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Ladislav Miko
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Directorate-General for Health and Food Safety
Acting Director-General
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Your message from	Your reference	Our reference	Date
		REG/rc-bvl/15-00331	10/06/15

Concerning: organisms developed using new modification technologies

Dear Mr. Miko

In recent years different novel techniques have been developed through which alterations can be introduced into the genetic material of organisms. These techniques are being applied on a rapidly accelerating pace and that is why there is an urgent need to create regulatory clarity on whether or not the use of these techniques results in organisms that are subject to the requirements of the European GMO legislation.

Interpretation of the current European GMO regulatory framework
What is subject to the requirements of the European GMO regulatory framework is determined by articles 2 and 3 and annexes Ia, and Ib of EU directives 2009/41/EC and 2001/18/EC. These articles and annexes provide a definition of genetically modified (micro-)organism, a definition of what constitute techniques of genetic modification, a definition of techniques which are not genetic modification and a definition of techniques of genetic modification that result in organisms which are exempt from the requirements of the GMO legislation. The definition of a genetically modified organism in directive 2001/18/EC reads as follows:

> *"An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"*

This definition should be interpreted in line with the definition of 'living modified organism' (LMO) of the Cartagena Protocol on Biosafety which both the European Union and the EU member states have ratified. The definition of LMO in the protocol reads as follows:

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"Any living organism that carries a novel combination of genetic material obtained through the use of modern technology"

The LMO definition clearly contains product-related and process-related criteria, which both have to be fulfilled to fall within the scope of the Biosafety Protocol. It is not enough to have used a certain technology to trigger the legislation. The use of the technology also needs to lead to the formation of a novel combination of genetic material. And novelty should be interpreted as not being able to occur in nature, because otherwise classical breeding technologies would also trigger the legislation.

In the annex to this letter you will find different examples of the use of modern genome editing technologies that we submit to the European Commission for confirmation that the resulting organisms are not subject to the European GMO legislation. This annex is confidential as the examples given represent concrete business opportunities and represents vulnerable information from the viewpoint of competition.

If you would have any questions concerning this matter, please do not hesitate to contact us. We would be happy to address them.

Yours sincerely

[redacted]

[redacted]

c.c. [redacted] DG Health and Food Safety

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