



# Case study 5: Risk assessment for in soil organisms: future approaches and perspective

Maria Arena  
Pesticides Unit, EFSA

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# SUBSTANCE PROPERTIES

I<sub>AD</sub> (anthranilic diamide insecticide) is efficacious for control of lepidopteran insect pests, as well as some species in the orders Coleoptera, Diptera and Hemiptera through impairment in the regulation of muscles contraction.

Function	Insecticide
Partition Coefficient	20 °C pH 4:2.77 pH 7:2.86 pH 9:2.80
Dissociation constant	10.88

High to very high persistence-DT<sub>90lab-f</sub> >1 y

# REPRESENTATIVE USES

Crop	Country	F or G or I	Pest or group of pests controlled	Growth stage	Number of appl.	Interval between appl.	Appl. rate (g a.s./ha)
<b>Pome fruits</b>	NEU SEU	F	<i>Cydia pomonella</i> <i>Leafminers</i> <i>Leafrollers</i> <i>Opherophtera brumata</i>	BBCH 70- BBCH 87	1-2	14	60 (300 ml fp/ha)
<b>Stone fruits</b>	SEU	F	<i>Cydia molesta</i> <i>Anarsia lineatellata</i>	BBCH 73- BBCH 85	1-2	10-14	60 (300 ml fp/ha)
<b>Wine grapes</b>	NEU SEU	F	<i>L.botrana</i> <i>E.ambiguella</i>	BBCH 57- BBCH 83	1	n.a.	54 (270 ml fp/ha)
<b>Table grapes</b>	SEU	F	<i>L.botrana</i> <i>E.ambiguella</i>	BBCH 57- BBCH 85	1-2	10-14	43.2 (216 ml fp/ha)
<b>Fruiting vegetables</b>	SEU	F	<i>S.littoralis</i> <i>H.armigera</i> <i>S.exigua</i> <i>P.gamma</i>	BBCH 71- BBCH 89	1-2	7-14	42 (80-120 g fp/ha)
<b>Lettuce</b>	SEU	F	<i>S.exigua</i> <i>S.littoralis</i> <i>H.armigera</i>	BBCH 12- BBCH 49	1-2	7-14	42 (90-120 g fp/ha)


# EXPOSURE-CURRENT APPROACH (PARENT COMPOUND)

Parameter	Value	Crop	Appl. rate (g a.s./ha)	Interval	Crop intereception FOCUS (%)	PEC max (mg/kg)
Soil depth	5	Pome fruit	2x60	14	70	0.278
Soil dry bulk density	1.5	Stone fruits	2x60	10	70	0.278
		Grapes, wine	1x54	-	70	0.126
Molecular weight	483.	Grapes, table	2x43.5	10	70	0.202
Worst case DegT50	1,37	Lettuce	2x42	7	25+40	0.44
		Fruiting vegetables	2x42	7	80	0.13

# EXPOSURE-PERSAM-EFSA GD 2015 (PARENT COMPOUND)


Parameter	Value	Crop	Appl. rate (g a.s./ha)	Interval	Fsoil	PEC max (mg/kg)
Soil depth	1-2...	Pome fruit	2x60	14		
Soil dry bulk density	1.51 (Soil at Ti	Stone fruits	2x60	10		
Molecular weight	483.	Grapes, wine	1x54	-		
Fsoil	-	Grapes, table	2x43.5	10		
Geometric mean DegT50	597	Lettuce	2x42	7	0.85	0.51
		Fruiting vegetables	2x42	7	0.62	0.56

# PERTINENT SOIL METABOLITES



Metabolite	Partition coefficient	Persistence	Max PEC <sub>soil</sub> Lettuce 2x42 g a.s./ha (25+40% interception) App. Interval=7d	Max PEC <sub>soil</sub> Pome fruits/Stone fruits 2x60 g a.s./ha (70% interception) App. interval=10d	PEC <sub>soil</sub> (worst case)-PERSAM
Metabolite 1	3.9	1,164	0.27	0.171	0.63
Metabolite 2	5.1	4,257	0.209	0.132	0.48
Metabolite 3	-	159	0.012	0.0075	0.075
Metabolite 4	3.8	5,473	0.74	0.47	2.24

