

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>		

Physical and chemical properties of the active substance (B.2.1)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	Simon Delso: since Metalaxyl is systemic and with high potential for acropetal movement, contact with residues coming from guttation water or consumption of either guttation droplets/morning dew contaminated by residues from guttation is of relevant for bees. This way of exposure should be included into exposure assessment.	

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Further information (B.3)

Comments of Noa Simon Delso on the draft/assessment report/additional report on Metalaxyl-B

(18.02.2014) 2/17

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Methods of analysis (B.5)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Other comments

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

Toxicokinetics (B.6.1)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Acute toxicity (B.6.2)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Short-term toxicity (B.6.3)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Genotoxicity (B.6.4)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 2 - Mammalian toxicology (B.6)

Long-term toxicity and carcinogenicity (B.6.5)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Reproductive toxicity (B.6.6)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Neurotoxicity (B.6.7)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 2 - Mammalian toxicology (B.6)

Summary of mammalian toxicology and setting ADI, AOEL, ARfD (B.6.10)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Toxicity of the product(s) (B.6.11)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Dermal absorption (B.6.12)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Toxicity of non-active substances (B.6.13)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 2 - Mammalian toxicology (B.6)

Exposure data (B.6.14)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Other comments			
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(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 3 - Residues (B.7)

3. Residues (B.7)

Storage Stability (B.7.0)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Metabolism in plants (B.7.1)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Metabolism in livestock (B.7.2)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Residue definition (B.7.3)

No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 3 - Residues (B.7)

Use pattern, critical GAP, residues trials (B.7.4 to B.7.6)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Processing (B.7.7)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Livestock feeding (B.7.8)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Succeeding/Rotational crops (B.7.9)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 3 - Residues (B.7)

MRLs related issues and Consumer Risk Assessment (B.7.10 to B.7.15)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Other comments			
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(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 4 - Environmental fate and behaviour (B.8)

4. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Adsorption, desorption and mobility in soil (B.8.2)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

PEC in soil (B.8.3)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 4 - Environmental fate and behaviour (B.8)

PEC in surface water and ground water (B.8.6)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Definition of the residues (B.8.9)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
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Other comments			
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(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Section 4 - Environmental fate and behaviour (B.8)

Section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)			

Aquatic organisms (B.9.2)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
-1	B.9.4.1.	Simon-Delso: acute toxicity tests (oral and contact) have been run with winter bees (October/November), which are known for been more resistant and have longer lifespan than summer bees. It would be recommendable to run this tests with summer bees.	<u>For the basis of this comment please see:</u> Amdam GV, Omholt SW (2002) The regulatory anatomy of honeybee lifespan. Journal of theoretical biology 216: 209–228.
-2	B.9.4.1.	Simon-Delso: Only acute toxicity trials were performed. However, Metalaxyl M is systemic, and moderately persistent, and contaminates nectar and pollen over a long period. Bees are thus exposed chronically. Chronic toxicity trials should be performed as well as larvae toxicity	<u>Metalaxyl-M presence in pollen and nectar:</u> see among others the Bee-Net monitoring bulletin on the Reterurale website (Italia): Bollettino n°1 (2013) pp. 19-22 : http://www.reterurale.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/13084

Section 5 - Ecotoxicology (B.9)

