Environmental risk assessment of the pesticide Simplex with the active substances aminopyralid and fluroxypyr

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

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SUMMARY

Simplex is a new herbicide in Norway containing the active substances aminopyralid and fluroxypyr. Aminopyralid is a new active substance in Norway, but fluroxypyr is registered in several authorized products. The intended use of the plant protection product is in established grassland for forage, established ley and pasture and in grass at the first year of sowing.

During the spring of 2010, the Norwegian Scientific Committee for Food Safety (VKM) performed a human health risk assessment of the active substance aminopyralid and the product on request from the Norwegian Food Safety Authority. On further request from the Norwegian Food Safety Authority, VKM has performed a risk assessment on *the fate and the behaviour in the environment and the environmental risk with regard to the properties of the active substance aminopyralid and the product Simplex,* which was finalized at a meeting of VKM's Scientific Panel on plant protection products (Panel 2) on November 25, 2010. VKM Panel 2's conclusion is as follows: Aminopyralid is highly mobile in soil and the substance is very likely to reach ground water at concentrations above the threshold of 0.1µg/L. Experimental data (water-sediment studies) suggest that aminopyralid is persistent. However, aminopyralid concentrations in surface water are expected to decrease rapidly due to photolytic degradation. The overall risk for adverse effects on terrestrial and aquatic organisms following the proposed application of Simplex is considered to be minimal.

CONTRIBUTORS

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

Assessed by VKMs panel on plant protection products (Panel 2)

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1. 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 VKM's 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 October 11, 2010 for VKM to perform an environmental risk assessment of the herbicide Simplex containing the two active substances aminopyralid and fluroxypyr. The risk assessment of the product was finalized by VKM's Panel 2 at a meeting on November 25, 2010.

2. TERMS OF REFERENCE

Terms of reference as provided by the Norwegian Food Safety Authority are as follows:

"Simplex is a new herbicide in Norway containing the active substances aminopyralid and fluroxypyr. Aminopyralid is new to Norway, but fluroxypyr is registered in several authorised products. The intended use is in established grassland for forage, established ley and pasture and in grass at the first year of sawing. The Norwegian Food Safety Authority, in this regard, asks for an assessment of the following:

> *The fate and behaviour in the environment and environmental risk with regard to the properties of the active substance aminopyralid and the product Simplex. The Panel is in particular asked to look at persistence in soil and water/sediment, mobility in soil and exposure of groundwater."*

3. RISK ASSESSMENT (ENVIRONMENT)

3.1. Background documentation

The Panel's risk assessment is based on the Norwegian Food Safety Authority's evaluation (2010) of the documentation submitted by the applicant. The Norwegian Food Safety Authority publishes both their evaluation of Simplex and their final regulatory action on the registration of the product at their homepage http://www.mattilsynet.no.

3.2. 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 summary report on hazard identification, hazard characterization and assessment of exposure, which is included in the present document, is then reviewed by VKMs Panel 2. This review may result in some amendments in the original documents of both the summary report and the full report issued by the Norwegian Food Safety Authority (2010). The fourth step (risk characterization) is based on the three first steps and is the Panel's conclusions or risk assessment.

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 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 compartment 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 EUs FOCUS-scenarios. The models produce maximum PNEC and average PNEC calculated for specified periods after pesticide application. In the surface water scenarios PNEC 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 acceptable risk for different organisms, have been defined by the EU. In case the initial TER calculations indicate a risk for effects on aquatic organisms in surface water, further refinement of the calculation of PEC using models such as FOCUS step 2, 3 or 4 are used. It is also checked whether an acceptable risk can be achieved by applying a buffer zone. The risk is considered minimal when the TER **exceeds** 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.

The Panel 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, the Panel 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.

3.3. Summary by the Norwegian Food Safety Authority (hazard identification, hazard characterization and assessment of exposure)

Simplex is a new product containing two active substances (aminopyralid and fluroxypyr), of which one of the substances (aminopyralid) is a new active substance in Norway. The intended use is as herbicide in established grassland for forage, established ley and pasture and in grass at the first year of sowing. Bioforsk Plantehelse does not recommend use in the first year of sowing because of lack of efficacy data from the northern zone.

