Thiram

Addendum to the monograph
May 2003

B.9 Ecotoxicology

B.9.2.1Summary of effects to birds and mammals - Exposure and risk assessment (Annex IIIA 10.1)

The risk assessment to birds and mammals has been revised according to the new guidance document (SANCO/4145/2000). The risk assessment has been further refined, considering the actual residue in potential food items

Revision of the toxicological endpoints

Acute toxicity to mammals	LD50 rat = **1800** mg a.s./kg bw
Long term toxicity to mammals	Parental NOEL (2 gener., rat) = 30 mg a.s./kg food (equivalent to 1.5 mg a.s./kg bw/d) Reprod + develop NOEL (2 gener., rat) > 180 mg a.s./kg food (equivalent to > 9 mg a.s./kg bw/d) Foetal toxicity (terato, rat, 10 days exposure) = **15** mg a.s./kg bw/d Embryotox, terato (2 terato studies available in rabbit) > 5 mg and > 10 a.s./kg bw/d
Acute toxicity to birds	LD50 > **2000** mg a.s./kg bw
Dietary toxicity to birds	LC50 > 4423 mg a.s./kg food (equivalent to **947** mg a.s./kg bw/d)
Reproductive toxicity to birds	NOEC = 500 mg a.s./kg food (equivalent to **37.5** mg a.s./kg bw/d) Reversibility of the effects on reproduction was observed at 2500 mg a.s./kg food (equivalent to 187.5 mg a.s./kg bw/d) : the important effect on reproduction function disappears rapidly when normal feeding without a.s. is restored.

We consider that the previous evaluation which had been performed with a NOEL (effects on parents, rat) of 1.5 mg a.s./kg is a worst case situation. The NOEL for reproduction effect can be set at 15 mg a.s./kg bw/d.

Revision of the exposure to thiram residues.

The exposure to thiram has been based on the supervised residue trials which were available in the original monograph.
We considered that the most relevant trials were

- cherries, grapes, strawberries, (small fruit size, potential food source)
- lettuce (direct application on the leaves)

These results show the rapid residue decrease. There is no accumulation of the residue after repeated application.

The initial mean residue level of the various crops were 4.3, 4.0 and **5.7** mg a.s./kg respectively for cherries, grapes and strawberries.
The level of residue which were measured at 7-14 days can be considered as a 'time weighed average' : cherry 1.1-0.23 mg a.s./kg, grapes **3.6** mg a.s./kg, strawberries 1.8-0.8 mg a.s./kg, lettuce 2.4 mg a.s./kg.

The residue levels in plant material were considered as surrogate for the residue level in insects. The comparison of RUD figures indicate that the residues in insects are lower than the residues in plant material.

Supervised field trials in cherry – residue on the fruit in mg a.s./kg

	0 day	7 days	14 days	20-23 days
10 kg a.s./ha, 3 appl. (large trees)	2.09	2.52	0.18	0.18
1.5 kg a.s./ha, 3 appl.	1.72	0.22	0.25	0.12
2.4 kg a.s./ha, 3 appl.	6.63	1.55	0.41	0.70
2.4 kg a.s./ha, 3 appl.	6.7	0.3	0.1	-
Mean	4.3	1.1	0.23	

Supervised field trials in grape – residue on the fruit in mg a.s./kg

	0 day	10 days	21days	28 days	32-35 days
One sampling date					
3.2 kg a.s./ha, 3 appl					2.6
3.2 kg a.s./ha, 3 appl			5.6		
3.2 kg a.s./ha, 3 appl					0.7
3.2 kg a.s./ha, 3 appl			2.3		
3.2 kg a.s./ha, 3 appl					2.7 (48 days)
3.2 kg a.s./ha, 3 appl			4.5		
3.2 kg a.s./ha, 3 appl					1.1
3.2 kg a.s./ha, 3 appl			2.2		
Degradation curve					
3.2 kg a.s./ha, 3 appl	2.4	1.2	0.6	0.4	0.2
3.2 kg a.s./ha, 3 appl	5.6	5.9	2.7	1.3	0.2
Mean	4.0	3.6	3.0	0.9	

