

## **Maize MIR162, maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and subcombinations**

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**Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)**  
**Country: The Netherlands**  
**Type: Others...**

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### **Comments:**

We – the European GMO-Free Citizens and the Ekopark Foundation in Lelystad (the Netherlands) – do not wish to eat this genetically modified maize. We want to eat unsprayed food that has not been genetically manipulated. This is also better for the environment. Nor do we want genetically modified maize as animal feed. And we do not want you to put it back on the EU market. If you were to approve it (which we would regret), we would want every product and every end product to be labelled as a GMO, even if GMOs can no longer be detected in an end product.

See all our comments on GM maize of an earlier date.

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**Organisation: Testbiotech e.V. - Institute for Independent Impact Assessment of Biotechnology**  
**Country: Germany**  
**Type: Non Profit Organisation**

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### **Comments:**

In our previous comment on the opinion of EFSA (2022) we drew attention to effects of Vip3A described in the granted European patent EP 3632202 of company Syngenta (Testbiotech, 2022). In the description of the patent, the results from field trials are reported, involving maize event MIR162 that show unexpected reduction or increase of male fertility in maize plants.

According to the patent, the effects are dependent on the genetic background of the plants as well as on environmental stress conditions. These data reveal an unintended impact of the inserted transgene onto the biology of the plants via unknown mechanisms. Therefore, the question arises, if these unknown mechanisms may also impact food safety.

To conclude on this issue, further data to demonstrate safety of the food and feed derived from MIR162 events are necessary, for the risk assessment of the parental plants as well as for the stacked events. In this context, also the already existing data should be taken into account, showing the expression of the additionally inserted transgenes is highly variable and likely to depend on the genetic background and environmental conditions.

Therefore, we appreciate that the Commission approached EFSA to request further information from the patent holder. Syngenta replied that the claim of the patent ('Vip3 has been observed to cause decreased male fertility in certain inbred maize plants under normal growing conditions') is not yet fully validated by data. To determine whether the reduced male fertility observed in certain MIR162 inbred lines is due to a plant genomic region genetically linked to the additionally inserted DNA, Syngenta identified genes (and quantitative trait loci) related to male fertility and present in some inbred lines. However, according to Syngenta, the specific combination of the genetic regions leading to this effect, has not yet been adequately identified and characterised.

In reaction and in absence of specific data, EFSA suggests that the empirical findings as described in the patent would not be relevant for food safety. However to demonstrate safety, such vaguely argued assumptions are not sufficient. Specific data (such as on gene expression, plant composition and agronomic characteristics) from maize plants as described in the patent are necessary before any conclusions can be made. Therefore, it is not acceptable that EFSA did not require the necessary data from the company to perform the risk assessment as required by law.

## References

EFSA (2022a) Scientific Opinion on the assessment of genetically modified maize MIR162 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-025). EFSA J, 20( 9): 7562. <https://doi.org/10.2903/j.efsa.2022.7562>

Testbiotech (2022) Assessment of genetically modified maize MIR162 for renewal authorisation by Syngenta, <https://www.testbiotech.org/content/maize-mir162-renewal-authorisation-syngenta>