet sample of a bird by obtaining faecal (after Brensing, 1977) and/or stomach flushing samples (modified after Ralph *et al.*, 1985). Generally faecal sampling is favoured over stomach flushing as it is not intrusive and tends to give more reliable results (see e.g. Jenni *et al.*, 1990). Therefore, it is recommended that stomach flushing should only be used if no faeces can be obtained.

#### **2.1.1.1 Faeces sampling**

For collecting faeces, birds can be kept in a clean bird bag or held over a polythene sheet during handling (Sutherland, 2004). Droppings can often also be collected in the field, e.g. where birds perch, roost and at nests. Faeces samples should be stored separately and can be preserved with sodium chloride.

It is important to keep samples separate and not to pool them. Separation of the samples serves two purposes, to account for individual variability and to apply correction factors to the food contents in order to take account of digestibility (see 2.4.1). Since these correction factors are derived from individual samples, proper application requires separate storage and analysis of each sample.

#### 2.1.1.2 Stomach sampling

A vaseline coated narrow plastic tube is inserted into the stomach and lukewarm water is pumped in the stomach through a syringe until the contents of the oesophagus and stomach are voided (Sutherland, 2004). The obtained sample is transferred in a sample container and preserved with alcohol. As for faeces sampling it is important not to pool the samples.

## 2.2 Collection of reference material

For an accurate determination of the diet of a bird a "reference collection" is useful as it facilitates the identification of the taxa of the food items. Additionally, the collection of reference material or food items, (such as invertebrates, seeds, or plants) from the study area can help to estimate the original size of food items. As a rule, un-digestible fractions of one food item are not obtained as a whole but rather as food fragments ("remains"). In order to minimize the uncertainty of the size estimation of food items a regression analysis of the dimension (size) of the potential food items and parts of these food items likely to be found within the samples can be conducted. Reference material, i.e. potential food items can be collected within the crop and the assumed home range of the birds.

#### 2.3 Sample analysis

Food items are investigated via microscopic analysis (reflected light microscopy and transmission light microscopy; see e.g. Flinks and Pfeiffer, 1988). Insect remains can often be assigned at least to the family. The remains of other invertebrates can mostly be assigned at least to the class. For the



determination of the green plant material, structures of the cuticle, particularly stomata, are considered. Seeds can be identified by analysing husk remains.

The size of characteristic parts of invertebrates or plants (e.g. chitin fragments of arthropods, setae of earthworms, fragments of seeds (pericarp), plant material, i.e. area of leaves and stems) can be measured with a measuring ocular. The obtained sizes can be compared to the specimens from a reference library.

In order to quantify the number of food items (e.g. number of arthropods), within each sample food fragments found in the sample are counted and the minimum number of individuals required to account for the number of assigned remains is calculated (see e.g. Jenny *et al.*, 1990). For example, two right mandibles and one left mandible of a beetle species can be attributed to (at least) two individuals. In plant material, the number of fruits and seeds can be obtained by measuring the area of the fragments and dividing this figure by the area of a reference fruit or seed. From remains of leaves the area is measured and recorded.

The quality of the results obtained by the analysis of faeces or stomach flushing samples depends significantly on the ability of the processor to identify the remains accurately. Trials using captive birds fed with a variety of different food items can help to quantify the recovery rate (see also 2.4.1).

#### **2.4** Data evaluation

# 2.4.1 Conversion of the number of food items in the faeces samples or stomach flushes to the number of food items actually ingested

For estimating how many food items were ingested by a bird, based on the number of food items found in the faeces or stomach, correction factors (or correlation coefficients) can be applied. For each type of food a specific correction factor has to be used, because during the digestion process some food items may almost completely disappear while others remain almost intact. For example earthworms or other soil invertebrates are usually digested efficiently. In contrast, cuticle parts of many arthropods remain often unaffected and can easily be identified in the faeces. Correction factors for some food types and bird species can be derived from the literature (e.g. Jenni *et al.*, 1990; Green, 1984). For example it has been shown that the number of Araneida (spiders) ingested is about 3.9 times higher than the number found in the birds' faeces (100/25.5, Jenni *et al.*, 1990).

Alternatively bird species specific feeding trials can be carried out in captivity to identify traces found in faeces and stomach flushing samples when known food items are consumed. These data can be used to establish food item specific correction factors which compensate for differential digestion (Jordan, 2005). Feeding trials also offer the opportunity to account for the uncertainty and variability of correction factors.

