



Vitenskapskomiteen for mattrygghet  
Norwegian Scientific Committee for Food Safety

# Evaluation of the arguments in the appeal from Bayer Crop Science of the decision made by The Norwegian Food Safety Authority on the fungicide Infinito with the active substances fluopicolide and propamocarb

## Opinion of the Panel on plant protection products of the Norwegian Scientific Committee for Food Safety

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Persons working for VKM, either as appointed members of the Committee or as ad hoc experts, do this by virtue of their scientific expertise, not as representatives for their employers. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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## Summary

Infito is a new fungicide containing the two active substances fluopicolide and propamocarb-HCl intended to protect potatoes against the blight pathogen *Phytophthora infestans*. Fluopicolide is a new active substance in Norway, while propamocarb-HCl is already approved in several products. The risk assessment of Infito was finalized in a meeting on 29. May 2012 by the Panel on Plant Protection Products of the Norwegian Scientific Committee for Food Safety (VKM).

### **The main conclusions from the risk assessment of Infito were:**

- VKMs opinion is that both fluopicolide and its main metabolite M-01 (2,6-dichlorobenzamid (BAM)) are persistent in Norwegian soils and surface waters.
- Fluopicolide and its main metabolite M-01 may accumulate in Norwegian soils.
- The metabolite M-01 is highly mobile, while fluopicolide shows lower mobility in both studies and modelling.

Based on the environmental properties pointed out in the risk assessment, The Norwegian Food Safety Authority (Mattilsynet) turned down the application for use of Infito in Norway.

The decision made by Mattilsynet has been appealed by the applicant, Bayer Crop Science. No new studies have been presented.

Mattilsynet has asked VKM to consider the arguments in the appeal from Bayer Crop Science on the risk assessment of Infito. The appeal and arguments were discussed in a meeting in VKMs Panel on Plant Protection Products on 13. December 2013.

### **The conclusions were as follows:**

VKM maintains the previous conclusion on the risk assessment on persistence, accumulation and mobility of fluopicolide and one of the metabolites M-01.

Our conclusion is further strengthened by additional documentation on:

- Persistence of M-01 as indicated by data from the National Monitoring program (JOVA) and international studies
- Accumulation as related to results from 4 year field studies and model calculations using the Finnish PEC calculator
- Mobility of M-01 as identified by FOCUS PELMO, FOCUS PEARL and MACRO simulations using Swedish and Norwegian scenarios in addition to monitoring results from groundwater in Norway
- Opinion from EFSA indicating that model simulations and risk of leaching to groundwater from row crops are under-estimated by a factor of six, and should be revised in the new FOCUS scenarios. Half-life calculations based on field studies of mobile substances should be avoided as some of the substances could have escaped to deeper layers and therefore showing artificially high degradation rates.

## Background

VKM performs risk assessments in the context of pesticide registration cf. Regulation on Pesticides § 4. The Norwegian Food Safety Authority, National Registration Section, is responsible for reviewing and evaluating the documentation submitted by the pesticide notifier. The Norwegian Food Safety Authority takes the final regulatory action regarding registration or deregistration of pesticides based on VKMs risk assessment, along with a comparative assessment of risk and benefits and the availability of alternatives (the principle of substitution).

The risk assessment of the fungicide Infinito was finalized in a meeting on 29. May 2012 by VKMs Panel on Plant Protection Products. Based on concern over the environmental properties of fluopicolide and its main metabolite, which were pointed out in the risk assessment, The Norwegian Food Safety Authority (Mattilsynet) turned down the application for use of Infinito in Norway. This decision was appealed by the applicant, and Mattilsynet has asked VKM to perform an assessment of the arguments presented in the appeal. The arguments were discussed in a meeting in VKMs Panel on Plant Protection Products on 13. December 2013.

## Terms of reference

Infinito is a new fungicide containing the active substances fluopicolide and propamocarb-HCl. Fluopicolide is a new active substance in Norway, but propamocarb-HCl is already approved in several products. Infinito is a new-generation fungicide to protect potatoes against the blight pathogen *Phytophthora infestans*.

Mattilsynet would like an assessment of the arguments presented in the appeal following their decision to turn down the application for use of Infinito in Norway.

## 1 Background documentation

VKM's risk assessment is based on the Norwegian Food Safety Authority's evaluation (2012) of the documentation submitted by the applicant. The Norwegian Food Safety Authority publishes both their evaluation of Infinito and their final regulatory action on the registration of the pesticide product at their homepage [www.mattilsynet.no](http://www.mattilsynet.no). No new documentation was presented in the appeal.

## 2 Procedure

The first three steps of the risk assessment (hazard identification, hazard characterization and assessment of exposure) are performed by the Norwegian Food Safety Authority and involve an assessment of the documentation submitted by the pesticide notifier. The resulting report on hazard identification, hazard characterization and assessment of exposure, from which the summary is included in the present document, is then reviewed by VKM. This review may result in some amendments in the original documents of both the summary and the full report issued by the Norwegian Food Safety Authority (2012). The fourth step (risk characterization) is based on the three first steps and is VKM's conclusions or risk assessment.

## 2.1 Environmental risk assessment

The environmental risk assessment of pesticides involves predictions of exposure concentrations in various environmental compartments (e.g. soil and surface waters) that may occur after application of the pesticide. These predicted effect concentrations (PECs) are compared to exposure levels that are known to cause toxic effects to important groups of organisms representing the environmental compartments.

The environmental fate and possible ecotoxicological effects of pesticides are investigated in several laboratory- and field experiments. In environmental risk assessments of pesticides, Predicted Environmental Concentrations (PECs) are estimated by use of different scenarios for different parts of the environment (terrestrial, aquatic). The first parameter estimated is usually the initial concentration (PIEC, Predicted Initial Environmental Concentration), e.g. the concentration just after application (usually spraying). PIEC in soil is calculated assuming a homogenous distribution of areal dose in the upper 5 cm soil layer. For surface water, the PIEC is based on deposition of pesticides from spray drift in a standard size water body. The calculations are performed with application of buffer zones between the sprayed area and the water body.

The further exposure regime in different compartments is affected on the fate of the pesticide. The fate is dependent on processes such as photodegradation, hydrolysis, biodegradation and sorption to soil particles. These processes are studied in several standardised laboratory tests. In addition, field tests are used to study the dissipation of the pesticide in various agricultural soils. Based on the experimental fate studies, factors describing different fate processes may be derived and used in models that describe the fate of the pesticide in the soil as well as the transport to surface water and ground water. The concentrations of the pesticide in water are estimated by use of models with relevant scenarios based on EU's FOCUS-scenarios. The models produce maximum PEC and average PEC calculated for specified periods after pesticide application. In the surface water scenarios PEC is also calculated for the sediment phase.

