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#### 'I/A' ITEM NOTE

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From: General Secretariat of the Council  
To: Permanent Representatives Committee/Council

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Subject: Council Decision regarding the status of novel genomic techniques under Union law  
- *Adoption*

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- (1) Directive 2001/18/EC of the European Parliament and of the Council<sup>1</sup> defines a genetically modified organism (GMO) as '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'. Lists of techniques through which use of genetic modification occurs, complete this definition. The definition and the lists of techniques have been drafted in the light of those breeding techniques that were available and used at the time of its adoption.
- (2) Since then, there has been substantial progress in the development of new breeding techniques, leading to uncertainty on whether those new breeding techniques come under the definition of a GMO and the scope of the Directive or not and, as a consequence, whether products obtained by them should be subject to the obligations laid down in Directive 2001/18/EC.

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<sup>1</sup> 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 - OJ L 106, 17.4.2001, p.1.

- (3) By its judgment in Case C-528/16 , the Court of Justice, after considering the overall objectives of Directive 2001/18/EC, ruled that new mutagenesis techniques fall within the scope of that Directive and are subject to the obligations laid down therein.
- (4) Following consultations with delegations, the Presidency tabled on 26 August 2019 a draft Council Decision based on Article 241 TFEU requesting the Commission to submit a study on the Union's options for addressing the legal situation of new plant breeding techniques taking into account the existing legal framework provided by Directive 2001/18/EC of the European Parliament and the Council and the Court of Justice's judgment in Case C-528/16.<sup>2</sup> Under Article 241 TFEU, the Council acts by simple majority.
- (5) The Working Party of Agricultural Counsellors/Attaches ('the Working Party') discussed that draft at its meeting of 6 September. Following an informal silence procedure, the Working Party agreed by simple majority on the text set out in document 11347/3/19 REV 3.
- (6) The Committee of Permanent Representatives is therefore invited to:
- confirm, by simple majority, the agreement reached by the Working Party; and
  - recommend that the Council:
    - adopt, by simple majority, the draft Council Decision set out in document 12781/19 (text finalised by the Jurist-Linguists) as an "A" item on the agenda of one of its forthcoming sessions; and
    - decide to publish it in the EU Official Journal ("L" series) as soon as possible.

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<sup>2</sup> 11347/19.