Risk Assessment of the Insecticide Plenum 50 WG with the Active Substances Pymetrozine

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Abstract

Plenum is a new insecticide containing the new active substance pymetrozine. Plenum is an insecticide against different pests in ornamentals, lettuce, cucumber and tomato in greenhouse and against pollen beetles in oilseed- and turnip rapes. The risk assessment was finalized at a meeting Mai 29, 2012, by VKM’s Scientific Panel on plant protection products (VKM). The Panel is in particular asked by the Norwegian Food Safety Authority to look at the following:

- The human health risk for operators related to the properties of the active substance and the product. The Panel is in particular asked to look at the following: o The effects seen in studies on...
The effects reported in the repeated dose toxicity studies with dogs should be considered as adverse.

The increased incidence of liver and lung tumors should be considered as relevant for humans. It cannot be excluded that a genotoxic mechanism could be involved in the formation of the liver tumors, which would have implications for risk assessment. It should therefore be considered to test pymetrozine in more sensitive in vivo genotoxic endpoints in liver.

The effects reported in the teratogenicity studies in rats and rabbits and in the developmental neurotoxicity study in rats should be considered for a classification of pymetrozine for developmental toxicity.

Risk calculations with both the German model and the UK POEM show low risk if personal protection equipment is used.

VKM propose:

- NOAEL of 0.6 mg/kg bw/day for pymetrozine based on the 1-year study in dogs.
- AOEL of 0.006 mg/kg bw/day for pymetrozine based on the NOAEL value at 0.6 mg/kg bw/day from the one year study in dogs and an UF of 100.
- ADI of 0.006 for pymetrozine based on the NOAEL value at 0.6 mg/kg bw/day from the one year study in dogs and an UF of 100.
- ARfD of 0.02 mg/kg bw/day for pymetrozine based on the LOAEL value at 8.1 mg/kg bw/day from the developmental neurotoxicity study and an UF of 500 (10 x interspecies difference, 10 x intraspecies difference, 3 x due to the use of a LOAEL value and 2 x due to the adversity of the neurodevelopmental effects).

VKM supports the classification proposal from Norwegian Food Safety Authority.

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

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NOTE:

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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COMPETING INTERESTS

Authors have declared that no competing interests exist.