Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Risk assessment of the fungicide Bontima with the active substances cyprodinil and isopyrazam

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

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Summary

Bontima is a new fungicide containing the two active substances isopyrazam and cyprodinil. Bontima is a fungicide against the most important diseases in winter and spring barley. Isopyrazam is a new active ingredient with new mechanisms of action that may delay the development of fungicide resistance in treated crops.

The risk assessment was finalized at a meeting May 29, 2012, by the Panel on plant protection products of the Norwegian Scientific Committee for Food Safety (VKM).

The Norwegian Food Safety Authority would like, in this regard, an assessment of the following:

- The fate and behaviour in the environment and the ecotoxicological effects and risks with regard to the properties of Bontima and the active substances. The Panel is particularly asked to look at the following:
    - The persistence of isopyrazam and its metabolites.
    - The leaching potential of isopyrazam and its metabolites.

VKM's conclusion is as follows:

Fate-related issues

Isopyrazam is likely to be persistent in Norwegian soils with an associated risk of accumulation after repeated use.

Isopyrazam exhibits low mobility in soil and is not expected to reach groundwater, however the two main metabolites are likely to exceed the EUs drinking water limit of 0.1 µg/L in groundwater.

Since drainage and runoff, as well as drift, contributes to concentrations in surface water the risk assessment have to consider all these sources. In the EU DAR step 4 calculations, buffer zones of 20 m have been used to reduce runoff levels contributions by 80 %. VKM does not accept the use of these buffer zone modifications for Norwegian topographic conditions (with e.g. steeper agricultural areas).

Risk to the environment

There is minimal risk for toxic effects of isopyrazam to terrestrial organisms.

For the aquatic compartment, there is a high risk for toxic effects of isopyrazam to aquatic organisms with the proposed application regime. This is based on calculations of runoff without buffer zone modifications, from which the resulting TER calculations show high risk of acute effects on fish and a medium risk of acute effects on invertebrates. A minimal risk for toxic effects was calculated for sediment dwelling organisms, aquatic plants, and algae.

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 Norwegian Food Safety Authority submitted a request on April 20, 2012 for VKM to perform a risk assessment on use of the pesticide Bontima containing the active substances cyprodinil and isopyrazam. The environmental risk assessments of the product were finalized by VKM in June, 2012.

Terms of reference

Bontima is a new fungicide containing the active substances cyprodinil and isopyrazam. Cyprodinil is already approved in several products, but isopyrazam is a new active substance in Norway. Bontima is a fungicide against diseases in winter and spring barley.

The Norwegian Food Safety Authority would like, in this regard, an assessment of the following:

- The fate and behaviour in the environment and the ecotoxicological effects and risks with regard to the properties of Bontima and the active substances. The Panel is particularly asked to look at the following:
    - The persistence of isopyrazam and its metabolites.
    - The leaching potential of isopyrazam and its metabolites.

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 Bontima and their final regulatory action on the registration of the pesticide product at their homepage www.Mattilsynet.no

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 LC50, EC50, 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_O) and contact toxicity (HQ_C) are estimated for bees. HQ_O evt. HQ_C is the ratio between the standardized area dose of the product (g v.s./ha) and acute toxicity for the bee (LD50, 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 (LR50, 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:

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

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 assessment of exposure)

Bontima is a new product containing cyprodinil (187.5 g/L) and the new active ingredient isopyrazam (62.5 g/L). The product is an emulsifiable concentrate (EC) formulation.

Bontima is a fungicide against the most important diseases in winter and spring barley. The effect seems to be similar to the alternative products on the Norwegian market. Bontima contains, however, active ingredients with new mechanisms of action that may delay development of fungicide resistance.

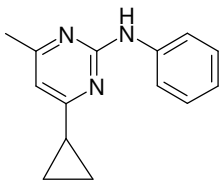
The proposed maximum application rate is 2 L product (375 g cyprodinil and 125 g isopyrazam) per hectare. The product should be applied in a volume of 200 – 400 L water per hectare, with a broadcast sprayer. Maximum two applications per year, with the last treatment no later than five weeks before harvest.