# TOXICITY DATA ON SOIL ORGANISMS



Test organisms	Test substance	Time scale	Endpoint
Earthworms			
<i>Eisenia fetida</i>	Active	Acute 14 days	LC50 > 1000 mg a.s./kg d.w. soil
<i>Eisenia fetida</i>	Formulation1	Acute 14 days	LC50 > 1000 mg product/kg d.w. soil (>200 a.s.)
<i>Eisenia fetida</i>	Formulation2	Acute 14 days	LC50 > 1000 mg product/kg d.w. soil (>350 a.s.)
<i>Eisenia fetida</i>	Formulation2	Chronic, 56 days	NOEC = 1000 mg product/kg d.w. soil (350 a.s.)

# TOXICITY DATA


Test organisms	Test substance	Time scale	Endpoint
Other soil macro-organisms			
<i>Folsomia candida</i>	Active	Chronic 28 days	NOEC=0.39 mg a.s./kg d.w. soil
<i>Hyapoaspis aculeifer</i>	Active	Chronic 16 days	NOEC=100 mg a.s./kg d.w. soil

Test organisms	Test substance	Time scale	Endpoint
Microorganisms			
Nitrogen and Carbon mineralisation	Active	28 days	<25% effects at 0.700 mg a.s./kg d.w. soil
Nitrogen and Carbon mineralisation	Formulation2	42 days	<25% effects at 0.814 mg product/kg d.w. soil
Nitrogen and Carbon mineralisation	Formulation2	42 days	<25% effects at 0.802 mg product/kg d.w. soil

Data on adsorption/desorption in general soils suggested that sorption is not greater in the artificial soil compared to natural soils. Consequently, it is expected to exhibit similar bioavailability in natural and artificial soils. Therefore the factor of 2, as suggested by the SANCO GD on terrestrial ecotoxicology for lipophilic substances, was reasonably not applied to the toxicity endpoint.




# RISK CHARACTERISATION



Test organisms	Time scale	Endpoint	PEC (worst case-current approach)	PEC (new approach-EFSA GD 2015)	TER
<i>Eisenia fetida</i>	Acute	LC50>1000 mg a.s./kg d.w. soil	0.44	0.56	>2273/>1785
<i>Eisenia fetida</i>	Chronic	NOEC=1000 mg product/kg d.w. soil (350 a.s.)	0.44	0.56	2273/1785
<i>Hyapoaspis aculeifer</i>	Chronic	NOEC=100 mg a.s./kg d.w. soil	0.44	0.56	227/178

**According to the trigger as defined in the Reg.546/2011  
low risk to earthworms and mites for all the representative uses**

# RISK CHARACTERISATION



Crop	Test organisms	Time scale	Endpoint	PEC (current approach)	PEC (new approach- EFSA GD 2015)	TER
<b>Lettuce</b>	<i>Folsomia candida</i>	Chronic	NOEC=0.39 mg a.s./kg d.w. soil	0.44	0.51	0.89/0.76
<b>Pome fruits/Stone fruits</b>	<i>Folsomia candida</i>	Chronic	NOEC=0.39 mg a.s./kg d.w. soil	0.278	-	1.4
<b>Grapes, table</b>	<i>Folsomia candida</i>	Chronic	NOEC=0.39 mg a.s./kg d.w. soil	0.202	-	1.9
<b>Grapes, wine</b>	<i>Folsomia candida</i>	Chronic	NOEC=0.39 mg a.s./kg d.w. soil	0.126	-	3.1
<b>Fruiting vegetables</b>	<i>Folsomia candida</i>	Chronic	NOEC=0.39 mg a.s./kg d.w. soil	0.13	0.56	3/0.7