Then the Toxicity Exposure Ratio (TER) is estimated for different groups of organisms. The TER is calculated as the ratio between the toxicity for the organism in question (expressed as LC<sub>50</sub>, EC<sub>50</sub>, NOEC etc., depending on organism and study type) and PEC or PIEC. Trigger values for TER, which express the acceptability of the risk for different organisms, have been defined by the EU. The risk is considered minimal when the TER does not exceed the trigger value.

In the terrestrial environment, the risk for toxic effects on bees and non-target arthropods is assessed according to other criteria. Hazard quotients for oral- (HQ<sub>O</sub>) and contact toxicity (HQ<sub>C</sub>) are estimated for bees. HQ<sub>O</sub> evt. HQ<sub>C</sub> is the ratio between the standardized area dose of the product (g v.s./ha) and acute toxicity for the bee (LD<sub>50</sub>, µg active ingredient/bee). Field experiments and expert evaluation is triggered whenever the hazard quotient is above 50.

For the non-target arthropods, the estimated hazard quotient (HQ) is the ratio between the area dose of the product (g active ingredient/ha), which is multiplied with a factor for multiple applications (MAF, multiple application factor) when appropriate, and the acute toxicity for the organism (LR<sub>50</sub>, g active ingredient/ha). According to EU, whenever the ratio value exceeds 2, further investigations are triggered.

VKM makes use of a scale in order to describe the risk of exposure for different organisms which live within and outside the spraying field. The scale is based on the ratio between the estimated exposure and the limit or the ratio between the TER and the TER trigger value designated each group of organism.

The following risk scale is used:

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Very high risk	more than 500% of the limit
High risk	300 – 500% of the limit
Medium risk	150-300% of the limit
Moderate risk	110-150% of the limit
Minimal risk	the limit is not exceeded

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The estimates of exposure concentrations are based on maximal concentrations, which exist during or shortly after spraying. The group of organism assessed (for example birds or leaf dwelling non-target organisms) is not always present during the period of maximal concentration. In the final risk assessment, VKM therefore takes into consideration whether, or to which extent, the organism in question actually will be exposed. This may cause that the risk is assessed lower than indicated by the scale above.

Additionally, uncertainties in the data base both with regard to establishments of limits and models of exposure concentrations are taken into consideration if relevant. This may also cause that the risk is assessed lower or higher than the risk scale. Any deviation from the risk scale is justified in this document.

### **3 Summary by the Norwegian Food Safety Authority (Hazard identification, hazard characterization and exposure assessment) for Infinito**

Infinito is a new product containing propamocarb-HCl (625 g/L) and the new active ingredient fluopicolide (62.5 g/L). The product is a suspension concentrate (SC) formulation.

Infinito is a new-generation fungicide to protect potatoes against the blight pathogen *Phytophthora infestans*. Fluopicolide represent a new chemical class, acylpicolides, which works by disorganizing the pathogen's cell structure and propamocarb-HCl which is a well know and established active ingredient and works with systemic behaviour.

The proposed application rate is from 1.2 L product (750 g propamokarb-HCl and 75 g fluopicolide) to 1.6 L product (1000 g propamokarb-HCl and 100 g fluopicolide) per hectare. The product should be applied in a volume of 150–400 L water per hectare with a broadcast sprayer. Maximum four applications per year using the lowest dose and three applications when using the maximum dose. The application interval is 7–10 days, and no later than 7 days before harvest.

Both active ingredients are evaluated in the EU and included in Annex I.

#### **3.1 Identity and physical/chemical data**

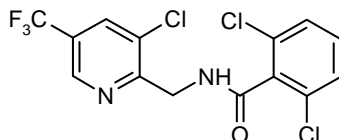
Product name	Infinito
Formulation	Suspension concentrate
Active substance	Fluopicolide
Concentration of	

active substance 62.5 g/L

IUPAC-name 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide

CAS number 239110-15-7

Structural formula



Molecular weight 383.6 g/mole

Water solubility Moderate 2.9 mg/L (20°C)

Vapour pressure Low  $3.03 \times 10^{-7}$  Pa (20°C)

Henry's law const. Low  $4.15 \times 10^{-5}$  Pa m<sup>3</sup>/mole

log Pow Medium 2.9 (20°C)

pKa No dissociation

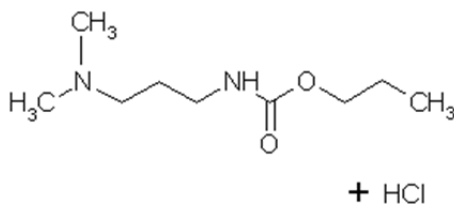
Active substance Propamocarb-HCl

Concentration of active substance 625 g/L

IUPAC-name Propyl 3-(dimethylamino) propylcarbamate hydrochloride

CAS number 25606-41-1 (Propamocarb HCl), 24579-73-5 (Propamocarb)

Structural formula



Molecular weight 224.7 g/mole

Water solubility Moderate 2.9 mg/l (20°C)

Vapour pressure Medium  $1.66 \times 10^{-3}$  Pa (20°C)

Henry's law const. Low  $8.5 \times 10^{-9}$  Pa m<sup>3</sup>/mole

log Pow Low -1.3 (20°C)



pKa 9.6 (20°C)

## 3.2 Mammalian toxicology

Mammalian toxicology is not discussed in this report.

## 3.3 Environmental fate and ecotoxicological effects

This assessment is based on an Estonian product evaluation for the Northern zone in the EU (E1). This is in turn based on documentation and a Draft Registration Report submitted by the applicant as well as Draft Assessment Reports for the active substances fluopicolide (UK 2005) and propamocarb (Ireland 2004).

### 3.3.1 Environmental fate and behaviour

#### 3.3.1.1 Degradation in soil

**Fluopicolide** is initially degraded in soil to form the hydroxylated metabolite M-03, and then undergoes cleavage to form M-02 containing the pyridine ring and M-01 containing the phenyl ring. Metabolite M-01 (2,6-Dichlorobenzamide, BAM) is a well-known metabolite also from the active substance dichlobenil. Un-extracted soil bound residues account for between 5 and 23% of the applied fluopicolide at the end of the soil laboratory studies. Levels of carbon dioxide were low, with less than 3% of the applied radioactivity by the end of the study. The metabolites M-01, M-02 and M-03 were observed in aerobic soil laboratory degradation studies conducted with the parent compound. M-01 and M-03 can be defined as major metabolites exceeding 10% of applied radioactivity. M-01 has been identified in soils with maximum percentages ranging from 5 to 40%. The occurrence of M-03 has been shown to have a strong pH dependence and the metabolite was only observed as a major metabolite in acidic soils (<pH 6) at a maximum of 11%, whilst in neutral to alkali soils it was either not detected or detected occasionally at a maximum of 3%. M-02 was detected as a minor metabolite in soil at a maximum of 7% under aerobic conditions before declining to less than 2%.

