Comments of the Norwegian Scientific Committee for Food and Environment (VKM) on the draft (renewal) assessment report on Clofentezine (20.12.2018) 1/19

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.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Physical and chemical properties of the active substance (B.2.1)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.2.2, Summary of physical and chemical properties of the plant protection product	VKM – It will be helpful if the solvent of the plant protection product is stated	Solvent might have an impact on the uptake in biological tissues and impact exposure

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

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

Methods of analysis (B.5)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Effectiveness against target organisms			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.3.2 Summary of information of the development of resistance	VKM: It will be very helpful if the target protein is known	If the target protein is expressed in mammalian species, including humans this might potentially impact the safety profile including developmental studies. In addition, knowledge of the target protein might help in the identification of non-target species affected by the acaricide.
	Vol 3., B3.6, Mode of action	VKM: “During the last stages of the embryo, the structure of forming cells is interrupted. In consequence formation of respiratory organs is blocked.” Are these colony forming cells? Please specify.	

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

Occurrence of Resistance, Effects on quality/Processes/Yield/Phytotoxicity/Succeeding and Adjacent crops/Plants for propagation			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B4.4, Possible occurrence of pesticide degradates from drinking water treatments	VKM: Information regarding the potential of clofentezine to reach underground drinking water reservoirs as well as its stability in surface water would be useful.	

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

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Section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

Toxicokinetics (B.6.1)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1 - 2.6.1	VKM: Clofentezine appears to be an enzyme inducer of the phenobarbitone type: please state that these observations were made in the rat and mice. Was this studied in other species including the baboon?	
(2)	Vol III B.6.1.1-27, *In vitro* comparative metabolism	VKM: Why is this paragraph referred to as “in vitro comparative metabolism” when only in vivo studies are presented?	

Acute toxicity (B.6.2)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. III, B.6.2.2.-02, Second study (rat)	Please consider including observations that were made on the skin at the place of application in order to judge potential local effects	

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Section 2 - Mammalian toxicology (B.6)

Short-term toxicity (B.6.3)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Table B.6.3.2.1-01/1, Mortality and body weight, food consumption and water consumption for rats killed following 90-day dosing with clofentezine	215 as bw in week 14 for control males must be a typographical error.	

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

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

Section 2 - Mammalian toxicology (B.6)

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

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

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.6.8, Summary of further toxicological studies on the active substance	VKM: A reference should be included why the effects on thyroid are considered rat specific and not of relevance for humans.	

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Section 2 - Mammalian toxicology (B.6)

Other toxicological studies & Medical data (B.6.8-B.6.9)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(2)	Vol. 1 2.6.8.2, Summary of studies on immunotoxicity	VKM: There are no indications that clofentezine has immunological potential. Please state what parameters from the regulatory toxicology studies were examined that support this statement.	
(3)	Vol. 1, 2.6.10, Summary of medical data and information	VKM: No findings of adverse effects in the results of the periodic medical examination. How many workers were examined and what was the duration of exposure? Were these workers involved in manufacturing or in the application?	

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

Section 2 - Mammalian toxicology (B.6)

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

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

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

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Section 2 - Mammalian toxicology (B.6)

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

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

3. Residues (B.7)

Storage Stability (B.7.0)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Metabolism in plants (B.7.1)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Metabolism in livestock (B.7.2)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

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Section 3 - Residues (B.7)

Residue definition (B.7.3)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

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

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

Section 3 - Residues (B.7)

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

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

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

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Section 3 - Residues (B.7)

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

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4. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.8.1.2.1.2.3, metabolite photolysis degradation	VKM: metabolite photolysis rates not presented	
(2)	Vol. 1, 2.8.1.2.1.1.1, aerobic degradation	VKM: as described in the first paragraph, kinetics of all studies were re-assessed according to FOCUS (guidance) and normalised. It appears however, that no normalised values are presented throughout this section. VKM: Second paragraph and throughout section; please specify unambiguous source of DT values, original or re-assessed. VKM: typographic error in fourth paragraph; "…four different European soils"	Description in first paragraph is sufficient
(3)	Vol. 1, 2.8.1.1.1, Summary of aerobic degradation studies in soil	VKM: Table 2.8.1.1.1-1; is it possible that MWHC of Bottisham Clay loam is 113? Also, OC-content very high (14.7%).	

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

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

PEC in soil (B.8.3)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 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.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3-B.8, B.8.2.2.2/01, New study on aerobic mineralisation in SW	VKM: highest nominal test concentration (41 ug/l) exceed proposed clofentezine water solubility (34 ug/l; vol. 1, B.2.2.1)	
(2)	Vol. 3-B.8, B.8.2.2.3/03, New study on aerobic aquatic sediment metabolism	VKM: nominal test concentration (0,3 mg/l) by far exceed proposed clofentezine water solubility (34 ug/l; vol. 1, B.2.2.1)	

Vitenskapskomiteen for mat og miljø
Norwegian Scientific Committee for Food and Environment

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

Fate and behaviour in water and impact on water treatment procedures (B.8.4 – B.8.5)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		VKM: if possible, a table showing individual metabolites of "other unknowns" should be presented. AR>5% at three consecutive timepoints.	

PEC in surface water and ground water (B.8.6)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.8.5.3, table 2.8.5.3-1	VKM: Clofentezine water solubility – header row mg/l, but input value corresponds to g/l.	

Fate and behaviour in air and PEC in air (B.8.7 – B.8.8)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.8.4, Air monitoring	VKM: "It can be assumed that the low use, low toxicity and low volatility of the active substance have precluded any cause for concern by Regulatory Agencies around the world." Last sentence appears to be speculative, please reconsider.	

Vitenskapskomiteen for mat og miljø
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Section 4 - Environmental fate and behaviour (B.8)

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

Other comments			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 2.8.2, Summary of fate and behaviour in water and sediment – last section	VKM: degradation occurs in both water and sediment phase being more pronounced in the sediment phase. Please state what parameters were examined that support this statement.	
(2)	Vol. 1, 2.8.1.2.3, Assessment of persistence (P) in soil	VKM: in second paragraph p.111 time point 333 HAT is used, even though this data point is not valid (total AR less than 90; Vol. 3-B.8, table 8.1.1.3/02-3)	

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Section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

Birds and mammals (B.9.1 and B.9.3)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

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

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

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Section 5 - Ecotoxicology (B.9)

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. #, <<data point>>, <<description>>	<< Identifier >>: <<comment>>	

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