**According to the trigger as defined in the Reg.546/2011  
high risk to Collembola for all the representative uses**

# RISK CHARACTERISATION-METABOLITES

	Test organisms	Time scale	Endpoint	PECsoil (worst case)	PECsoil (worst case)-PERSAM	TER
Metabolite 1	<i>Eisenia fetida</i>	Acute	LC50>1000 mg met/kg d.w. soil	0.27	0.63	>3703/>1587
		Chronic (56d)	NOEC=1000 mg met/kg d.w.	0.27	0.63	3703/1587
Metabolite 2	<i>Eisenia fetida</i>	Acute	LC50>1000 mg met/kg d.w. soil (350 a.s.)	0.209	0.48	>4785>2083
		Chronic (56d)	NOEC=1000 mg met/kg d.w.	0.209	0.48	4785/2083
Metabolite 3	<i>Eisenia fetida</i>	Acute	LC50=632.5 mg met/kg d.w. soil	0.012	0.075	52958/8433
Metabolite 4	<i>Eisenia fetida</i>	Acute	LC50>1000 mg met/kg d.w. soil	0.74	2.24	>1351/>446
		Chronic (56d)	NOEC=1000 mg met/kg d.w.	0.74	2.24	1351/446

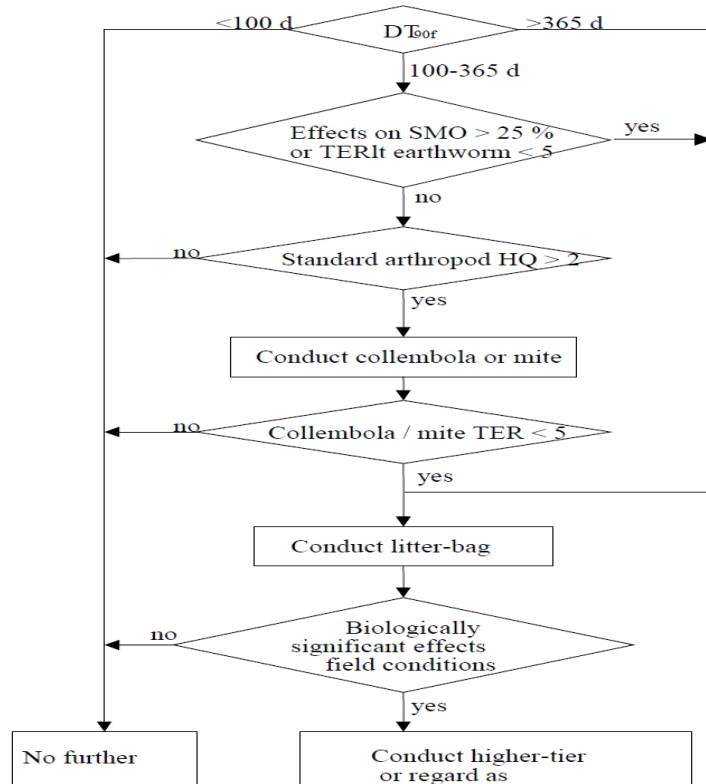
**According to the trigger as defined in the Reg.546/2011  
low risk to earthworms identified for the pertinent soil metabolites**

# RISK CHARACTERISATION-METABOLITES

According to the trigger as defined in the Reg. 546/2011 low risk to soil invertebrates other than earthworms and soil microorganisms was identified for the pertinent soil metabolites

	Test organisms	Time scale	Endpoint	PECsoil (Worst case)	PECsoil (Worst case) PERSAM	TER
Metabolite 1	<i>Folsomia candida</i>	Chronic (28 d)	NOEC=100 mg met/kg d.w.	0.27	0.63	370/159
Metabolite 2	<i>Folsomia</i>	Chronic	NOEC=100 mg	0.209	0.48	478/2.08
Metabolite 3	<b>Test organisms</b>	<b>Test substance</b>	<b>Time scale</b>	<b>Endpoint</b>		8333/1333
	Microorganisms					
Metabolite 4	Nitrogen and Carbon mineralisation	Metabolite1	28 days	<25% effects at 0.800 mg met/kg d.w. soil		135/45
	Nitrogen and Carbon mineralisation	Metabolite2	28 days	<25% effects at 0.800 mg met/kg d.w. soil		
	Nitrogen and Carbon mineralisation	Metabolite3	28 days	<25% effects at 0.840 mg met/kg d.w. soil		

