

Re: Open Source Detection Test for First Commercialized Gene-edited Plant Ready for Integration in Routine EU and National GMO Controls

Dear [REDACTED],

With this letter, we would like to inform you, the chair of the Regulatory Committee 2001/18/EC, about the successful development of a detection method for the first commercialised gene-edited crop, a rapeseed produced by US company Cibus. The research has been funded by a consortium of NGOs, Non-GMO food organisations and organic food and farming associations from Europe, the US and New Zealand.

The test¹ shows that it is possible to detect and quantify genetically modified organisms (GMOs) engineered with gene editing, and to distinguish such crops from similar crops developed with other methods.

Importantly, it allows EU authorities to test imports for the presence of this GM crop, which is grown in the US and Canada and has no GMO authorisation in the EU. The test thereby supports EU member states in implementing the 2018 ruling of the European Court of Justice.²

The detection test is open source and can be used by any regulatory and private laboratory. It meets all EU criteria for GMO detection methods. Its robustness and reliability have been validated by the GMO analysis laboratory of Environment Agency Austria (Umweltbundesamt).

From a scientific perspective, the approach used to develop the test can be employed to develop detection tests for most, if not all, gene-edited crops.

Dear [REDACTED], following the publication of this breakthrough research, we ask you to

- Inform the Regulatory Committee 2001/18/EC on this specific detection method. National inspection bodies should integrate the test into their GMO testing routine in order to identify any illegal presence of this GM crop on the EU market.
- Support a mandate given to the European Network of GMO Laboratories (ENGL) to build on this test and develop screening methods to identify further gene-edited GM crops.
- Support an ENGL validation of test.

Now we have provided visibility to the first commercialised gene-edited GM crop, we are confident that analytical capabilities to detect new GMOs will keep up with developments in GM technology, and that existing EU GMO regulations can be applied to gene-edited GM crops as well.

We hope that the successful development of the detection test demonstrates that EU member states' fears that gene-edited products "cannot be distinguished, using current methods, from products resulting from natural mutation" are in fact disproportionate.³

¹ A Real-Time Quantitative PCR Method Specific for Detection and Quantification of the First Commercialized Genome-Edited Plant <https://www.mdpi.com/2304-8158/9/9/1245>

² Ruling of 25 July 2018 in case C-528/16

³ Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study

Please keep us informed about the steps you are taking in the Regulatory Committee 2001/18/EC and what are you doing with regard to ENGL.

We look forward to your answer and remain at your disposal for any further questions you may have.

On behalf of the organisations which enabled the development of the test

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