Cyprodinil was included in Annex I in 2007, while isopyrazam is currently still pending.

3.1 IDENTITY AND PHYSICAL/CHEMICAL DATA

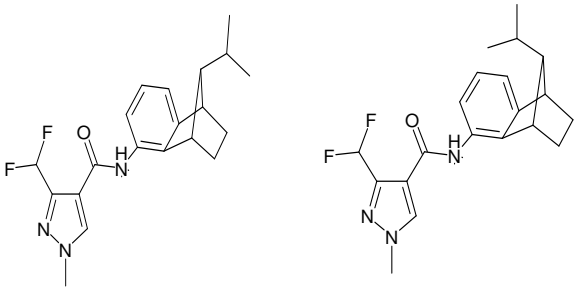
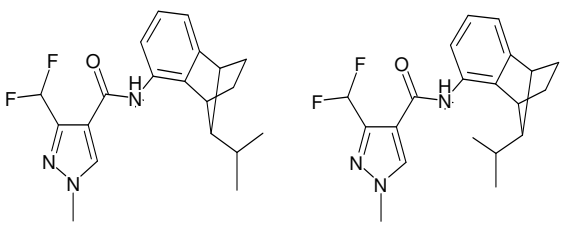
Product name	Bontima
Active substances	187.5 g cyprodinil 62.5 g isopyrazam
Formulation	Emulsifiable concentrate (EC)

3.1.1 CYPRODINIL

IUPAC-name		(4-cyclopropyl-6-methyl-pyrimidin-2-yl)-phenyl-amine
CAS number		121552-61-2
Structural formula		
Molecular weight		225.3
Solubility in water	Medium	13 mg/L (25°C, pH 7.0)
Vapour pressure	Medium	4.7-5.1 x 10^{-4} Pa (crystal modification A, 25°C) and 4.7 x 10^{-4} Pa (crystal modification B, 25°C)
Henry's law constant	Medium	6.6 x 10^{-3} - 7.2 x 10^{-3} Pa · m^3/mol

log Pow	High	4.0 (25°C)
pKa		4.44

3.1.2 ISOPYRAZAM

IUPAC-name	3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9RS)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide (*syn*-isomer – 50:50 mix of two enantiomers) and 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9SR)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide (*anti*-isomer– 50:50 mix of two enantiomers)
CAS number	881685-58-1 (*syn*-isomer: 683777-13-1 / *anti*-isomer: 683777-14-2)
Structural formula	
	syn(1*R*,4*S*,9*R*)-enantiomer *anti*(1*R*,4*S*,9*S*)-enantiomer
	

		syn(1*S*,4*R*,9*S*)-enantiomer *anti*(1*S*,4*R*,9*R*)-enantiomer
Molecular weight		359.4
Solubility in water	Moderate	*syn* -isomer 1.05 mg/L (25°C, pH 7) *anti* -isomer 0.55 mg/L (25°C, pH 7)
Vapour pressure	Low	*syn*-isomer 2.4 x 10^{-7} Pa (20°C) *anti*-isomer 2.2 x 10^{-8} Pa (20°C)
Henrys law constant	Low	*syn*-isomer 1.9 x 10^{-4} Pa m^3/ mol *anti*-isomer 3.7 x 10^{-5} Pa m^3/mol
log Pow	High	*syn*-isomer log Pow = 4.1 (25°C, pH 7.3) *anti*-isomer log Pow = 4.4 (25°C, pH 7.8)
pKa	No dissociation	

3.2 MAMMALIAN TOXICOLOGY

Mammalian toxicology is not discussed in this report.

3.2.1 RESIDUES

Residues are not discussed in this report.

