

Ugradert

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Vitenskapskomiteen for mattrygghet
Postboks 4404 Nydalen
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Statens tilsyn for planter, fisk, dyr og næringsmidler



BESTILLING AV RISIKOVURDERING FOR PLANTEVERN MIDLET AVIATOR XPRO EC 225 – BIXAFEN + PROTIOKONAZOL

Det er avtalt møte i VKMs faggruppe 2 den 24. mai 2013. Mattilsynet bestiller herved nedenstående vurdering. Mattilsynet ønsker at VKMs vurdering skal skrives på engelsk, så selve bestillingsteksten er også på engelsk:

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

The Norwegian Food Safety Authority would like, in this regard, an assessment of the following:

- The human health risk for operators related to the properties of bixafen used in Aviator Xpro EC 225. Prothioconazole has been assessed earlier. The Panel is in particular asked to look at the following:
 - Evaluation of the effects of bixafen on the liver and the perturbation of the coagulation parameters observed at low doses, and if these should be considered as adverse effects.
 - Evaluation of the arguments put forward by the notifier stating that the perturbation of the coagulation parameters observed in studies on rat and mouse was due to vitamin K deficiency in the diet.
 - The relevance for humans of tumors observed in thyroid in the rat study.
 - Evaluation of the reproductive effects of bixafen observed in rats, especially fetus mortality and changes in pup body weight and organ weight during lactation.
 - Evaluation of the effects of bixafen observed in the teratogenicity study on rabbits.
 - The establishment of NOAELs and reference values (ADI, AOEL and ARfD).
- The fate and behaviour in the environment and the ecotoxicological effects and risks with regard to the properties of bixafen used in Aviator Xpro EC 225.

Vedlagt oversendes Mattilsynets rapport for Aviator Xpro EC 225 med vedlegg. Sakspapirene er unntatt offentlighet. Mattilsynets rapport vil bli publisert etter at endelig vedtak er fattet i saken.

Vi ber om at faggruppens medlemmer gjøres kjent med innholdet i dette brevet.

Med hilsen

Tor Erik Jørgensen
seksjonssjef

Erlend Spikkerud
seniorrådgiver

Kopi til (kun brev):
Mattilsynet, Hovedkontoret, Stab regelverk v/Kirstin Færden

Vedlegg