The Standardized Area Dose is 200 g product per decare (or 6 g aminopyralid and 20 g fluroxypyr per decare). Simplex will be used either before the first cutting (May/June) or between the first cutting and the second cutting (July/August). The application will be with tractor mounted sprayer, but in some cases it can also be relevant to use hand-held sprayer (spot spraying).

Simplex has effect against broad-leaf weeds, and will be especially important for use against creeping thistle (*Cirsium arvence*), spear thistle (*Cirsium vulgare*) and dock (*Rumex longifolius*).

Both substances in Simplex belong to the chemical group of pyridine carboxylic acid. Because of infrequently use and influence on several action sites in the plants, there will be a low risk of development of resistance.

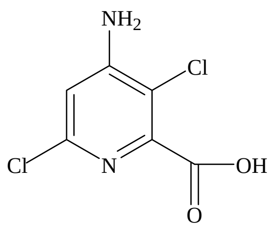
3.3.1. Identity and physical/chemical data

Product name	Simplex
Active substance	Aminopyralid and fluroxypyr
Formulation	Emulsion, water in oil.
Concentration of active substance	30 g aminopyralid/L and 100 g fluroxypyr/L.

Aminopyralid

IUPAC-navn	4-amino-3,6-dichloropyridine-2-carboxylic acid
CAS number	150114-71-9

Structural formula



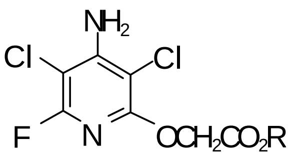
Aminopyralid

Molecular mass		207.026 g/mole
Solubility in water	Very high	205 mg/L (20°C, pH 7)
Vapour pressure	Low	9.52×10^{-9} Pa (20°C)
Henrys law constant	Low	9.61×10^{-12} Pa m^3/mol (20°C, pH 7)
log Pow	Low	-2.87 (19°C, pH 7)
pKa		2,56

Fluroxypyr

IUPAC-name	1-methylheptyl [(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate
CAS number	81406-37-3

Structural formula



Molecular mass		367.2 g/mole
Solubility in water	Low	0.09 mg/L (20°C)
Vapour pressure	High	1.349×10^{-3} Pa (20°C)
Henrys law constant	Medium	1.06×10^{-3} Pa m^3/mol
log Pow	High	4.53
pKa		

3.3.2. Mammalian toxicology

See VKMs risk assessment dated 29th of June, 2010 (VKM 2010, Risk assessment of health for Simplex - aminopyralid and fluroxypyr, VKM opinion: 10/204-final. ISBN: 978-82-8082-418-9). The assessment is published at www.vkm.no.

3.3.3. Residues in food and feed

Residues in food and feed are not discussed in this report.

3.3.4. Environmental fate and ecotoxicological effects

Environmental fate and behaviour

Degradation in soil

Aminopyralid was steadily degraded in soil under aerobic conditions. The only metabolite observed was CO_2 indicating that the phenyl ring of aminopyralid is mineralised. The aerobic degradation rate is medium, DT50: 26-147 days, geometric mean 56 days. DT90: 88-488 days. The degradation rate is dependent on temperature. Bound residue and mineralization accounted for 10-23 and 24-69% of AR (Applied radioactivity) respectively. At 10°C the degradation rate is slow. DT50: 402 days. DT90: 1335 days. Bound residue and mineralization accounted for 6 and 9% of AR respectively. Some DT50 and DT90 values are extrapolated beyond the duration of the degradation studies and should be regarded as uncertain. Aminopyralid was very stable under anaerobic conditions and no degradation rate was estimated. Only minor metabolites were observed. Photolysis can be regarded as an important route of degradation for aminopyralid in soil as the substance degrades much more rapid when irradiated than under dark conditions. The field dissipation of aminopyralid in soil was found to be medium to high with DT50: 4-22 days, geometric mean 12 days, and DT90: 13-72 days.

Sorption/mobility

The sorption of aminopyralid to soil can be classified as low with Kf: 0.01-0.73 (arithmetic mean 0.17) and Koc: 0.31-21.7 (arithmetic mean 8.3). The Freundlich exponent (1/n) ranged from 0.32 to 1.52 (arithmetic mean 0.85) indicating some non-proportional dependence of adsorption on the concentration. There is evidence that the sorption is stronger at low pH (acidic soils).