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	<u>Column 1</u> Reference to assessment report	<u>Column 2</u> Comment (restricted to 500 characters, ca.10 lines)	<u>Column 3</u> Further explanations
		tests. Mainly if considered the synergistic effect of Metalaxyl with other molecules.	<p>Mullin CA, Frazier M, Frazier JL, Ashcraft S, Simonds R, et al. (2010) High Levels of Miticides and Agrochemicals in North American Apiaries: Implications for Honey Bee Health. PLoS ONE 5: e9754. doi:10.1371/journal.pone.0009754.</p> <p><u>Chronic Vs acute toxicity:</u> Fiedler L, 1987: Assessment of chronic toxicity of selected insecticides to honeybees, Journal of Apicultural Research 26 (2): 115-122 Illarionov AI, 1991: Toxic effects of some insecticides on the honeybee. Agrokhimiya 8:121–125</p> <p><u>Synergistic effects:</u> see patent Krohn et al 2008. Synergistic mixtures exhibiting insecticidal and fungicidal action. See patent Gewehr et al 2012. Pesticidal mixtures As shown by multiple studies, within a bee colony there is always a mixture of residues contaminating bee matrices. If required, a list of references can be sent.</p>
-3	B.9.4.1.	Simon-Delso: Only acute toxicity trials were performed. However, Metalaxyl M is systemic, and moderately persistent, and contaminates nectar and pollen over a long period. Bees are thus exposed chronically. As fungicide, Metalaxyl may affect bee's intestinal microflora leading to dysbiosis and eventual weakening of bees, disease development or indigestion/reduced digestibility of food.	Anderson KE, Sheehan TH, Eckholm BJ, Mott BM, DeGrandi-Hoffman G (2011) An emerging paradigm of colony health: microbial balance of the honey bee and hive (Apis mellifera). Insectes Sociaux 58: 431–444. doi:10.1007/s00040-011-0194-6.

Section 5 - Ecotoxicology (B.9)

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
-4	B.9.4.2. B.9.4.2.: Metalaxyl-M does not act as an insect growth regulator and therefore this study is not required	Simon-Delso: Larvae are chronically exposed to Metalaxyl-M since the substance contaminates pollen (therefore, bee bread) and nectar. Pesticides toxicity to bees larvae may widely differ from toxicity to adult bees. A bee brood feeding test (such as the one performed by Zhu et al. (2014) should be performed.	Zhu W, Schmehl DR, Mullin CA, Frazier JL (2014) Four Common Pesticides, Their Mixtures and a Formulation Solvent in the Hive Environment Have High Oral Toxicity to Honey Bee Larvae. PLoS ONE 9(1): e77547. doi:10.1371/journal.pone.0077547
-5	B.9.4.2.: Metalaxyl-M does not act as an insect growth regulator and therefore this study is not required	Simon-Delso: As a fungicide Metalaxyl-M may disturb the pollen microflora that ensures pollen digestibility for bees. Fungicides modify the amino acid profile of pollen and beebread and severely decrease the rate in several essential amino acids, particularly Tryptophan and Phenylalanin Moreover fungicides are suspected to affect negatively queen development when queens are reared with contained pollen (DeGrandi-Hoffman 2013).	DeGrandi-Hoffman et al., undated slide show: http://www.alfredstate.edu/files/downloads/New-York-Beekeepers-GDH.pdf Yoder JA, Jajack AJ, Rosselot AE, Smith TJ, Yerke MC, et al. (2013) Fungicide Contamination Reduces Beneficial Fungi in Bee Bread Based on an Area-Wide Field Study in Honey Bee, <i>Apis mellifera</i> , Colonies. Journal of Toxicology and Environmental Health, Part A 76: 587–600. doi:10.1080/15287394.2013.798846. DeGrandi-Hoffman G, Chen Y and Simonds R, 2013: The Effects of Pesticides on Queen Rearing and Virus Titers in Honey Bees (<i>Apis mellifera</i> L.), Insects 2013, 4, 71-89; doi:10.3390/insects4010071.

Section 5 - Ecotoxicology (B.9)

-6	B.9.4.8.2. Exposure	Simon Delso: since Metalaxyl is systemic and with high potential for acropetal movement, regardless if the treatment is done as seed coating or as spraying, (1) contact with residues coming from guttation water or (2) consumption of either guttation (2a) droplets or morning dew contaminated by residues from guttation (2b) are relevant exposure routes for bees. This ways of exposure should be included into exposure assessment regardless of the product/way of application considered.	It needs to be highlighted that as most terrestrial animals bee colonies consume water. See EFSA (2012) Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (Apis mellifera , Bombus spp . and solitary bees) 1 EFSA Panel on Plant Protection Products and their. EFSA Journal 10: 1–275.
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Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)

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(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)

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Other comments

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