



GMO Panel statement on maize MIR162

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Background

- New information: a recently approved European patent claims a link between Vip3 proteins and altered male fertility
- May be directly relevant for the safety of MIR162 (expressing Vip3Aa20)
- Mandate from EC: assess the impact of this information on the conclusions of the GMO Panel opinions on MIR162 as a single and as part of maize stacks
- The potential impact is on 10 events (plus subcombinations) owned by three applicants/authorisation holders



Assessment of the GMO Panel

- Based on the data provided by the patent owner, there is scarce support for a link between Vip3 and decreased fertility
- In general, it is not possible to confirm that there is an association between event MIR162 and altered fertility
- Even if such an association existed, the GMO Panel did not identify any implication of a decrease in male fertility for food/feed or environmental safety
- The GMO Panel concludes that the previous conclusions on maize MIR162 and stacked events containing MIR162 remain valid



Considerations of the GMO Panel

- The existence of the patent was communicated to the EC in the public consultation on two recently adopted applications.
- However, the patent was filed in 2015. According to Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013, new information potentially relevant for safety should be provided to EFSA as soon as such information arises.
- GMO Panel: 'it is incumbent on all applicants to complete a comprehensive search of all relevant published literature and patents and guarantee the delivery of potentially relevant scientific information to EFSA to assist in the processing of applications.'



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