Degradation in water

Aminopyralid was completely stable to hydrolysis under all tested conditions. Photolysis is an important degradation pathway for aminopyralid if one compares half lives from the irradiated samples with half lives from the dark controls. Two major photoproducts were seen in the irradiated samples, oxamic acid and malonamic acid. Aminopyralid is classified as ‘not readily biodegradeable. The degradation for a whole water/sediment system was recalculated by RMS using the biphasic Hockey Stick approach and the degradation can be classified as moderate with DT50: 83-104 days when assessing the first phase. Geometric mean was 93 days. When assessing the second phase DT50 was 829-1495 days. Geometric mean was 1113 days. Bound residue constitutes between 3 and 15% of AR after 101 days. The mineralization was low, reaching between 1 and 3% of AR after 101 days in the different systems. Only minor unknown metabolites <5% were observed at any time point.

Fate in air

No significant volatilisation (0.2% AR) of ^{14}C-phenyl-aminopyralid was observed from plant surfaces. The estimated atmospheric half-life was 6.4 days.

Exposure

Soil

According to a simple model recommended by the EU working group FOCUS, the expected PIEC (Predicted Initial Environmental Concentration) in soil is 0.04 mg a.s./kg soil after the application of 60 g a.s./ha with 50% interception (plant cover). Aminopyralid concentrations were calculated assuming a worst case DT50 (lab, 20°C) of 147 days. With an interception of 90%, the PIEC is 0.008 mg a.s./kg soil.

Groundwater

The leaching behaviour of aminopyralid was estimated using all the nine FOCUS groundwater scenarios and the two recommended models, FOCUS-PELMO (version 3.3.2) and FOCUSPEARL (version 2.2.2). The use considered was Simplex in pasture grass according to the representative GAP, i.e. a single application of 60 g a.s./ha. The cropping scenario chosen for these simulations was "grass/alfalfa", the recommended interception (plant cover) is 90 %, thus the application rate used for all scenarios was 60 g a.s./ha x 10%, or 6 g a.s./ha. These modelling assessments indicate that there are situations where contamination of groundwater is likely to occur. The trigger of 0.1 µg/L is exceeded in 6 of the 9 FOCUS scenarios. The highest concentration estimated in these scenarios was 0.31µg/L with the Jokioinen scenario.

The leaching behaviour of aminopyralid was also estimated using the Norwegian (Heia) and Swedish (Önnestad and Krusenberg) groundwater scenarios with the FOCUS crop grass/alfalfa, using the model MACRO (4.4.2). The same input values for the active substance were used, except more realistic application dates. Application in June using a geo mean half life from laboratory studies and an interception of 50 % gave the highest PEC values (80^{th} percentile) with levels between 1.6 and 2.1 µg/l for all three scenarios. Application in late May with only 50 % interception and the same half life, gave PEC values between 1.4 and 2.0 µg/l. Applications in late May and in August also gave values well above the threshold of 0.1µg/l, even with an interception of 90 %.

Surface water

FOCUS SWASH was used to estimate the exposure of surface water and sediment. The highest predicted concentration in water from the assumed most relevant scenario, D1-Lanna, was 5.7 µg a.s./L. For the same scenario, global max in sediment was 1.8 µg a.s./kg dw. The highest estimated concentration in water overall was predicted from the D2-Brimstone scenario, with 22.6 µg a.s./L. The respective concentration in sediment was 3.3 µg a.s./kg dw.

Terrestrial organisms

Mammals

Aminopyralid showed low acute (LD50: >5000 mg a.s./kg bw) and reproductive (NOEL: 1000 mg a.s./kg bw/d) toxicity. Calculated TER values (>600 and 298, respectively) are above the relevant triggers (Acute: <10, Chronic: <5). Similar calculations based on low acute toxicity (LD50 >5000 mg/kg bw) of Simplex resulted in an acute TER value (>13) above the trigger (<10).

For the short-term and long-term scenarios it is assumed that the two active substances are unlikely to co-exist in the same proportions as in the original formulation. Hence it can be argued that since fluroxypyr has Annex I listing for use at rates up to 40 g/decare, that the lower rate of use in Simplex (20 g/decare) should not pose unacceptable short or long term risks to mammals.