#### 2.4.2 Calculation of dry weight from length of food items ingested

In order to convert the calculated numerical proportions into mass proportions length-weight regressions derived from the literature (e.g. Collins, 1992; Henschel *et al.*, 1996, Klotz *et al.*, 2002; Rogers *et al.*, 1976; Sample *et al.*, 1993) can be applied, which are available for different invertebrate taxa and plant seeds. Hence, the approximate dry weight of food items can be calculated from their estimated length.

#### 2.4.3 Quantification of percentiles of the diet of farmland birds

Since the quantification of the diet of birds involves several measurement errors and also natural variability (e.g. body size of food items) the mean or median may include biases. Therefore, a percentile could be used instead of the arithmetic mean for deterministic assessments. A probabilistic approach for estimating the diet of birds offers the advantage that the different levels of variability and uncertainty can be included. A probabilistic approach uses distributions instead of constant parameter



values, from which parameter values are sampled many times in order to calculate the distribution of food groups for which RUDs are available (using a Monte Carlo method). This approach also allows an estimation of percentiles.

#### 3. How to determine a mammal's diet

The method of faeces analysis outlined above in section 2.1.1.1 can also be used for mammals. It is also possible to analyse stomach contents for mammals caught in snap-taps (mice, voles etc.) or shoot by hunters (hares, rabbits etc.) However, stomach flushing is not appropriate for mammals.

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# **APPENDIX R**

## NESTLING SCENARIOS FOR LONG-TERM ASSESSMENTS<sup>1</sup>

In the phased approach to the long-term risk assessment in birds, it was suggested (Shore et al., 2005) to turn to the  $LC_{50}$  study and use the  $LC_{05}$  as an indication of a dietary dose that could be tolerated by young birds. Unfortunately, the  $LC_{50}$  test has been plagued with problems (Mineau et al., 1994) and, furthermore, will no longer be required at an early tier in EU registration procedures. Therefore, it was agreed that an alternate strategy utilising the  $LD_{50}$  would be developed.

In order to estimate the ability of nestlings to survive a pesticide application, an approach parallel to that used for the acute assessment in adult birds has been developed. The approach uses information on the measured energetic needs of young birds, coupled to a feeding model and calculates a TER.

#### 1. Toxicity

The sensitivity of altricial nestlings to pesticides is known to be higher than that of adults in the case of organophosphorous insecticides (Wolfe and Kendall, 1998). This is in part because the cholinesterase system of altricial birds is not fully developed at birth. It is possible that altricial chicks are more sensitive to other classes of compounds as well but, unfortunately, no information is available on which to base a correction factor.

In the case of precocial chicks, available information does not suggest that a correction factor is required. The relationship between chick toxicity and adult toxicity follows roughly a 1:1 relationship (Fig. 1). Therefore, we propose at this stage to use adult  $LD_{50}$  values to reflect chick toxicity. More research is needed to characterize the toxicity of different pesticides to altricial chicks.

<sup>&</sup>lt;sup>1</sup> Acknowledgement: EFSA wishes to thank Pierre Mineau, Science and Technology Branch, Environment Canada, for the elaboration of this Appendix.

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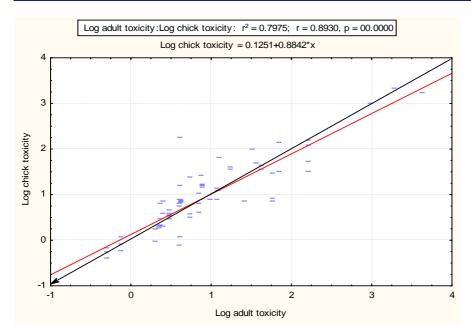


Figure 1. Log-log plot of chick  $LD_{50}$  (aged 1.5 - 60 days; median and mode age of 7 days) for bobwhite, mallard and japanese quail against the geometric mean  $LD_{50}$  in the adult. Exact values only. N = 69. Data source: Environment Canada database.

#### 2. Exposure

Comparisons provided in Kendeigh *et al.* (1977) suggest that gross energy intakes expressed as a proportion of body weight are higher in altricial nestlings than in precocial ones. Therefore, in order to be protective of all bird species, a generic exposure scenario used in the assessment of reproductive effects should be based on the energetic needs of a precocial species.