An overview over fluopicolide's metabolites and where they are observed are given in the Draft Registration Report (E1, Section 5, Table 9-2, page 11/137).

Fluopicolide showed low to moderate degradation rates in aerobic soil (DT50: 194-333 days, geomean: 271 days), and low degradation rates (to M-01 and M-02) in anaerobic soil (DT50: 424 days). M-03 was rapidly degraded (DT50: 0.1-4.7 days) in soil (to M-01 and M-02) under aerobic conditions. It was not possible to derive reliable degradation rates for M-01 in studies conducted with the parent or M-03. Supplemental data were provided by a laboratory study conducted with the metabolite M-01 incubated under EPA conditions for up to 365 days (DT50: 808-1848 days). M-02 was very rapidly degraded in soil to a number of metabolites (DT50: 2.5-3.0 days), with a significant portion (>20%) completely mineralised to CO<sub>2</sub>.

The potential for accumulation of fluopicolide and its metabolites in soil has been investigated over a four year period at Senas (Southern France), Philippsburg (Germany) and Appilly (Northern France). The study design at all sites represented a worst-case assessment with a single annual application of 400 or 500 g a.s./ha each year to bare soil. EFSA concluded that fluopicolide residues had reached plateau concentrations in the Philippsburg

and Senas trials (high: 0.34-0.39 mg/kg, low: 0.082-0.094 mg/kg), but the results were inconclusive in the Appilly trial. For M-01 residues remaining were lower and appeared to reach a plateau only in the Senas trial (high: 0.047 mg/kg, low: 0.015 mg/kg). The metabolites M-02 and M-03 were rapidly degraded in soil and were either not detected or disappeared completely within one month.

Soil dissipation studies were conducted at six European locations to investigate the behaviour of fluopicolide and its soil metabolites M-01, M-02 and M-03 under field conditions.

Generally M-02 and M-03 were rapidly degraded in soil and detected only in a few early time points at levels close to the limit of quantification. The experimental data were evaluated to determine degradation half-lives (normalised to 20 °C) for fluopicolide (geomean DT50: 134 days), its metabolite M-01 (geomean DT50: 53 days) and at one site for the metabolite M-03 (worst-case DT50: 37 days). Under field conditions, the dissipation behaviour of fluopicolide was found to be biphasic, with rapid initial degradation followed by a slower second phase of dissipation.

**Propamocarb-HCl** was metabolised under aerobic conditions in top soils (DT50: 11-137 days) to the principal products carbon dioxide (60 to 90%) and non-extractable soil bound residues (maximum 10 to 34%). Several unidentified metabolites were detected although none exceeded 5.5% of applied radioactivity.

The route of metabolism of propamocarb-HCl under anaerobic conditions follows basically the same route as the metabolism under aerobic conditions although it is slower (DT50: 66-459 days). No significant degradation products were formed under anaerobic conditions. Field dissipation studies for propamocarb-HCl were conducted at two locations in the USA (DT50: 17-24 days).

### 3.3.1.2 Sorption/mobility

**Fluopicolide** showed low to medium mobility (Koc: 321). The metabolites showed higher mobility: M-01 (Koc: 41), M-02 (Koc: 6.0), M-03 (Koc: 109), M-05 (Koc: 26) and M-10 (Koc: 6.3). All values are arithmetic means.

A lysimeter study was conducted in Germany in an acidic silty sand soil with low organic carbon content over a three year period with lysimeters treated at the maximum annual application rate (400 g/ha) in the first year and one lysimeter re-treated in the second year. The study suggested that there is low potential for fluopicolide and the metabolites M-02 and M-03 to appear in groundwater even under unfavourable soil and weather conditions. It was not possible to detect M-01, since the radiolabelling was in the pyridine ring. A number of metabolites (M-05, M-10, M-11, M-12, M-13, M-14, M-15 and M-16) were detected in concentrations ranging from 0.080 to 0.902 µg/L in the leachate. EFSA have concluded that all the fluopicolide metabolites are considered not relevant according to the guidance document on groundwater metabolites.

**Propamocarb-HCl** showed moderate potential for mobility (Koc: 536).

### 3.3.1.3 Degradation in water

**Fluopicolide** and the metabolite M-01 were stable to hydrolysis and photolysis under abiotic conditions. The rate of hydrolysis of M-03 was strongly dependent on pH (DT50: 8.4 minutes, 45 minutes, 4.7 hours and 46 hours at pH 8, 7, 6 and 5, respectively).

In water/sediment systems fluopicolide was relatively stable and dissipated in the water by a combination of degradation and partitioning to sediment. Fluopicolide undergoes cleavage to form the metabolites M-02 and M-01. M-01 was detected as a major metabolite (max 18.2%) in the water phase of aerobic water sediment systems and was also observed as a minor metabolite in the sediment phase. No other major metabolites (>10 %) were detected. M-02 was detected as a minor metabolite in the water phase (max 7.4%) and was observed at detectable levels in the sediment (<1%).

Rapid dissipation of fluopicolide from the water phase was observed in sediment with high organic carbon content and cation exchange capacity. Fluopicolide showed similar degradation rates in abiotic and biotic water sediment systems, indicating that the degradation was not enhanced by microbial activity in water (DT50 (water dissipation): 8.9-263 days, DT50 (total system): 873-1428 days.)

**Propamocarb-HCl** was stable to hydrolysis and photolysis under abiotic conditions.

Propamocarb-HCl was readily degraded (DT50: 10-15 days) in both aerobic and anaerobic water sediment systems, with up to 37% observed in the aerobic sediment phase. Overall DT50 values for degradation in water sediment systems were 16 to 21 days. The compound was readily mineralised to carbon dioxide with no accumulation of intermediate degradation products. Sediment bound residues represented <10% after 105 days.

#### 3.3.1.4 *Fate in air*

**Fluopicolide** has a very low vapour pressure and Henry's Law constant and thus would not be expected to be found in any significant concentration in the air. The theoretical half-life is 2.2 to 3.4 days.

**Propamocarb-HCl** also has a very low vapour pressure and Henry's Law constant and would not be expected to be found in any significant concentration in the air. The theoretical half-life is <0.17 days.

