EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
**Biotechnology**

Brussels,
SANTE/E3 sante.ddg2.e.3(2018)6102537

Dear ,

**Subject: Regulatory requirements for the experimental release of plants obtained with genome editing CRISPR/Cas9**

Thank you for your letter of 27 September 2018[1] (Registro Ufficiale.U.0021635.27-09-2018), where you reiterate your request of 4 November 2016 for clarification on whether organisms modified through the technique of genome editing 'CRISPR/Cas9' fall under the scope of Directive 2001/18/EC[2].

In my reply of 2 December 2016[3], I informed you that, pending the ruling of the Court of Justice of the European Union (CJEU) on case C-528/16 on mutagenesis[4], the Commission was not in a position to reply to your request.

The judgement of the CJEU, delivered on 25 July 2018, has clarified, *inter alia*, that the Directive 2001/18/EC applies to organisms obtained by mutagenesis techniques or methods that have appeared or have been mostly developed since its adoption. Therefore, organisms produced with the technique of genome editing 'CRISPR/Cas9' are subject to the requirements of the Directive. In particular, any experimental release of an organism produced from CRISPR/Cas9 is subject to the requirements of Part B of Directive 2001/18/EC.

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[1] Our reference Ares(2018)5210330.

[2] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration (OJ L 106, 17.4.2001, p. 1–39).

[3] Our reference Ares(2016)6764489.

[4] Case C-528/16, *Confédération paysanne and Others*, Judgement of 25 July 2018, ECLI:EU:C:2018:583.

Dott.
Ministero dell'Ambiente e della Tutela del Territorio e del Mare
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Member States are primary responsible for the implementation of EU legislation. In this regard, the legal status and requirements for particular organisms or products must be assessed on a case-by-case basis by the authorities of the Member State in which an application is submitted. For this reason, we are only in a position to provide you with a general reply to your questions, as a concrete answer can only be given following an in-depth regulatory analysis of a specific application.

Yours sincerely,