3.3 ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL EFFECTS

3.3.1 ENVIRONMENTAL FATE AND BEHAVIOUR

3.3.1.1 *Degradation in soil*

The route of degradation of isopyrazam appears to be degradation through metabolites CSCD460260 (maximum 23.6 % AR at 195 days after treatment, DAT) and CSCD465008 (11.5 % AR 150 DAT, with pyrazole labeled a.s.) to a number of minor unidentified products to form predominantly unextracted material (maximum 25.7 % AR at 123 DAT). Ultimate mineralisation from isopyrazam is relatively slow maximum 3.2 % AR at 120 DAT). No other metabolites occurred at > 5 % of AR at any time point. CSCD460260 is a mixture of CSCD459488 and CSCD459489 which are the *syn*:*anti* isomers of this hydroxylated metabolite of isopyrazam. CSCD459488 is the dominant isomer in the mixture. Based on the geometrical mean of normalised lab data the degradation rate of isopyrazam can be classified as low with DT50: 88-760 days and a geometric mean of 244 days (Single First Order, SFO). DT90: 132->1000 days. There are no indications of single factors influencing the degradation rate more than others.

Based on the geometric mean of the normalised DT50 values the aerobic degradation of the metabolites is: CSCD459488: low (DT50: 102-884 days, geo mean 432 days), CSCD465008: moderate (DT50: 56-190, geo mean 123 days). DT90 values are often seen to be well above a year.

Using a temperature correction factor of 2.58 (Q10) and multiplying this to the geometric mean of the normalised DT50 values indicates that the degradation of isopyrazam at 10 °C will be very slow with a DT50 of 630 days.

The anaerobic degradation of isopyrazam is considered stable. Very low levels of both bound residues and CO_2 were measured. No metabolites were formed under anaerobic conditions.

Photolysis does not seem to be a very important route of degradation for isopyrazam in soil. In two 21 day studies, the photolysis DT50 was estimated to be 65-72 days in dry soil at 30-50°N. CO_2 and bound residues amounted to a maximum of 5.9 and 4.2 % AR respectively. The two metabolites, CSCC210616 and CSAA798670, were observed at a maximum of 8 and 5.4 % AR respectively. The dark controls were stable.

The degradation of CSCC210616 was shown to be high with DT50 1.7-4.1 days (geo mean 2.8 days) and DT90 5.5-13.7 days. Two additional metabolites were identified, CSAA798670 and CSCD465008. These metabolites reached a maximum of 41-65 and 60-78 % AR respectively. The formation of bound residue and CO_2 in studies with metabolite CSCC210612 shows that the maximum amount of bound residues and CO_2 was 35 and 33 % AR respectively.

Based on the geometric mean of normalised field DT50s of 72 days the dissipation of isopyrazam can be regarded as moderate with DT50s ranging widely from 9-710 days (SFO). DT90 values ranged from 31-2089 days, indicating that isopyrazam can be very persistent in soil. The two metabolites CSCD459488 and CSCD465008 were observed at maximum levels of 10 and 17 % respectively. Most of the soils tested are relevant for Norwegian conditions, but the climate are in general warmer in most of the test areas, at least during the cold season.

3.3.1.2 *Sorption/mobility*

The sorption of isopyrazam to soil can be classified as **very high** with Kf: 12-52 mL/g (average 30 mL/g) and Koc: 1732-2491 mL/g (average 2416 mL/g). 1/n: 0.92-0.97 (average 0.94). Sorption is correlated with organic carbon content. Desorption coefficients were higher than the adsorption coefficients indicating that the adsorption was not completely reversible.

Based on average Koc values the sorption of metabolite CSCD459488 was **medium** with Koc: 96-161 mL/g (average 149 mL/g) and the sorption of metabolite CSCD465008 was **low** with Koc: 0.7-3.7 mL/g (average 2.1 mL/g). Desorption Kfoc values were higher than the adsorption values for both metabolites indicating that adsorption was not completely reversible. For metabolite CSCD459488 sorption (measured as Kf) correlated with organic carbon content.