# Correction factor for digestive inefficiency and thermoregulatory status of very young altricial nestlings.

Based on the work of Kendeigh *et al.* (1977) in house sparrows, young birds aged 1-4 days have a food assimilation efficiency approximately 15% lower than that of adults. Based on the information provided for that species, correction factors of 0.83, 0.87, 0.87, and 0.93 are applied to ages 1-4 days respectively.

It has been shown by Williams and Prints (1987) that laboratory studies of energy use in altricial nestlings conducted under thermo neutral conditions underestimate field energy use because they do not usually take into account the thermoregulatory costs of 'outdoor living`. Information from that work was used to correct the maintenance portion of the daily energy needs of the nestlings. Correction factors were estimated from Figure 4 of Williams and Prints (1987) (Table 1). The discrepancy between the two measures increases with age which corresponds to the decrease in adult brooding behaviour over time.

#### **Body Mass**

Nestling weights of different species are dependant on egg size (and therefore clutch size and reproductive strategy) and on growth rate. The latter varies with age and is also subject to a number of ecological constraints. Based on examples gleaned from the literature (Kendeigh for house sparrows, Williams and colleagues in savannah sparrows), it is probably safe to use



a hatching weight of 11% of female adult body mass for scenarios involving freshly hatched altricial passerines. Maximum exposure (see table 1 below) in nestling savannah sparrows occurred when the birds were 2 days of age (48-72 hours post hatch), approximately 25% of adult female body weight. This percentage should be applied to the indicator species or generic focal species of concern unless more reliable data are available to estimate the weight of nestlings at 2 days of age.

#### Choice of scenario

Few if any of the generic focal species (Appendix A1) have been studied from the point of view of nestling energetics. It is therefore proposed that the exposure scenario for an altricial chick be based on the combined work of Williams and Prints (1987) on the savannah sparrow, and that of Kendeigh *et al.* (1977) in the house sparrow. Calculations suggest that an altricial chick is at its most vulnerable a few days after birth when its FIR/bw peaks (Table 1). We therefore propose that, until such time as better information becomes available, the max. FIR/bw value of 1.08 calculated in the savannah sparrow for the 48-72 hour period after hatch (25% of adult female bodyweight) should be used to model peak vulnerability to pesticide exposure in altricial insectivores.

**Table 1.**Energy budget of a nestling savannah sparrow based on Williams and Prints (1987) and<br/>Kendeigh *et al.* (1977).

Age(d)	<b>BW</b> <sup>1</sup> (g)	Energy for growth (kj/d)	Energy for main- tenance (kj/d)	Correction for thermo- regulation <sup>2</sup>	DEE (kj/d)	Food energy (kj/g dry wt)	Moi sture (%)	Assimi- lation efficiency (%) <sup>3</sup>	FIR (g/ day)	FIR /bw
0 to 1	1.79	4.96	1.67	1.3	7.13	21.9	70.5	63	1.75	0.98
1 to 2	2.81	8.53	2.19	1.35	11.49	21.9	70.5	66	2.69	0.96
2 to 3	4.24	13.19	4.54	1.4	19.55	21.9	70.5	66	4.58	1.08
3 to 4	6.04	17.56	6.55	1.45	27.06	21.9	70.5	71	5.90	0.98
4 to 5	8.05	19.15	10.36	1.5	34.69	21.9	70.5	76	7.07	0.88
5 to 6	10.02	16.84	15.33	1.55	40.60	21.9	70.5	76	8.27	0.83
6 to 7	11.70	12.24	20.37	1.6	44.83	21.9	70.5	76	9.13	0.78
7 to 8	12.98	7.73	24.59	1.65	48.30	21.9	70.5	76	9.84	0.76

<sup>1</sup> based on growth equation (g)

<sup>2</sup> estimated from Fig. 4 in Williams and Prints (1987)

<sup>3</sup> corrected for inefficiency in young house sparrow after table 5.6 in Kendeigh

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# APPENDIX S

# BIOACCUMULATION OF CHEMICALS IN TERRESTRIAL VERTEBRATES

This Appendix is predominantly based on Appendix III of EC (2002), thus containing the paper of Pablos et al. "Proposal to establish an initial risk assessment of terrestrial vertebrates for the estimation of pesticides with biomagnification potential". However, the example calculations were adapted to new values.

