



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Acting Director-General

Brussels,
 SANTE/E1/IC/nn_sante.ddg2.e.1(2015)3084491

Dear [REDACTED],

Subject: Organisms developed using new modification technologies

Thank you for your letter dated 10 June 2015, in which you asked for confirmation that the organisms described are not subject to the EU legislation on GMOs.

As my services discussed with you in a meeting on 5 June 2015, the European Commission is carrying out a legal analysis of a group of new plant breeding techniques, in order to evaluate whether they fall under the scope of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Directive 2009/41/EC on the contained use of genetically modified micro-organisms. Techniques applicable also to organisms other than plants and including cisgenesis and genome editing technologies, like CRISPR/Cas9, are being considered in this legal analysis.

The services of the Commission expect to complete this legal analysis by the end of this year. However we are not yet in the position to present a conclusion and therefore we cannot confirm at this stage whether the organisms described in the annex to your letter are falling or not under the scope of the GMO legislation.

In the context of the current legal uncertainty, we recommend that, if using these techniques, you adopt the most protective approach until the status of the techniques is clarified, in order to be able to adapt to the requirement of EU legislation on GMOs if it is concluded that the techniques lead to the creation of GMOs.

When the legal analysis will be available, I am confident that you will find an answer to your question.

Yours sincerely,

Ladislav Miko

[REDACTED] - VIB
 [REDACTED]
 Rijvisschestraat 120
 B – 9052 Gent

Email: vib@vib.be