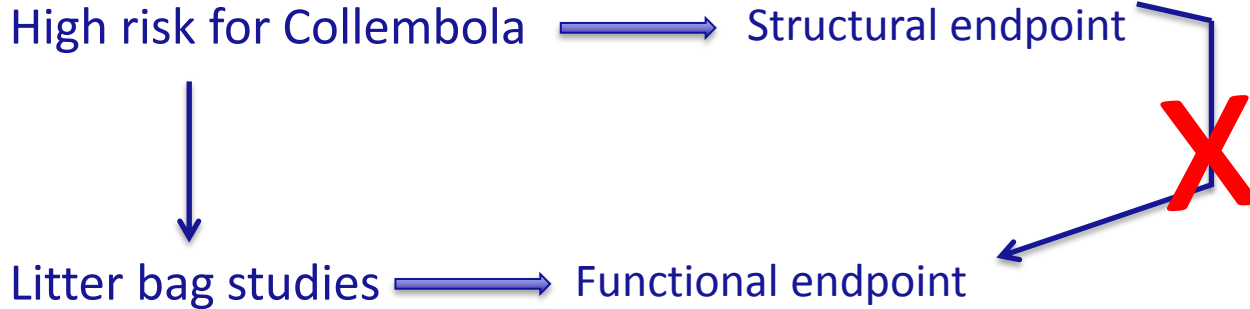
# HIGHER TIER TESTINGS



## 2 litter bag studies available

1. The study was conducted using Formulation1 and no effects were seen on degradability of soil organic matter in 12 months under exposure conditions simulating 10 years continual use at annual rate of 150 g a.s./ha
2. The study was conducted using Formulation2 and metabolites and no effects were seen on degradability of soil organic matter in 17 months simulating 10 years continual use at annual rate of 240 g a.s./ha

# CURRENT APPROACH



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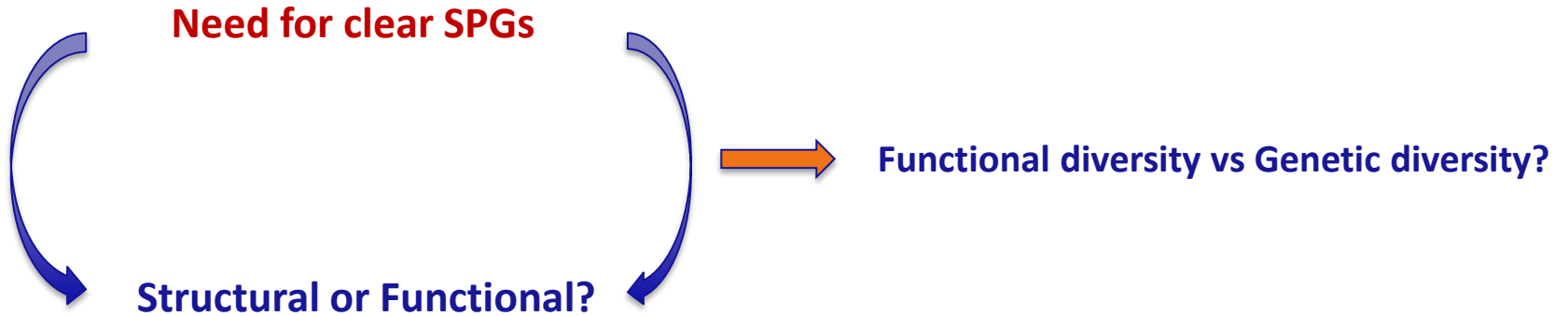


Applying a factor of 2 to the toxicity endpoint if the test is carried out by using an OECD soil with 10 % or 5% sphagnum peat



Are the standard test species sensitive enough to protect the soil ecosystem (biodiversity and functions)?

# FUTURE PROSPECTIVE



## Bioavailability

Bioavailability of the test item in the test systems (e.g. lipophilic substances)





**THANK YOU**

GRACIAS  
ARIGATO  
SHUKURIA  
DANKSCHEEN  
TASHAKKUR ATU  
SUKSAMA  
MURAHATI  
TANGKI  
BIYAN  
SHUKRIA  
YAHMANYELAY  
MALAKI  
GRAZIE  
MEHRBANI  
PALLOES  
GOZAMASHTA  
EFCCHARISTO  
KOMASATJUMANDA  
JUSPAYAR  
BOLZIN  
MERCII