### 3.3.2 ENVIRONMENTAL EXPOSURE

#### 3.3.2.1 *Soil*

The highest PEC<sub>soil</sub> values arise from the EU FOCUS-scenario for onions (3 x 100 g fluopicolide/ha and 3 x 1000 g propamocarb-HCl/ha with 10%, 10% and 25% crop interception, interval 7 days). This is the same application scheme as for potatoes in Norway, but with lower crop interception, i.e. more worst case. Using the Finnish PEC<sub>soil</sub>-calculator, the rapporteur member state (RMS) gives the following values for fluopicolide, its metabolites and for propamocarb-HCl (which is rapidly degraded to carbon dioxide and non-extractable soil bound residues with no significant metabolites formed):

Fluopicolide	PEC <sub>soil</sub> , max = 0.79 mg/kg, initial = 0.33 mg/kg
M-01	PEC <sub>soil</sub> , max = 0.0480 mg/kg
M-02	PEC <sub>soil</sub> , max = 0.0260 mg/kg
M-03	PEC <sub>soil</sub> , max = 0.0298 mg/kg
Propamocarb-HCl	PEC <sub>soil</sub> , max = 8.99 mg/kg, initial = 3.33 mg/kg

### 3.3.2.2 Groundwater

The predicted 80th percentile average groundwater concentrations in potatoes (BBCH 21-95) at 1 m depth (4x100 g fluopicolide/ha, 4x1000 g propamocarb-HCl/ha, 50%, 80%, 80% and 50% interception, 7 d interval, every year, FOCUS PEARL and PELMO) are used. This is earlier application and one more application per season than the Norwegian GAP (BBCH 40-89, 3 applications).

Concentrations of **fluopicolide**, metabolite M-02 and the lysimeter metabolite M-14 were predicted to be <0.1 µg/L for both the Hamburg and Jokioinen scenarios. The metabolites M-01 (max 2.786 µg/L), M-03 (max 0.302 µg/L) and several lysimeter metabolites (M-05 max 0.913 µg/L, M-10 max 0.806 µg/L and M-11 max 0.624 µg/L, M-12 max 0.416 µg/L, M-13 max 0.353 µg/L) were predicted to reach groundwater at concentrations in excess of 0.1 µg/L.

**Propamocarb-HCl** concentrations were predicted to be ≤0.01 µg/L in all of the FOCUS scenarios, except for Jokioinen (maximum value: 0.195 µg/L). The predicted concentrations at Jokioinen with the PEARL model are a factor of 50 to 100 times higher than those predicted with the PELMO model, whilst all other scenarios are consistent. Thus the PEARL values at Jokioinen are considered to be outliers. Since propamocarb-HCl is readily mineralised to carbon dioxide with no accumulation of intermediate degradation products, no modelling of metabolites is considered necessary.

### 3.3.2.3 Surface water

PEC values have been calculated for the use of in potatoes (4x100 g fluopicolide/ha, 4x1000 g propamocarb-HCl/ha with 50% interception, which is one more application than the Norwegian GAP).

The maximum PEC<sub>sw</sub> values for **fluopicolide** were 97.0, 10.6 and 1.38 µg a.s./L for Step 1, 2 and 3, respectively. The corresponding sediment values were 308, 33.3 and 7.84 µg a.s./kg. The maximum Step 2 PEC<sub>sw</sub> values were 1.49, 0.35 and 0.39 µg/L for the metabolites M-01, M-02 and M-03, respectively. The corresponding sediment values were 0.61, 0.02 and 0.42 µg/kg.

The maximum PEC<sub>sw</sub> values for **propamocarb-HCl** were 811 and 45 µg a.s./L for Step 1 and 2, respectively. The corresponding sediment values were 4190 and 228 µg a.s./kg. Since propamocarb-HCl is readily mineralised to carbon dioxide with no accumulation of intermediate degradation products, no modelling of metabolites is considered necessary.

## 3.3.3 EFFECTS ON TERRESTRIAL ORGANISMS

For mammals and birds, the risk assessment is performed according to the EU Guidance Document for Birds and Mammals (EFSA 2009). The EU triggers (birds and mammals) are ≥10 and ≥5 for TER<sub>acute</sub> (TER<sub>a</sub>) and TER<sub>long-term</sub> (TER<sub>lt</sub>), respectively.

### 3.3.3.1 Mammals

**Fluopicolide** showed low acute toxicity (LD<sub>50</sub>: >5000 mg a.s./kg bw). In a chronic toxicity test, the NO(A)EL was 20 mg a.s./kg bw/d. Metabolite M-01 showed moderate acute toxicity (LD<sub>50</sub>: 500 mg/kg bw). The metabolites M-02, M-05 and M-10 showed low acute toxicity (LD<sub>50</sub>: >2000, >5000 and >5000 mg/kg bw, respectively).

Fluopicolide pass the EU trigger value for acute exposure (TER<sub>a</sub> >235) according to the EU screening step with an application rate of 4x100 g a.s./ha in potatoes. Fluopicolide also passes

the EU trigger for chronic exposure ( $TER_{it}$  7.9) calculated according to the EU Tier 1 scenarios.

**Propamocarb-HCl** showed moderate acute toxicity ( $LD_{50}$ : >1330 mg a.s./kg bw). In a chronic toxicity test, the NO(A)EL was 104 mg/kg bw/d.

According to Tier 1 calculations using an application rate of 1000 g a.s./ha in potatoes, propamocarb-HCl pass the acute and long-term trigger for most of the scenarios ( $TER_a$  21,  $TER_{it}$  4.1). The failure to meet the acceptability trigger for small herbivorous mammals (vole) do not trigger higher tier studies, since other mammal scenarios give acceptable risk.

**Infinito** showed low acute toxicity ( $LD_{50}$ : >2000 mg/kg bw). A comparison of the acute  $LD_{50}$  values derived for the formulation and the active substances indicates that the formulation is not more toxic than expected based on the content of of the active ingredient. Thus, the risk assessment performed above covers the risk from use of Infinito.

### 3.3.3.2 *Birds*

**Fluopicolide** showed low acute toxicity ( $LD_{50}$ : >2250 mg a.s./kg bw) and low short-term dietary toxicity ( $LC_{50}$ : >5620 mg a.s./kg diet,  $LDD_{50}$ : >1744 mg a.s./kg bw/d). In a chronic toxicity test, the NOEC was 1000 mg a.s./kg diet (NOEL: 89 mg a.s./kg bw/d). Metabolite M-01 showed moderate short-term dietary toxicity ( $LC_{50}$ : 3897 mg/kg diet,  $LDD_{50}$ : 1171 mg/kg bw/d).

Fluopicolide pass the EU trigger values for acute ( $\geq 10$ ) and long-term ( $\geq 5$ ) exposure ( $TER_a$  >79,  $TER_{it}$  12) according to the EU screening step with a application rate of 4x100 g a.s./ha in potatoes.

