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# **Risk Assessment of the Fungicide Aviator Xpro EC 225 with the Active Substances Bixafen and Prothioconazole**

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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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## **ABSTRACT**

Aviator Xpro EC 225 is a new fungicide for use in cereals, containing the new active substance bixafen and the already approved active substance prothioconazole. Prothioconazole was assessed by the Norwegian Scientific Committee for Food Safety in 2006, and is therefore not included in this report.

VKM was requested by the Norwegian Food Safety Authority to consider the possible health risk for operators related to the properties of bixafen used in Aviator Xpro EC 225; in particular to

evaluate the relevance of the effects of bixafen on liver and coagulation parameters observed in rats and mice, thyroid tumours and reproductive effects observed in rats, and the establishment of NOAELs and reference values. VKM was also asked to evaluate the fate and behaviour of bixafen in the environment, and the ecotoxicological effects and risks related to its use. The risk assessment was finalized in a meeting on May 24, 2013 by VKM's Scientific Panel on Plant Protection Products.

VKM's conclusions are as follows:

**Health:**

VKM concluded that the liver effects reported in sub-chronic and chronic studies in rats, dogs and mice exposed to bixafen, as well as the effects on coagulating parameters, should be considered adverse and of relevance to humans.

It is the opinion of VKM that the thyroid follicular cell tumours reported in female rats exposed to bixafen is not sufficient to suggest that bixafen has a tumour inducing potential.

It is further the opinion of VKM that it cannot be excluded that the reduced pup weight during lactation in the two-generation study is mediated by bixafen via the milk, and that bixafen has a direct effect on the number of stillborn pups in the F1 and F2 generation.

Finally, the pup developmental variants and anomalies reported in the teratogenicity study are considered treatment related, and not as secondary effects related to maternal toxicity.

VKM proposes a NOAEL of 2.0 mg/kg bw/day based on a 2 year feeding study in rats.

VKM support/propose:

- ADI: 0.02 mg/kg bw/day
- AOEL: 0.13 mg/kg bw/day
- ARfD: 0.2 mg/kg bw/day

Risk calculations show minimal risk if personal protective equipment is used.

**Environment:**

Bixafen is shown to be persistent in soil. VKM considers the results from a field study on a German site and the Finnish PEC calculator to be relevant and concludes that repeated annual applications can cause accumulation in soil under Norwegian conditions. There is also a potential for groundwater contamination from leaching of the metabolite M44.

VKM has concluded that the use of bixafen as an ingredient in Aviator Xpro EC 225 with the proposed application regime in Norway will represent a minimal risk for toxic effects to terrestrial organisms.

The toxicity of bixafen to aquatic organisms is high, and minimal risk of effects in surface waters can be achieved only if risk mitigation measures with bufferzones of 10 m are applied.

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

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**NOTE:**

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**COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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