Birds

Aminopyralid showed low acute (>2250 mg a.s./kg bw), dietary (>5620 mg a.s./kg diet) and reproductive (NOEC: 2700 mg a.s./kg diet) toxicity. All calculated TER values (>600, >726 and 103-175, respectively) are above the relevant triggers (Acute: <10, Chronic: <5). Similar calculations based on low acute toxicity (LD50: >2250 mg/kg bw) of Simplex resulted in acute TER values (>18) above the trigger (<10).

For the short-term and long-term scenarios it is assumed that the two active substances are unlikely to co-exist in the same proportions as in the original formulation. Hence it can be argued that since fluroxypyr has Annex I listing for use at rates up to 40 g/decare, that the lower rate of use in Simplex (20 g/decare) should not pose unacceptable short or long term risks to birds.

Bees

Aminopyralid showed low contact toxicity to bees (LD50: >100 µg/bee) and low oral toxicity to bees (LD50: >120 µg/bee). Hazard quotients for contact (Qhc) and oral exposure (Qho) are estimated to be 0.6 and 0.5, respectively. These do not exceed the trigger value (>50).

Simplex showed low contact toxicity to bees (LD50: >200 µg/bee) and low oral toxicity to bees (LD50: >100 µg/bee). Hazard quotients for contact (Qhc) and oral exposure (Qho) are estimated to be 10 and 20, respectively. These do not exceed the trigger value (>50).

Non-target arthropods
In Tier 1 laboratory acute contact toxicity studies, aminopyralid showed low effects on predatory mites (*T. pyri*) and parasitoids (*A. rhopalosiphi*). Although precise LR50 values can not be calculated, it can be seen that LR50 values for both species are >6 g/decare. Hazard quotients are below the trigger (>2) both in-field and off-field. Simplex was tested in extended lab studies with *A. rhopalosiphi* and *T. pyri*, and in a first tier study with *A. carnea*. The tests did not show effects above the trigger effect level of 50%.

Earthworms
Aminopyralid showed low acute toxicity (LC50: >1000 mg/kg d.w. soil), and TER is estimated to be >25000. Simplex showed moderate acute toxicity (LC50: 710 mg/kg d.w. soil), and TER is estimated to be 534. These values do not exceed the trigger (<10). Since the log Pow for aminopyralid is <2.0 the toxicity is not corrected to take account of the relatively high organic matter content of the artificial test soils. A 50% crop interception is used in the calculations.

Microorganisms
Soils treated with up to 100 times the normal application rate of aminopyralid did deviate less than 25% (trigger) from untreated controls with respect to carbon mineralisation/respiration and nitrogen mineralisation. Soils treated with up to 4.2 times the normal application rate of Simplex showed negligible deviation (<2%) from untreated controls with respect to carbon mineralisation/respiration and nitrogen mineralisation.

Aquatic organisms

The TER calculations for aminopyralid below are based on maximum PEC-values from FOCUS surface water modelling Step 1 and the lowest acute (LC50 or EC50) or chronic (NOEC) values for the different organism groups. All calculations are based on an application rate of 6 g a.s./decare.

For Simplex, it should be safe to assume that the runoff and drain flow will not move the intact formulation into the aquatic environment, due to the varying adsorption and degradation properties of the formulation’s constituents. Spray drift is the only realistic source of contamination of the aquatic environment by intact Simplex. TER values are calculated based on spray drift estimations with 1 meter buffer zone according to Rautmann et al. (2001).

Fish
Aminopyralid showed low acute toxicity (LC50: >100 mg a.s./L) and low toxicity (NOEC: 1,3 mg a.s./L) in an early life stage test. Calculated TER values are >4902 and 64, respectively. These do not exceed the relevant triggers (Acute: <100, Chronic: <10).

Simplex was toxic to rainbow trout (LC50: 7.6 mg/L), but the TER (412) was above the relevant trigger (<100).

Invertebrates
Aminopyralid showed low acute toxicity (EC50: >100 mg a.s./L) and low reproductive toxicity (NOEC: 100 mg a.s./L). Calculated TER values are >4902 and 4902, respectively. These do not exceed the relevant triggers (Acute: <10, Chronic: <5).

Simplex showed moderate toxicity to *Daphnia magna* (EC50: 35 mg/L), but the TER (1895) was above the relevant trigger (<100).