3.3.1.3 *Degradation in water*

Isopyrazam was hydrolytically stable in sterile aqueous buffer solutions at pH 4, 5, 7and 9 at both 50 and 25 °C.

Photolysis could contribute to the degradation of isopyrazam in the aquatic environment with estimated DT50 values of 61-64 days summer sunlight at 30-50 °N assuming 12 hour days. No degradation was observed in the dark control.

Isopyrazam was found not to be readily degradable.

The aerobic degradation for the whole systems in water/sediment studies can be classified as **low** with DT50: 487-809 days (SFO, system values), geometric mean 627 days. DT90 >>1 year. Isopyrazam dissipates rather quickly to the sediments. Maximum bound residue and mineralization amounts to 4.1 and 0.8 % AR respectively in the two systems. Two metabolites were observed but both at levels < 3 % AR.

3.3.1.4 *Fate in air*

A theoretical calculation of the potential for photo-oxidation of isopyrazam in the atmosphere was submitted. A first order DT50 of 0.191 days (2.29 hours) was calculated. This indicates that even if isopyrazam were to reach the upper atmosphere, it would not be expected to be subject to long-range transport. Isopyrazam has a vapour pressure and a Henry's Law constant and it is considered that the risk of volatilisation of isopyrazam from soil and leaf surfaces is low.

3.3.2 ENVIRONMENTAL EXPOSURE

3.3.2.1 *Soil*

According to a simple model recommended by the EU working group FOCUS PIEC (predicted initial environmental concentration) in soil after the application of 125 g active substance/ha is **0.07 mg/kg**. Highest peak plateau concentration is **0.75 mg/kg** but a "steady state" concentration is not reached and cannot be determined in this case.

PEC values for the metabolites CSCD459488 and CSCD465008 has also been calculated by Mattilsynet using the Finnish PEC Soil Calculator. PIEC and PEC plateau for CSCD459488 was 0.0163 and 0.186 mg/kg respectively and PIEC and PEC plateau for CSCD465008 was 0.0051 and 0.0176 mg/kg respectively.

3.3.2.2 *Groundwater*

FOCUSgw modeling was conducted for isopyrazam and its two main aerobic soil metabolites, CSCD459488 and CSCD465008. The modeling was conducted using FOCUSgw models PEARL v3.3.3, PRZM v2.4.1 & PELMO v3.3.2. The Tier 1 results indicate that for isopyrazam, the results of all the simulations were <0.001 µg/L(80th percentile at 1m depth), irrespective of which model was used, the crop simulated or the DT50 selected. For worst case EU risk assessment of metabolites in groundwater, CSCD459488 concentration is 4.6 µg/L and CSCD465008 concentration is 0.9µg/L, both exceeding the trigger of 0.1 µg/L.

3.3.2.3 *Surface water/sediment*

FOCUSsw modelling was conducted on isopyrazam at Steps 1 – 4. The worst case PEC values from steps 1-2 and step 3 (0.973 µg/l) were used in the risk assessment.

3.3.3 EFFECTS ON TERRESTRIAL ORGANISMS

Isopyrazam contains two diasteroisomers, designated syn- and anti-isomers, which are contained in technical isopyrazam in a range of syn:anti isomer ratios between 70:30 and 100:0. Both isomers are biologically active but the anti-isomer has been shown to be 4-5

times more toxic to fish than the syn-isomer. Many of the submitted ecotoxicological studies were conducted with the technical isopyrazam containing 70:30 syn:anti isomer ratio, which according to the applicant provide conservative endpoints.

Where there are indications that the plant protection product is more toxic than what can be explained by the content of active substance (or studies are only conducted with the product), or identified metabolites are more toxic than the active substance, these calculations are included in the summary below. If this is not the case, these values and calculations are omitted.

3.3.3.1 *Mammals*

Low acute toxicity to mammals (LD50: >2000 mg/kg bw/d). TER acute for the indicator species in cereals is calculated to be 110, which pass the trigger (<10). NOAEL: 217 mg/kg. TER chronic is calculated to be 48, which pass the trigger (<5).