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# PROPOSAL TO ESTABLISH AN INITIAL RISK ASSESSMENT OF TERRESTRIAL VERTEBRATES FOR THE ESTIMATION OF PESTICIDES WITH BIOMAGNIFICATION POTENTIAL

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The current model assesses the potential for consumption of sprayed items and bioaccumulation of pesticides. Other hazards, such as biomagnification are not taken into account in this evaluation, but are important aspects for the protection of top predators. If the substance is persistent and likely to bioaccumulate (on the aquatic and/or terrestrial compartment), it would be necessary to apply an additional biomagnification model. For this assessment, it is necessary to calculate for each trophic level, the percentage of the total intake that is retained by the organism. These data can be obtained from the studies of both, metabolism on mammals and bioaccumulation on fish. Therefore an initial biomagnification assessment can be easily done with the available information.

This proposal presents a simplified model to assess the potential for biomagnification through the food chain.

#### **BIOACCUMULATION OF CHEMICALS IN TERRESTRIAL VERTEBRATES**

The bioaccumulation of pesticides in terrestrial vertebrates is estimated from the food-organism bioaccumulation factor (BAF):

$$BAF = \frac{C_{Organism}}{C_{food}}$$

where C organism and C food represent the steady-state concentrations of the chemical in the organism and the food respectively.

The BAF can be directly obtained from experimental assays or estimated from a combination of default values and the available data on the toxicokinetics of the pesticide in mammals.

The following equation is proposed for the estimation of the BAF:

$$BAF_{organisms, food} = \frac{\alpha F}{k_2}$$

This is a modification of the typical equation

$$ssBCF = \frac{k_1}{k_2}$$

where the uptake rate is represented by the product of the assimilation efficiency ( $\alpha$ ) and the feeding rate (F) while  $k_2$  represents the depuration rate.

The assimilation efficiency ( $\alpha$ ) represents the ratio between the amount of chemical existing in the



food and the amount of chemical absorbed by the organisms. This information is generally available in the toxicokinetic studies on mammals.

The feeding rate (F) represents the food intake rate related to body weight (FIR/bw). Appendix 12 and 13 of the Guidance Document offer estimated values for several bird and mammal species. The following table covers predators and top-predators.

Table 1:	Food intake rate (FIR) and Food intake rate related to body weight (FIR/bw) for
	predatory birds and mammals (table of former guidance document updated with
	information from Appendices 12 and 13.

Indicator species	Example	Body weight (g)	DEE <sup>1</sup> (kJ/d)	Food characteristics		Assimi- lation efficiency (%)	FIR (g fresh weight /d)	FIR/b w	
				Food type	Energy (kJ/g dry weight)	Moisture (%)			
Predatory bird	Peregrine falcon	1000	701	Birds	22.6	68.8	84	118	0.118
Predatory bird	Golden eagle	5000	2059	Birds & mammals	22.6	68.8	84	348	0.070
Predatory mammal	Fox	8000	4024	Birds & mammals	22.6	68.8	85	671	0.084
Predatory mammal	Linx	20000	7749	Birds & mammals	22.6	68.8	85	1293	0.065
Predatory mammal	Wolf	40000	12720	Birds & mammals	22.6	68.8	85	2122	0.053

 $^{1}$  = Daily energy expenditure calculations for predatory birds based on values for non passerines and for predatory mammals on values for mammals, excluding desert and marine eutherians.

The deputation rate  $(k_2)$  is obtained from the metabolism studies in mammals, using the elimination half-life  $T_{1/2}$  in the following equation:

$$k_2 = \frac{\ln(2)}{T_{1/2}}$$

For a first tier assessment the estimation could consider a steady state concentration (ss), estimated as:

$$ssPEC_{organisms} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{food}$$

where PEC food is estimated from the application rate and the RUD ( $90^{th}$  percentiles).

For the refinement, the dissipation of the pesticide in the environment can be incorporated, assuming first order kinetics, by a slightly modified equation frequently used for oral exposures (i.e. Fisk et al.,



1998):

$$PEC_{organisms} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{food} \left(1 - e^{-\left(\frac{\ln(2)}{DT_{50}}t\right)}\right)$$

## A SIMPLIFIED SCHEME FOR FOOD-CHAIN RELATIONSHIPS

Ecosystems are constructed by a set of assembled food chains producing very complex structures. For the inclusion of biomagnification in the environmental risk assessment of pesticides, these structures must be simplified to workable schemes.

Tables 2 and 3 describe the different links of the food-chain considered in the proposal for birds and mammals respectively.