**Propamocarb-HCl** showed moderate acute toxicity ( $LD_{50}$ : >1472 mg a.s./kg bw) and low short-term dietary toxicity ( $LC_{50}$ : >4789 mg a.s./kg diet,  $LDD_{50}$ : >962 mg a.s./kg bw/d). In a chronic toxicity test, the NOEC was 500 mg a.s./kg diet (NOEL: 33 mg a.s./kg bw/d)

Propamocarb-HCl pass the EU trigger values for acute and long-term exposure ( $TER_a$  >42,  $TER_{it}$  8.3) according to the EU Tier 1 calculations with a application rate of 4x1000 g a.s./ha in potatoes.

### 3.3.3.3 *Bees*

**Fluopicolide** showed low oral ( $LD_{50}$ : >241  $\mu$ g a.s./bee) and contact toxicity ( $LD_{50}$ : >100  $\mu$ g a.s./bee).

**Propamocarb-HCl** showed moderate oral toxicity ( $LD_{50}$ : >84  $\mu$ g a.s./bee) and low contact toxicity ( $LD_{50}$ : >100  $\mu$ g a.s./bee).

**Infinito** showed low oral ( $LD_{50}$ : >204  $\mu$ g/bee) and contact toxicity ( $LD_{50}$ : >143  $\mu$ g/bee). All hazard quotients for oral and contact exposure are below the trigger of concern ( $Q_{HO}$  and  $Q_{HC}$  < 50).

### 3.3.3.4 *Non-target arthropods*

**Infinito** was tested on parasitoids (*Aphidius rhopalosiphi*), predatory mites (*Typhlodromus pyri*) and leaf dwelling predators (*Crysoperla carnea*) in Tier 1 laboratory acute studies. Effects above the trigger effect level of 30% were seen on both mortality and reproduction at

relevant application rates for parasitoids and predatory mites, but not for leaf dwelling predators. LR50 values were 2.48, 3.24 and >6.4 L product/ha, respectively.

Extended laboratory studies with parasitoids (*A. rhopalosiphi*), predatory mites (*T. pyri*) and leaf dwelling predators (*Coccinella septempunctata*) did not show effects above the trigger effect level of 50% at relevant application rates. LR50 values were >8.0, >4.17 and >4.8 L product/ha, respectively). Both the in-field and the off-field HQ values are below the trigger of concern (HQ <2).

### 3.3.3.5 Earthworms

**Fluopicolide** and the metabolites M-01 and M-03 showed moderate acute toxicity (14d LC50: >500, 750 and >500 mg/kg dws (dry weight soil), respectively). Metabolite M-02 showed low acute toxicity (LC50: >1000 mg/kg dws). In chronic toxicity tests, the NOEC for fluopicolide and M-01 was 62.5 and 250 mg/kg dws, respectively.

Fluopicolide and the metabolites M-01, M-02 and M-03 pass the EU trigger value ( $\geq 10$ ) for acute exposure ( $TER_a > 633, 949, > 1266$  and  $> 633$ , respectively). Fluopicolide and M-01 pass the EU trigger values for chronic ( $\geq 5$ ) exposure ( $TER_{lt}$  79 and 317, respectively).

**Propamocarb-HCl** showed moderate acute toxicity (14d LC50: >660 mg/kg dws). In a chronic toxicity test the NOEC was 362 mg/kg dws. Propamocarb-HCl pass the EU trigger value for acute ( $\geq 10$ ) and chronic ( $\geq 5$ ) exposure ( $TER_a > 73, TER_{lt}$  40).

**Infinito** showed moderate acute toxicity (14d LC50: >500 mg product/kg dws). In a chronic toxicity test, the NOEC was  $\geq 30$  mg product/kg dws.

### 3.3.3.6 Other soil macro-organisms

**Fluopicolide** and metabolite M-01 showed low to moderate toxicity to the springtail *Folsomia candida* (28d NOEC: 31.25 and 25.0 mg/kg dws, respectively). Fluopicolide and M-01 pass the EU trigger value for chronic ( $\geq 5$ ) exposure ( $TER_{lt}$ : 40 and 32, respectively).

### 3.3.3.7 Microorganisms

Separate litter bag studies with relevant concentrations of **fluopicolide** and the metabolite M-01 did not show significant effects on the breakdown of organic matter 1, 3 and 6 months after application.

**Fluopicolide** and metabolite M-01 showed no effects on the carbon and nitrogen transformation at application rates up to 1.38 and 0.69 kg/ha, respectively (1.84 and 0.92 mg/kg soil).

**Propamocarb-HCl** showed no effects on the carbon and nitrogen transformation at application rates up to 28.9 kg/ha.

**Infinito** showed no effects on the carbon and nitrogen transformation at application rates up to 16 L product/ha.

Five different soil fungus strains representative to zygomycetes, oomycetes, deuteromycetes, ascomycetes and basidiomycetes were tested for their sensitivity to **fluopicolide**. Only *Phytophthora nicotianae* (oomycetes) indicated a relative sensitivity to fluopicolide with an EC50 value of 1.2 mg a.s./kg dry soil. This specific sensitivity is expected as *P. nicotianae* is considered as a target organism. As for the aquatic diatoms, this specific sensitivity of

oomycetes is explained by the specific mode of action of fluopicolide on zoospores. The other fungus strains were much less sensitive to fluopicolide with EC50 values > 30 mg a.s./kg soil (highest tested concentration). None of the fungus strains revealed to be sensitive to metabolite M-01 with EC50 values >30 mg/kg soil (highest tested concentration).

### 3.3.3.8 *Terrestrial plants*

Seedling emergence and vegetative vigour studies have been conducted with **Infinito** on 6 species (lettuce, oilseed rape, cucumber, soybean, oats and onion) tested at the maximum application rate of 2.13 L product/ha. The effects were well below the trigger of 50% effect (max 31%). Metabolite M-01 has been tested on seedling emergence to non-target plants. The study showed no effects > 50% on seedling germination and growth at application rates up to 0.0121 mg/kg soil.

### 3.3.4 EFFECTS ON AQUATIC ORGANISMS

The TER calculations below are based on maximum PEC-values from FOCUS surface water modelling (without extra buffer zones) and the lowest acute (LC50 or EC50) or chronic (NOEC) values for the different organism groups. A tiered approach is applied, where TER based on Step 1 first is calculated. If the TER fails the triggers, Step 2 is calculated and so on. The EU triggers for TER<sub>acute</sub> (TER<sub>a</sub>) and TER<sub>long-term</sub> (TER<sub>lt</sub>) are  $\geq 100$  and  $\geq 10$ , respectively.