3.3.3.2 *Birds*

Isopyrazam has low acute toxicity to birds (LD50: 3228 mg/kg bw). TER acute for the indicator species in cereals is calculated to be 296, which pass the trigger (<10). There was no mortality in dietary toxicity studies (LC50: >1310 mg/kg feed). TER short-term for the indicator species in cereals is estimated as >347, which pass the trigger (<10). NOEC from reproductive toxicity study is 32.5 mg/kg bw/day. TER chronic is estimated to be 8.6 which pass the trigger (<5).

3.3.3.3 *Bees*

Low contact toxicity (LD50: >200 µg/bee) and low oral toxicity to bees (LD50: >192 µg/bee). Hazard quotients (HQ) for contact and oral exposure are estimated to be <0.6 and <0.7, respectively. The HQs for both contact and oral exposure pass the trigger (>50).

3.3.3.4 *Non-target arthropods*

In Tier 1 laboratory acute contact toxicity studies, Bontima showed >30% effects on reproduction for predatory mites at relevant application rates and >80% effects on mortality for parasitoids at rates lower than the application rate for Norway. HQ off-field values for the parasitoid *Aphidius rhopalosiphi* and the predatory mite *Typhlodromus pyri*, as well as HQ in-field for *T. pyri* pass the trigger, but the HQ in-field for *A. rhopalosiphi* fail the trigger and further consideration is required. Extended laboratory studies did not show effects above the trigger effect level of 50% at relevant application rates.

3.3.3.5 *Earthworms*

Moderate acute toxicity to earthworms (LC50corr: >500 mg/kg d.w. soil). TERacute is calculated to be >667, which pass the trigger (<10). The 56 day NOEC for *Eisenia foetida andrei* was 30 mg a.s./kg soil. TERchronic is calculated to be 40, which pass the trigger (<5).

3.3.3.6 *Other soil macro organisms*

Since the soil DT90 for isopyrazam is >365 days, the need for consideration of risk to soil macro organisms other than earthworms is triggered. The toxicity to the springtail *F. candida* has been tested with the two metabolites CSCD459488 (NOECcorrected: 25 mg/kg d.w. soil) and CSCD465008 (NOEC: 50 mg/kg d.w. soil). The TERs of 1389 and 28571 for CSCD459488 and CSCD465008, respectively, pass the trigger (<5).

3.3.3.7 *Microorganisms*

Neither mineralization nor nitrogen transformation by soil microflora of soils treated with isopyrazam up to 10 x the maximum application rate differed from untreated soils by greater than 25 % (trigger) after 28 days.

3.3.3.8 *Terrestrial plants*

No significant effects in any tested species concerning phytotoxic effects and seedling emergence were observed at rates up to 200 mL Bontima/daa.

3.3.4 EFFECTS ON AQUATIC ORGANISMS

The TER calculations below are based on maximum PEC-values from FOCUS surface water modeling and the lowest acute (LC50 or EC50) or chronic (NOEC) values for the different test organisms. All calculations are based on a maximum application rate of 12.5 g a.s./daa.

3.3.4.1 *Fish*

Isopyrazam showed very high acute toxicity (96h LC50: 0.0258 mg a.s./L) and high chronic toxicity to fish (NOEC: 0.00287 mg a.s./L). Bontima showed high acute toxicity to rainbow trout (96h LC50: 0.36 mg/L). TER calculations for isopyrazam, both acute TER of 26.5 and chronic TER of 3, fail the EU triggers (acute: 100, chronic: 10).

3.3.4.2 *Invertebrates*

Isopyrazam showed very high acute toxicity to Daphnia magna (isopyrazam (70:30) 48h EC50: 0.044 mg a.s./L, isopyrazam (90:10) 48 h EC50: 0.13 mg a.s./L,) and high toxicity to other invertebrates (LC50s: >0.7->1.0 mg a.s./L tested with isopyrazam (95:5)). Isopyrazam is chronically toxic to Daphnia magna (21d NOEC: 0.013 µg a.s./L). Bontima showed high acute toxicity to Daphnia magna (48h EC50: 0.22 mg/L). TER calculations for isopyrazam, both acute and chronic, pass the EU triggers (acute: 100, chronic: 10).