Supervised field trials in strawberries – residue on the fruit in mg a.s./kg

	0	7 days	14 days	21 days	
1.6 kg a.s./ha, 12 appl.					0.84 to 2.12 (measurement at each appl.
1.6 kg a.s./ha, 7 appl.	2.7	1.4	0.87	0.79	
1.6 kg a.s./ha, 8 appl.	3.3	2.8	0.45	0.06	
1.6 kg a.s./ha, 12 appl.					0.32-1.52 (measurement at each appl.)
1.6 kg a.s./ha, 6 appl.	15.89	2.10	1.72	0.45	
1.6 kg a.s./ha, 16 appl.					0.64-5.81 (measurement at each appl.)
1.6 kg a.s./ha, 14 appl.					1.0-10.70 (measurement at each appl.)
3.2 kg a.s./ha, 2 appl.	2.60	0.80	0.45		
3.2 kg a.s./ha, 2 appl.	2.32	0.99	0.86		
2.4 kg a.s./ha, 4 appl.	7.71	2.26	0.54		
2.4 kg a.s./ha, 3 appl.	4.0	1.3	0.5		
2.4 kg a.s./ha, 3 appl.	7.4	2.8	1.5		
Mean	5.7	1.8	0.9		

Supervised field trials - foliar treatment in lettuce – residue on the leaves in mg a.s./kg

	14 days	28 days	42 days
8 kg a.s./ha	-	0.8	<0.3
8 kg a.s./ha	-	1.8	<0.3
2 kg a.s./ha, 2 appl.	3.8	<0.3	
2 kg a.s./ha, 2 appl.	0.94	<0.2	
Mean	2.4		

First tier risk assessment according to the Guidance document on risk assessment for birds and mammals (SANCO/4145/2000)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
2.4 kg a.s./ha, 4 appl.	Orchards	insectivorous bird (early/late)	Acute	15.4	10
		insectivorous bird (early/late)	short term	8.3	10
		insectivorous bird (early/late)	long term	0.3	5
		herbivorous mammal (early/late)	Acute	6.3	10
		herbivorous mammal (early/late)	long term	0.1	5
3.2 kg a.s./ha, 4 appl.	Vineyard	insectivorous bird (early/late)	Acute	11.6	10
		insectivorous bird (early/late)	short term	6.2	10
		insectivorous bird (early/late)	long term	0.2	5
		herbivorous mammal (early/late)	Acute	4.8	10
		herbivorous mammal (early/late)	long term	0.1	5
2.5 kg a.s./ha 3 appl.	Strawberry	med. herbivorous bird	Acute	12.1	10
		insectivorous bird	acute	14.8	10
		med. herbivorous bird	short term	7.9	10
		insectivorous bird	short term	8.0	10
		med. herbivorous bird	long term	0.6	5
		insectivorous bird	long term	0.3	5
		med. herbivorous mammal	Acute	29.6	10
		med. herbivorous mammal	long term	0.6	5

Refined risk assessment based on measured residue levels

The following assumptions were made

- the Food Intake Rates which are proposed in the new guidance document were taken into consideration
- The initial residue level of 5.7 mg/kg food which has been derived from the supervised field trials is used for the acute risk assessment
- The residue level at day 7-14 of 3.6 mg/kg food is used for the short term and long term risk assessment
- These residue levels are considered as representative of all proposed crop types : They are based on a large number of trials on various crops (several applications, some trials with application rates and number of applications above the proposed GAP)

Some important mitigations factors were not considered in the risk calculation because precise numerical determination is not feasible. However they should be taken into account in the overall risk assessment : animals ingest 100% of contaminated diet, no foraging outside the field, avoidance is not considered, the actual presence/absence of birds and mammals in intensive crops (vegetables, strawberries,…) is not considered.

The TER calculations have been made according to the scenarios proposed in the guidance.

Refined risk assessment based on measured residue levels

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
2.4 to 3.2 kg a.s./ha, 4 appl.	Orchards, grapes, field crops	insectivorous bird (early/late)	Acute	2000/(1.04 * 5.7) = 337	10
		insectivorous bird (early/late)	short term	947/(1.04 * 5.7) = 160	10
		insectivorous bird (early/late)	long term	37.5/(1.04 * 3.6) = 10	5
		herbivorous mammal (early/late)	Acute	1800/(1.39 * 5.7) = 227	10
		herbivorous mammal (early/late)	long term	15/ (1.39* 3.6) = 3	5

Conclusion :
The acute, short term, long term risk to mammals an birds in orchards, vineyards and field crops is considered acceptable.

General concern on the the new guidance document : This assessment (acute and short term TER close or below the trigger with LD50, LC50 of 1000-2000 mg/kg) reveals that the assumptions which are made in the new guidance document are conservative and that further risk refinement is required for almost all crop scenarios. Uniform guidance should be given on the possible mitigations measures (determination of PD and PT figures at EU level, adaptation of trigger values ?, …)