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# 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

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#### Authors' contributions

This work was carried out in collaboration between all authors. The opinion has been assessed and approved by the Panel on Plant Protection Products of VKM. All authors read and approved the final manuscript.

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Grey Literature

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## ABSTRACT

Infinito is a new fungicide containing the two active substances fluopicolide and propamocarb-HCl intended to protect potatoes against the blight pathogen Phytophtora infestans. Fluopicolide is a new active substance in Norway, while propamocarb-HCl is already approved in several products. The risk assessment of Infinito 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).

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### The main conclusions from the risk assessment of Infinito 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 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. 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.

Keywords: VKM; assessment; Norwegian Scientific Committee for Food Safety; Infinito.

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#### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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