Diet/nutrition	Food composition	Body size
Insectivore	100 % contaminated insects 100 % contaminated soil-dwelling invertebrates	Medium & small
Herbivore	100 % contaminated plants	Medium & large
Omnivore	<ul><li>33 % contaminated invertebrates, 33% contaminated seeds,</li><li>33 % contaminated plants</li></ul>	Small
Carnivore	100 % contaminated birds and mammals	Medium
Carnivore/piscivore	50 % contaminated birds and mammals 50 % contaminated fish	Large & medium
Piscivore	100 % contaminated fish	Medium & large
Aquatic herbivore/insectivore	50 % contaminated aquatic invertebrates 50 % contaminated aquatic plants	Medium

Table 2. Characteristics of selected birds.

Table 3. Characte	eristics of selecte	d mammals
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Diet/nutrition	Food composition	Body size
Insectivore	100 % contaminated insects	Small
Herbivore	100 % contaminated plants	Small & medium
Omnivore	<ul><li>33 % contaminated invertebrates, 33% contaminated seeds,</li><li>33 % contaminated plants</li></ul>	Medium
Carnivore	100 % contaminated mammals	Medium
Piscivore	100 % contaminated fish	Medium



#### ESTIMATION OF PEC FOR THE DIFFERENT FOOD CHAIN LEVELS.

The simplified proposal can be easily quantified using the equations described previously. For steady state conditions, each trophic level is considered to feed exclusively on contaminated food, corresponding to the previous trophic level.

The initial assessment, to quantify the concentration in the food items for intermediate consumers (birds and mammals) considers the consumption of sprayed food items, fish from contaminated waters and earthworms from contaminated soils.

The steady state concentration for the intermediate consumers is therefore calculated by:

$$PEC_{int\ ermediate \cdot consumers} = \frac{\alpha F}{k_2} \times (ETE) = \left(\frac{\alpha F \times T_{1/2} \times application \cdot rate \times RUD}{\ln(2)}\right)$$

In the case of omnivores the estimation assumes that the feeding of the animal is distributed proportionally between leaves, grass and insects; therefore, the estimation is:

$$PEC_{\text{int ermediate} \cdot consumers} \cdot (omnivores) = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times (application \cdot rate \times R_p)$$

The  $R_p$  is the averaged coefficient assuming the different proportions of the animal diet. This  $R_p$  is estimated as:

$$R_{p} = \frac{\left(\frac{\sum_{i}^{n} RUD_{i}}{P_{i}}\right)}{n}$$

The steady state concentration for predators is estimated assuming that contaminated intermediate consumers constitute 100% of their diet; the equations are different depending on the predators are piscivores, insectivores or carnivores. PECs can be estimated as:

$$PEC_{predators \cdot (piscivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{sw} \times BCF$$

$$PEC_{predators \cdot (in \, \text{sec tivores})} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{soil} \times BAF_{soil-earthworms}$$



$$PEC_{predators \cdot (carnivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{\text{int ermediate \cdot consumers (omnivores)}}$$
$$PEC_{predators \cdot (carnivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times application \cdot rate \times R_{p})$$

The same values for  $\alpha$  and  $k_2$  than those used for intermediary consumers can be used for the preliminary assessment. Only those insectivore species feeding on soil dwelling organisms are considered in this assessment as those feeding on foliar insects have been already covered as intermediate consumers. Earthworms are suggested as model since QSARs for soil bioaccumulation are available. Other soil-dwelling organisms can also be considered.

Similarly, the steady state concentration for top predators is estimated assuming that contaminated predators constitute 100% of their diet:

$$PEC_{toppredators} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{mammals \cdot \& \cdot birds}$$

Depending on the relevant compartment, the equations are:

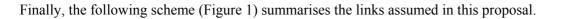
$$PEC_{toppredators} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{predatores(piscivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{sw} \times BCF$$