3.3.4.3 *Sediment dwelling organisms*

Isopyrazam showed low chronic toxicity to *Chironomus riparius* larvae (27d NOEC: 1 mg a.s./L (spiked water); 28d NOEC: 56 mg a.s./kg (spiked sediment)). All TER calculations pass the EU trigger (10).

3.3.4.4 *Aquatic plants*

Isopyrazam showed no effects on *Lemna gibba* at the highest concentration tested (7d EC50: >0.5 mg a.s./L, NOEC: 0.5 mg a.s./L). The TER calculation for isopyrazam passed the EU trigger (10).

3.3.4.5 *Algae*

Isopyrazam is acutely toxic to algae (72h ErC50: 2.2 mg a.s./L). Bontima is acutely toxic to algae (72h EC50: 5.7 mg/L). All TER calculations pass the EU trigger (10).

3.3.5 BIOCONCENTRATION

Isopyrazam shows a potential for bioconcentration; in bluegill sunfish the whole fish BCF was 441. Rapid depuration occurred (DT90: 1.15 days).

4 Risk characterization

4.1 FATE ASSESSMENT

The Panel on plant protection products of the Norwegian Scientific Committee for Food Safety (VKM) has reviewed the actual documentation and points out the following inherent properties of the product, the active substances and possible metabolites:

4.1.1 DEGRADATION AND ACCUMULATION IN SOIL

Isopyrazam is slowly degraded in soils, with an estimated half-life (DT50) of 244 days (geometric mean) from laboratory studies. The degradation in soils is also slow for the main metabolites CSCD459488 and CSCD465008 with half-lifves of 432 and 123 days respectively (geometric means). 13 field studies have been performed across Northern and Southern Europe. Normalised field DT50s ranged from 9 to 710 days with a geometric mean of 72 days. The range of the DT50s shows that isopyrazam can be persistent under certain conditions; however it is not possible to identify the main factors influencing the degradation rate from the results of the laboratory and field studies. The long half-lives indicate a high potential for accumulation in soil after repeated use. No accumulation studies have been submitted. Model calculations with the Finnish PEC soil calculator using the worst case DT50 value of 976 days from laboratory studies resulted in a maximum concentration of 0.75 mg/kg in soil, and no steady state concentration was reached within 20 years. VKM therefore concludes that isopyrazam is likely to be persistent in Norwegian soils with an associated risk of accumulation after repeated use.

4.1.2 MOBILITY IN SOILS.

Tier 1 $FOCUS_{gw}$ (groundwater) modeling was conducted for isopyrazam and its two main metabolites. Isopyrazam exhibits low mobility in soil and is not expected to reach groundwater. The metabolite CSCD459488 has a medium mobility in soil and the metabolite CSCD465008 is highly mobile in soil. Model calculations indicate that both metabolites may be expected to reach groundwater at concentrations exceeding the limit of 0.1µg/l (4.6µg/l and 0.9µg/l respectively). The two soil metabolites are considered toxicologically relevant by EFSA (EFSA, 2012). VKM concludes that the metabolites are likely to exceed the drinking water limit of 0.1µg/l in groundwater.

4.1.3 SURFACE WATER/SEDIMENT

For isopyrazam, both drainage and runoff, as well as drift contributes to the exposure to surface water. In the EU DAR step 4 calculations, buffer zones have been used to modify runoff and spray drift contributions. For 20 m buffer zones runoff levels are reduced by 80 %. VKM questions the relevance of using these buffer zone modifications under Norwegian topographic conditions (with e.g. steeper agricultural areas).