#### 3.3.4.1 *Fish*

**Fluopicolide** showed high acute toxicity (96h LC50: 0.36 mg a.s./L) and moderate chronic toxicity (33d NOEC: 0.155 mg a.s./L). The metabolites M-01, M-02 and M-05 showed low acute toxicity (96h LC50: 240, >102 and >101 mg a.s./L, respectively).

Based on Step 2, TER<sub>a</sub> for fluopicolide is calculated to be 35, which fail the EU trigger. Using Step 3 gives a TER<sub>a</sub> of 261, which pass the EU trigger. Based on the FOCUS Step 2, TER<sub>lt</sub> for fluopicolide is 15, which pass the EU trigger. The TER<sub>a</sub> for the metabolites M-01 and M-02 also pass the EU trigger (>160 000).

**Propamocarb-HCl** showed low acute (96h LC50: >92 mg a.s./L) and chronic toxicity (33d NOEC: 6.3 mg a.s./L).

Based on Step 2, TER<sub>a</sub> for propamocarb-HCl is >3117, which pass the EU trigger. Using Step 2, TER<sub>lt</sub> for propamocarb-HCl is 213, which pass the EU trigger.

**Infinito** was acutely toxic (96h LC50: 6.57 mg/L).

#### 3.3.4.2 *Invertebrates*

**Fluopicolide** was acutely toxic to *Daphnia magna* (48h EC50: >1.8 mg a.s./L), mysids (96h EC50: 3.2 mg a.s./L) and oysters (96h EC50: 2.6 mg a.s./L), and showed moderate chronic toxicity (21d NOEC: 0.370 mg a.s./L) to *D. magna*. M-01 was acutely toxic to *D. magna* (48h EC50: 180 mg a.s./L).

Based on Step 2, TER<sub>a</sub> for fluopicolide is >175, which pass the EU trigger. TER<sub>lt</sub> for fluopicolide is 35, which pass the EU trigger. TER<sub>a</sub> for M-01 is 121 622, which pass the EU trigger.

**Propamocarb-HCl** showed low acute (48h EC50: >100 mg a.s./L) and chronic toxicity (21d NOEC: 12.3 mg a.s./L) to *D. magna*.

Based on Step 2,  $TER_a$  for propamocarb-HCl is >3387, which pass the EU trigger.  $TER_{it}$  for propamocarb-HCl is 271, which pass the EU trigger.

**Infinito** showed low acute toxicity (48h EC50: >100 mg/L) to *D. magna*.

#### 3.3.4.3 *Sediment dwelling organisms*

**Fluopicolide** showed low chronic toxicity (28d NOEC: 49 mg a.s./kg) to chironomid larvae in a spiked sediment test.

Based on Step 2,  $TER_{it}$  for fluopicolide is 1470, which pass the EU trigger.

#### 3.3.4.4 *Aquatic plants*

**Fluopicolide** was acutely toxic to duckweed (7d EC50: >3.2 mg a.s./L). M-01 showed moderate toxicity to duckweed (7d EC50: 80 mg a.s./L).

Based on Step 2,  $TER_{it}$  for fluopicolide is >302, which pass the EU trigger. TER for M-01 is 53 691, which pass the EU trigger.

**Propamocarb-HCl** showed moderate toxicity to duckweed (7d EC50: >18 mg a.s./L).

Based on Step 2,  $TER_{it}$  for propamocarb-HCl is >397, which pass the EU trigger.

#### 3.3.4.5 *Algae*

**Fluopicolide** showed extremely high toxicity (72h EbC50: 0.029 mg a.s./L, 72h ErC50: 0.066 mg a.s./L). The metabolites M-01, M-02 and M-05 showed low acute toxicity (72h EC50: >10, >32 and >10 mg a.s./L, respectively).

Based on Step 2, TER for fluopicolide is 2.7, which fail the EU trigger. Using Step 3 gives TER 21, which pass the EU trigger. Using Step 2, TER for the metabolites M-01 and M-03 are >6711 and 74, respectively, which pass the EU trigger.

**Propamocarb-HCl** is acutely toxic (72h EbC50: >85 mg a.s./L, 72h ErC50: >85 mg a.s./L).

Based on Step 2, TER for propamocarb-HCl is >1874, which pass the EU trigger.

**Infinito** showed very high toxicity (72h EbC50: 0.40 mg/L, 72h ErC50: 0.63 mg/L).

#### 3.3.4.6 *Microcosm/Mesocosm studies*

No studies submitted.

### 3.3.5 BIOCONCENTRATION

Log Pow for **fluopicolide** is 2.9. Fluopicolide showed a very rapid absorption in bluegill sunfish (time to 90% steady state was 1.5 days), a bioconcentration factor of 121 and a very rapid depuration half-life (maximum 0.51 days). This indicates a low fish bioaccumulation potential for fluopicolide and also a low potential for secondary poisoning of fish eating birds and wild mammals.

log Pow for **propamocarb-HCl** is -1.3. Bioconcentration factor values for bluegill sunfish were <10, and in channel catfish < 40. In both species, depuration was rapid, e.g. with residues falling below the detection limits after 10 days in bluegill sunfish. Propamocarb-HCl residues in fish are thus not of concern, and no additional residues data are necessary.



### 3.4 DOSSIER QUALITY AND COMPLETENESS

The dossier is complete and is adequate as a basis for an evaluation of the active substance, metabolites and product.

Draft Assessment Report (DAR), Fluopicolide. *Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8 of Council Directive 91/414/EEC*, November 2005. Chapter B8: Environmental Fate and behaviour and Chapter B9: Ecotoxicology

Draft Assessment Report (DAR), Propamocarb. *Report and Proposed Decision of Ireland made to the European Commission under Article 8 of Council Directive 91/414/EEC*, September 2004. Chapter B8: Environmental Fate and behaviour and Chapter B9: Ecotoxicology

## 4 Risk characterization

### 4.1 FATE ASSESSMENT

Based on the environmental properties pointed out in the risk assessment, Mattilsynet turned down the application for use of Infinito in Norway. The decision made by Mattilsynet has been appealed by the applicant, Bayer Crop Science. No new studies have been presented. Mattilsynet has asked VKM to consider the arguments in the appeal from Bayer Crop Science on the risk assessment of Infinito. VKMs Panel on Plant Protection Products has reviewed available documentation and discussed the appeal and arguments in a meeting on 13. December 2013.