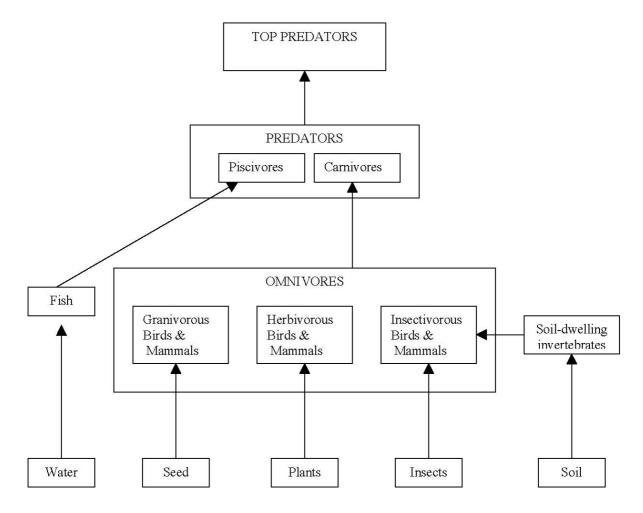
$$PEC_{toppredators} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{predatores(carnivores)}$$

$$= \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times \left[\frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times application \cdot rate \times R_{p}\right]$$

For episodic or intermittent exposures, the steady state calculations are not appropriate and the equations must be substituted by the kinetic equations. These equations can be modelled as combinations of two additive components, the chemical remaining from previous exposures and the newly absorbed chemical. Selecting  $\Delta t$  PEC values much lower than the  $T_{1/2}$ , the elimination component for the newly absorbed chemical becomes negligible, and the concentration in the organisms at time t, assuming first order dissipation kinetics, is represented by:

$$PEC_{organisms,t} = PEC_{organisms,(t-1)}(e^{-k2\Delta t}) + \left[ (\alpha F) PEC_{food,t} \Delta t \right]$$







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#### Worked example - Bioaccumulation issues

This example describes the risk to birds and mammals arising from bioaccumulation potential of a fictitious substance. It is assumed that the standard tier 1 assessment has been completed.

#### **Key endpoints**

long-term NOEL mammals	50 mg/kg bw/d
long-term NOEL birds	20 mg/kg bw/d
BCF (fish)	640
Adsorption, distribution,	Rate and extent of excretion: >95 % after 7 days
Excretion and metabolism in mammals	Potential for bioaccumulation: none
K <sub>OW</sub>	$20000 (\log K_{\rm OW} = 4.3)$
K <sub>OC</sub>	6200
PEC <sub>soil</sub>	1.4 mg/kg
PEC <sub>sw</sub>	0.001 mg/l

#### Initial trigger

It is noted that log  $K_{OW}$  is greater than 3 thus making necessary the considerations outlined in chapter 4.3.

#### Food chain from earthworms to earthworm-eating birds and mammals

Measured residues in earthworms are not available, nor experimentally determined bioconcentration factor for worms. Therefore the model calculation is applied.

- o  $PEC_{soil} = 1.4 \text{ mg/kg}$
- The BCF for worms is estimated as BCF =  $(0.84 + 0.01 K_{OW}) / (f_{OC} \times K_{OC})$

with

- $K_{OW} = 20000,$
- $K_{OC} = 3200,$
- and  $f_{OC} = 0.02$  (default value):

the resulting BCF is 1.6

- The estimated concentration in worm (PEC<sub>worm</sub>) is PEC<sub>soil</sub> × BCF, i.e.  $1.4 \times 1.6 = 2.2$  mg/kg.
- The daily dose for mammals is  $2.2 \times 1.28 = 2.82 \text{ mg/kg bw/d}$ , and for birds it is  $2.2 \times 1.05 = 2.31 \text{ mg/kg bw/d}$ .

The long-term TER-values are 50/2.82 = 17.7 for mammals and 20/2.4 = 8.66 for birds, and therefore the risk is acceptable.



#### Food chain from fish to fish-eating birds and mammals

- A model calculation is applied using the PEC for surface water and the experimentally determined BCF for fish.  $PEC_{sw} = 0.001 \text{ mg/l}.$
- The estimated concentration in fish (PEC<sub>fish</sub>) is PEC<sub>sw</sub> × BCF, i.e.  $0.001 \times 640 = 0.64$  mg/kg.
- The daily dose for mammals is  $0.64 \times 0.137 = 0.088$  mg/kg bw/d, and for birds it is  $0.64 \times 0.205 = 0.131$  mg/kg bw/d.

The long-term TER-values are 50/0.088=568 for mammals and 20/0.205=98 for birds, and therefore the risk is acceptable.

#### **Biomagnification in terrestrial food chains**

As the evaluation of the toxicokinetic studies in the toxicology section concluded that the potential for bioaccumulation is low it can be assumed that there is no biomagnification along the food chain.