4.2 ENVIRONMENTAL RISK CHARACTERIZATION

The risk characterization of the product's ecotoxicological effects on terrestrial and aquatic organisms made by VKM is based on the summary from the Norwegian Food Safety Authority presented in section 5.3 and exposure-, dose/response assessments and risk scale described in section 5.2.2.

4.2.1 EFFECTS AND RISK TO TERRESTRIAL ORGANISMS

VKM concludes that there is minimal risk for toxic effects of isopyrazam to mammals, birds, bees, plants, earthworms and soil microorganisms with the proposed application regime.

4.2.1.1 *Non-target arthropods*

Standard laboratory studies showed effects above the trigger of >30% effect on reproduction for predatory mites, however, calculated Hazard Quotient (HQ) values pass the trigger of concern, indicating minimal risk. $HQ_{in\text{-}field}$ values for the leaf dwelling parasitoid *A. rhopalosiphi* fail the trigger of concern (HQ < 2) and further consideration is required. Extended laboratory studies on *A. rhopalosiphi* and the leaf dwelling predator *Chrysoperla carnea* were therefore conducted but they did not show effects above the trigger effect level of 50 % at relevant application rates indicating minimal risk also for these organisms. However one extended laboratory study on the ground dwelling predatory beetle *Aleochara bilineata,* has a control mortality of 41 % and VKM comments that the results from this experiment are not reliable and cannot be used in the environmental risk assessment.

4.2.2 EFFECTS AND RISK TO AQUATIC ORGANISMS

VKM concludes that there is minimal risk for toxic effects of isopyrazam to sediment dwelling organisms, aquatic plants, and algae with the proposed application regime. The calculations are based on a runoff scenario with a PEC value of 0.973 µg/l. In general VKM accepts the use of buffer zones to reduce drift levels but not to reduce runoff levels in model calculations. The resulting TER calculations show high risk of acute effects on fish and a medium risk of acute effects on invertebrates. VKM concludes that there is a high risk for toxic effects of Bontima to aquatic organisms with the proposed application regime.

4.3 QUALITY OF THE SUBMITTED DOCUMENTATION

VKM is of the opinion that the submitted documentation is adequate as a basis for an evaluation of the active substance, the metabolites, and for the technical material.

5 Conclusion

VKM concludes that isopyrazam is likely to be persistent in Norwegian soils with an associated risk of accumulation after repeated use.

Isopyrazam exhibits low mobility in soil and is not expected to reach groundwater, however the two main metabolites are likely to exceed the EUs drinking water limit of 0.1 µg/L in groundwater.

Since drainage and runoff, as well as drift, contributes to concentrations in surface water the risk assessment have to consider all these sources. In the EU DAR step 4 calculations, buffer zones of 20 m have been used to reduce runoff levels contributions by 80 %. VKM does not accept the use of these buffer zone modifications for Norwegian topographic conditions (with e.g. steeper agricultural areas).

There is minimal risk for toxic effects of isopyrazam to terrestrial organisms.

For the aquatic compartment, there is a high risk for toxic effects of isopyrazam to aquatic organisms with the proposed application regime. This is based on calculations of runoff without buffer zone modifications, from which the resulting TER calculations show high risk of acute effects on fish and a medium risk of acute effects on invertebrates. A minimal risk for toxic effects was calculated for sediment dwelling organisms, aquatic plants, and algae.

Attachment

Attached is The Norwegian Food Safety Authority's evaluation of the documentation submitted by the applicant, following application for registration of the fungicide Bontima www.Mattilsynet.no

References.

European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance isopyrazam EFSA Journal 2012;10(3):2600110pp.doi:10.2903/efsa.2012.2600

Draft Assessment Report (DAR), Isopyrazam. Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8 of Council Directive 91/414/EEC, April 2010. Chapter B8: Environmental Fate and behaviour and Chapter B9: Ecotoxicology

Final addendum to the Draft Assessment Report (DAR) - Initial risk assessment provided by the rapporteur Member State United Kingdom for the new active substance ISOPYRAZAM, February 2012