



Risk Assessment of the Metabolite M44 of Bixafen, One of the Active Substances in Aviator Xpro EC225

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Authors' contributions

This work was carried out in collaboration among 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

Aviator Xpro EC 225 containing the active substance bixafen was assessed by VKM in spring 2013, and it was concluded that the metabolite M44 has potential for groundwater contamination. Furthermore, VKM assessed in late 2013 the relevance of this metabolite in accordance with the EU guidance document on metabolites in groundwater, and concluded that the malformations

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observed in rabbits exposed to the metabolite should be considered treatment related. VKM also concluded that the data presented to evaluate the possible genotoxic properties of the metabolite was insufficient to reach a conclusion. Based on this, the Norwegian Food Safety Authority rejected the approval of Aviator Xpro EC 225.

The applicant has now submitted results from an in vivo study to strengthen the basis for assessment of genotoxic properties, and also submitted new historical controls in relation to the experimental studies on foetal developmental effects in rabbits. The VKM Panel on Plant Protection Products has discussed the questions raised by The Norwegian Food Safety Authority on the basis of the new data, and has the following opinion:

On the assessment of genotoxic properties of the M44 metabolite of bixafen, one of the active ingredients of Aviator Xpro EC 225.

It is the view of VKM Panel on Plant Protection Products that the new in vivo mouse micronucleus study, supplemented together with a separate study demonstrating bioavailability, overrides the results of the in vitro clastogenicity studies. Taken together, it is the opinion of VKM that under the conditions studied, M44 should be considered as non-genotoxic.

On the assessment of the relevance of the foetal malformations in M44 exposed animals.

VKMs Panel on Plant Protection products has assessed the arguments and new historical control data presented by the applicant, intended to show that metabolite M44 is not teratogenic. It is however the opinion of the Panel that the arguments and the new historical data provided by the applicant do not alter the panel's previous conclusion; that the malformations observed in rabbits exposed to the metabolite M44 should be considered treatment related.

Keywords: VKM; risk assessment; Norwegian scientific committee for food safety; pesticide; ground water; aviator; bixafen; metabolite; M44.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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