Sediment dwelling organisms

Aminopyralid showed low chronic toxicity to *C. riparius* larvae (NOEC: 130 mg a.s./L, NOEC: 46.7 mg a.s./kg sediment). Calculated TER values are 6373 and 58375, respectively. These do not exceed the relevant trigger (<5).

Aquatic plants

Aminopyralid showed low toxicity to duckweed (EC50: >88 mg a.s./L). Calculated TER is >4313, which do not exceed the relevant trigger (<10).

Algae

Aminopyralid showed moderate toxicity (EC50: 18->100 mg a.s./L). Calculated TER values are ≥882, which do not exceed the relevant trigger (<10).

Simplex was toxic to the freshwater diatom *N. pelliculosa* (EC50: 1.5-2.0 mg/L), but the TER (≥82) was above the relevant trigger (<10).

Microorganisms

Aminopyralid showed low toxicity to respiration of activated sewage sludge (EC50: >1000 mg a.s./L).

Bioconcentration

The log Pow for aminopyralid is given as -2.87 in pH 7 buffered solution. Bioconcentration studies are therefore not submitted, and aminopyralid is not expected to bioaccumulate.

3.3.5. Dossier quality and completeness

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

3.4. Panel 2's assessment of health

See VKMs risk assessment of health for Simplex dated 29th of June, 2010 (VKM 2010, Risk assessment of health for Simplex - aminopyralid and fluroxypyr, VKM opinion: 10/204-final. ISBN: 978-82-8082-418-9). The assessment is published at www.vkm.no.

3.5. Panel 2's assessment of environment

3.5.1. Summary of the environmental fate

Panel 2 has reviewed the actual documentation and points out the following inherent properties of the product, the active substance aminopyralid and its possible metabolites: Aminopyralid is highly mobile in soil due to the very low sorption. The field experiments indicate rapid dissipation from the top soil (20 cm) with an average half live of 12.1 days while the laboratory studies show an average half life of 56 days at 20ºC and 402 days at 10ºC.

The Panel is of the opinion that the discrepancy in half lives between the field- and the laboratory experiments may be due to leakage to lower soil layers. Thus, the half life derived from field experiments should not be used as input for degradation in ground water exposure modelling. Exposure simulations based on both field- and laboratory degradation rates show very high potential for ground water contamination above the threshold of 0.1 µg/L.

Degradation documented in water/sediment studies show DT50 values of 93 days (first phase) and 1113 days (second phase) suggesting that aminopyralid is persistent according to the EU PBT criteria (40 days for freshwater and 120 days for freshwater sediment). Under field conditions, however, photolysis is expected to contribute significantly to aminopyralid degradation in surface water. Calculated half life from photolytic degradation of aminopyralid was less than 2 days.

3.5.2. Environmental risk characterization

The risk characterization of the products ecotoxicological effects on the terrestrial and aquatic environments made by Panel 2 is based on the exposure- and dose-response assessments presented in section 3.3.3 by applying the risk scale described in section 3.2.

Ecotoxicological effects on terrestrial organisms

The Panel concludes that there is minimal risk for toxic effects on mammals, birds, bees, non-target arthropods, earthworms, and soil microorganisms with the proposed application regime.

Ecotoxicological effects on aquatic organisms

The Panel concludes that there is minimal risk for toxic effects on fish, invertebrates including sediment dwelling organisms, aquatic plants and algae even without use of buffer zones during spraying.

3.6. Quality of the submitted documentation

Panel 2 is of the opinion that the documentation submitted to VKM is adequate as a basis for an evaluation of the active substance, metabolites and product.

4. CONCLUSION

VKMs Panel 2 concludes as following:

Aminopyralid is highly mobile in soil and the Panel concludes that the substance is very likely to reach ground water at concentrations above the threshold of 0.1µg/L. Experimental data (water-sediment studies) suggest that aminopyralid is persistent. However, aminopyralid concentrations in surface water are expected to decrease rapidly due to photolytic degradation. The overall risk for adverse effects on terrestrial and aquatic organisms following the proposed application of Simplex is considered to be minimal.

5. ATTACHMENT

The Norwegian Food Safety Authority’s evaluation of the documentation submitted by the applicant following application for registration of the herbicide Simplex (aminopyralid and fluroxypyr) (2010).