#### 4.1.1 PERSISTENCE

##### 4.1.1.1 From VKMs first assessment of Infinito:

Fluopicolide is slowly degraded in soils and characterized with a high to very high persistence. Laboratory DT50 values (20 °C) ranged 194–411 days while at 10 °C a DT50 of 667 days was observed. The main metabolite M-01 is also slowly degraded in soils and characterized by EFSA as very highly persistent (DT50 (lab 20°C) = 557–1831 days). Metabolite M-01 (2,6-Dichlorobenzamide, BAM) is a well-known metabolite, also from the substance dichlobenil. Both fluopicolide and the M-01 metabolite show high persistence in water and water-sediment systems. VKM was therefore of the opinion that fluopicolide and its main metabolite should be regarded as persistent in Norwegian soils and surface waters.

In field studies, the dissipation behaviour of fluopicolide was found to be bi-phasic, rapid initial degradation followed by a slower second phase. The estimated DT90-values was between 691 and 1184 days, thus exceeding the duration of the studies.

The slow degradation of fluopicolide results in a significant potential for soil accumulation after repeated use. This is to some extent confirmed by calculations with the Finnish PEC calculator, where a plateau concentration was reached at 0.79 mg/kg compared to initial exposure concentration of 0.33 mg/kg. According to EFSA, the potential for accumulation of fluopicolide and the metabolite M-01 was confirmed by the PEC soil calculation and plateau concentrations were reached for the parent compound after 7 years in potatoes and 9 years in vines, and for the metabolite M-01 after 5 years in potatoes and 6 years in vines. VKM concluded that fluopicolide and its main metabolite M-01 may accumulate in Norwegian soils.

#### 4.1.1.2 *Main statements in the appeal from Bayer Crop Science*

*The values from the simulations (Leak & Mackenzie, 2013) “predict very little increase in fluopicolide over 20 years use on potato crops. Thus it is concluded that although fluopicolide has a long half-life in soil, crop rotations following normal agricultural practices in Norway will ensure absolute levels of fluopicolide to remain low in Norwegian soils. Even if the product is used continually every three years in the same field, a plateau will be reached within 9 to 15 years and the compound will not continually accumulate”*

*The values from the simulations (Leak & Mackenzie, 2013) “predict minimal increase in M-01 over 20 years use of fluopicolide on potato crops, confirming that despite a relatively long half-life in soil, crop rotations following normal agricultural practices in Norway will ensure that the absolute levels of M-01 will also remain low in Norwegian soils, and that a plateau will be reached within 3 to 9 years and thus the metabolite will not continually accumulate”.*

#### 4.1.1.3 *VKMs response to the statements from Bayer*

According to EFSA (2009), fluopicolide shows high to very high persistence in soil (DT50 lab 20 °C = 194 – 411 days) under aerobic conditions. A slower degradation rate is observed at 10 °C (DT50 lab 10°C = 667 days).

For PEC soil calculations, the PRAPeR 37 expert meeting agreed to use Single First Order (SFO) DT50 = 290 days for fluopicolide. Laboratory degradation studies reported in the Pesticide Properties Database (PPDB, 2013) gives a DT50 range of 194-333 days and a DT90 range of 644-2216 days. For field studies, DT50 values ranged 50-172 days and DT90 863-1184 days.

M-01 (2,6-dichlorobenamide (BAM)) is highly persistent in soil (DT50 lab 20 °C = 557 – 1831 d). Data from the Pesticide Properties Database (PPDB, 2013) confirm the persistence, and states that according to the EU Dossier lab studies the DT50 is 808-1848 days and the DT90 range 1850-6083 days. Furthermore, the field studies DT50 range 73-256.7 days and the literature values for DT50 field studies range 73-173 days.

Three soil dissipation and accumulation studies were conducted by the applicant in Germany (one site, 5 years), Northern France (one site, 4 years) and Southern France (one site, 4 years). For the study in Northern France the RMS (reporting member state) considers that the residues (fluopicolide and M-01) did not reach a plateau by the end of the study.

Simulations by Mattilsynet (2013) using the Finnish PEC calculator indicate a potential for accumulation for both fluopicolide and M-01, and a plateau seems to be reached after 10 years for fluopicolide. For M-01, a plateau is not reached within 20 years (Both calculated for potato crops).

The PEC calculations of Mattilsynet for fluopicolide are based on a homogenous distribution of the applied dose in the upper 5 cm soil layer and DT50=333 days, which represents the normalized worst case DT50 from laboratory studies. PEC calculations for M-01 are based on DT50=808 days, which is a normalized lab data value, but not worst case. VKM agrees with the input data used by Mattilsynet.

#### 4.1.2 MOBILITY IN SOILS

##### 4.1.2.1 *From VKMs first assessment of Infinito:*

Fluopicolide and the metabolites M-02 and M-03 had low potential for transport to groundwater, as suggested by a lysimeter study. Several metabolites were detected in concentrations above 0.1 µg/L, but were not considered relevant by EFSA. However, in the field leaching study, the metabolite M-01 reached an annual average concentration of 2.9 µg/L in the leachate at 120 cm depth the third year after the product had been applied. When modelling was performed with FOCUS PELMO and FOCUS PEARL, fluopicolide and its metabolites M-03, M-01, M-05, M-10, M-11, M-12 and M-13 would exceed the limit of 0.1 µg/L annual average concentration at 1 m depth for at least one of the simulated scenarios, but not for the most relevant Norwegian scenarios. From 1995 to 2004, the metabolite M-01 (2,6-dichlorobenzamid (BAM)) has been detected 37 times in 7 Norwegian groundwater wells, with a maximum concentration of 1.2 µg/L.

When applying time dependent sorption from some of the field studies, the half-lives for fluopicolide and M-01/BAM in groundwater simulations have been estimated to 134 and 53 days, respectively, suggesting that there should be little or no concern for groundwater contamination. However, the proposed guidance on how to conduct aged sorption studies, (Beulke and van Beinum et al. 2012) does not recommend to determine aged sorption parameters for use in regulatory leaching modelling from column or field studies. The derivation of aged sorption parameters from column or field studies is more complex than from laboratory studies. The methods required to evaluate such studies have not been addressed in the research underpinning the guidance. The guidance should therefore only be applied to laboratory based studies at this time. Because of the complexity and large uncertainty of such studies, laboratory incubation studies are recommended (Beulke and van Beinum et al. 2012).

##### 4.1.2.2 *Main statements in the appeal from Bayer Crop Science*

*The mobility simulations (Leake & Mackenzie, 2013) for fluopicolide show low mobility and conclude that concentrations will not exceed 0.1 µg/L at 1 m depth in soil following use in potato crops over a 60 year period. The metabolite M-01 shows some mobility, but concentrations will not exceed 1 µg/L at 1 m depth from potato fields over 60 years.*

##### 4.1.2.3 *VKMs response to the statements from Bayer*

From EFSA (2009) and the EU dossier the following statements are considered:

**Fluopicolide:** PPDB, 2013: EU dossier Kf range 1.42-9.27, Kfoc range 172-580 mL/g, 1/n range 0.86-0.93, Soils=8.

**M-01 (2,6-Dichlorobenamide (BAM)):** PPDB, 2013: EU dossier Kf range 0.21-1.76 mL/g, Kfoc range 31-51 mL/g, 1/n range 0.809-0.972, Soils=5.

**Fields studies:** A field lysimeter leaching study in South West Germany is available. Metabolite M-01 reached annual average concentrations up to 2.93 µg / L at 120 cm depth in the third year after application.

**Modelling:** Potential groundwater contamination was assessed by modelling with FOCUS PEARL and FOCUS PELMO.

By using FOCUS PELMO with application only once every three years on potatoes, the threshold value of 0.1 µg/L for the 80th percentile annual concentration at one meter depth was exceeded by M-01 in eight out of nine scenarios. Also other metabolites exceeded the limit (M-05, M-10, M11, M12 and M-13).

FOCUS PEARL modelling show that the 0.1 µg/L threshold for the predicted 80th percentile annual concentration at 1 m depth was exceeded by fluopicolide for one scenario and by M-01 for all nine scenarios.

EFSA has expressed some doubts on whether half-life calculations based on field studies are reliable for mobile substances such as M-01. The PRAPeR meeting agreed that the use of field data for highly mobile compounds is not recommended, since the substance could have leached to a deeper layer. From EFSA (2009), one of the critical areas of concern is the potential risk of groundwater contamination above the regulatory limit.

**General consideration on leaching assessment:** The PPR Panel recommends reconsidering the leaching assessment for potatoes, which can be selected in all nine FOCUS scenarios. Leaching for crops grown on ridges is likely to be significantly under-estimated by the FOCUS scenarios (EFSA 2013).

As appropriate calculation procedures for crops grown on ridges are not readily available, it seems advisable to introduce an assessment factor to account for the potentially higher leaching. Leistra and Boesten (2010) calculated a 6-fold higher leaching concentration for carbofuran in a ridge-furrow system compared to a levelled system. From their literature review, however, it is clear that only limited amounts of data were available from which to derive an assessment factor.

Since the currently approved models are not capable of calculating leaching from ridge/furrow systems correctly, the PPR Panel considers the inclusion of potatoes not warranted without accounting for the potential underestimation of leaching. In the absence of an appropriate model, use of a safety factor may temporarily solve the problem. VKM agrees with the PPR Panel that reconsideration of the leaching assessment for potatoes is recommended.

Modelling of fluopicolid and the metabolite M-01 by Mattilsynet (2013) has demonstrated transport to groundwater, depending on input parameters and time interval of application. When using geometric mean of normalized field DT50 values of 53 days for M-01 and 134 days for fluopicolide (as suggested by Bayer), modelling with MACRO 5.5.3 with Norwegian and Swedish scenarios, indicates exposure of groundwater above the drinking water limit for both substances.

#### **4.1.3 SUPPORTING DATA: NORWEGIAN MONITORING RESULTS FOR M-01/2,6-ICHLOROBENZAMID (BAM)**

##### **4.1.3.1 *Surface water.***

The degradation product M-01 (2,6-dichlorobenzamid/BAM) is also a metabolite of the herbicide diclobenil, a compound monitored in Norway since 1995. Diclobenil has not been approved for use in Norway since 1998, but M-01/BAM has been detected in surface waters even 12 years after the legal use of Diclobenil. M-01/BAM has been detected in 9 % of 1550 samples from creeks and brooks in areas with extensive agricultural production in the period 1995-2010. The average measured concentration is 0.04 µg/L with 0.6 µg/L as the maximum. The samples are volume proportional mixed water samples over 14 days, and do not represent

peak concentrations. The normal frequency of sampling is once a month during the summer season (Hauken et al., 2012).

#### 4.1.3.2 *Groundwater*

Groundwater monitoring from the period 2007 – 2012 showed that M-01/BAM is one of the most frequently found pesticides, and in 7 samples the concentration exceeded the drinking water limit (0,1µg/L) (Roseth, 2013).

#### 4.1.4 **SUPPORTING DATA: STUDIES ON DEGRADATION OF DICHLOBENIL AND M-01/2,6-DICHLOROBENZAMID (BAM)**

Björklund et al., 2011. For M-01/BAM groundwater concentrations can reach 1 µg/L. It is noteworthy that there appears to be no clear consensus on the sorption mechanisms for dichlobenil.

Pukkila & Kontro, 2013. After 1.4 year of incubation, dichlobenil and M-01/BAM concentrations were still approximately of the same level as after 56 days, suggesting persistency of these compounds also in Finnish groundwater. M-01/BAM was persistent in topsoil and subsurface deposits, indicating long-term persistence problems in groundwater also within the northern boreal region.

Clausen et al., 2005. A small but significant degradation of M-01/BAM was measured in the unsaturated zone with estimated half-lives of 3–16 years. No degradation of M-01/BAM was measured in the saturated zone. The results demonstrate that M-01/BAM is a very mobile and recalcitrant compound, and a potential threat to groundwater contamination.

Simonsen et al., 2005. Overall it appears that the M-01/BAM mineralisation potential is widely distributed in the tested soil profile down to a depth of 2 m below the surface. This may imply that M-01/BAM leaching down through the soil to these depths could be mineralised before reaching the groundwater. However, it appears that the M-01/BAM mineralization potential is limited below this depth.

Pukkila et al., 2009. Despite microbial M-01/BAM degradation activity in subsurface deposits, M-01/BAM was still found in the groundwater.

## 5 Conclusion

The Norwegian Scientific Committee of Food Safety (VKM) maintains its previous conclusions on persistence, accumulation and mobility of fluopicolide and one of the metabolites, M-01.

Our conclusion is further strengthened by additional documentation on:

1. **Persistence** of M-01 as indicated by the National Monitoring program (JOVA) and international studies
2. **Accumulation** as related to information from 4 years field studies and the Finnish PEC calculator
3. **Mobility** as identified by FOCUS PELMO, FOCUS PEARL and MACRO simulations using Swedish and Norwegian Scenarios in addition to monitoring results from groundwater in Norway
4. **Opinion from EFSA** indicating that model simulations and risk of leaching to groundwater from row crops are under-estimated with a factor of six, and should be revised in the new FOCUS scenarios. Half-life calculations based on field studies of

mobile substances should be avoided as some of the substances could have escaped to deeper layers and thus showing artificially high degradation rates.

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