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European Union

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### CONTRIBUTION

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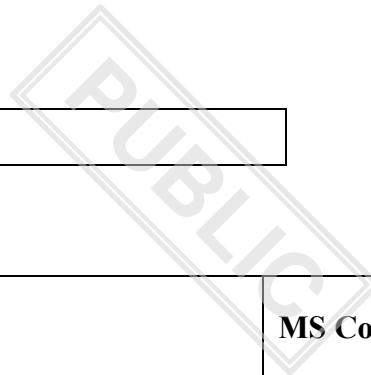
From: General Secretariat of the Council  
To: Delegations

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Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material) - Comments from Romania

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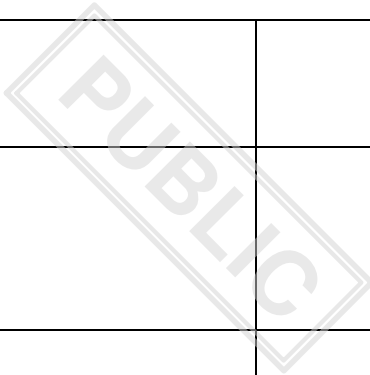
Delegations will find in Annex comments from Romania on the above proposal. The comments pertain to Articles 1 – 3 (27).



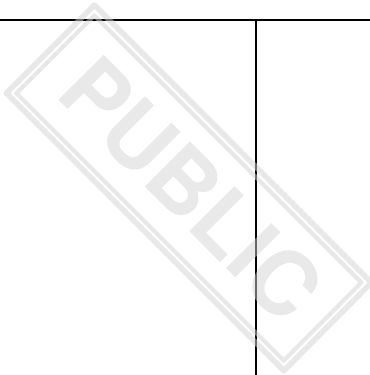
<b>Member State:</b>	<b>Romania</b>
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<b>Commission proposal (PRM)</b>	<b>MS Drafting Suggestions</b>	<b>MS Comments</b>
<b>CHAPTER I</b> <b>GENERAL PROVISIONS</b>		
<i>Article 1</i> <i>Subject matter</i>		
<p>This Regulation lays down rules for the production and marketing in the Union of plant reproductive material ('PRM'), and in particular requirements for the production of PRM in the field and other sites, categories of material, identity and quality requirements, certification, labelling, packaging, imports, professional operators and the registration of varieties.</p> <p>This Regulation also lays down rules concerning</p>	<p>This Regulation also lays down rules concerning the conditions of cultivation <del>of certain varieties</del></p>	

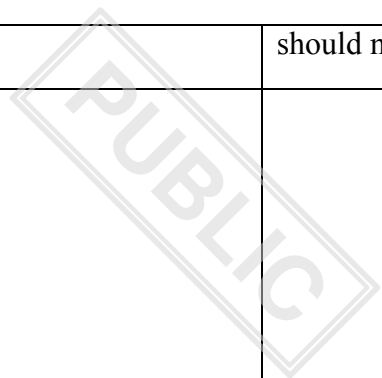
<p>the conditions of cultivation of certain varieties that could have undesirable agronomic effects, including the cultivation for purposes beyond the production and marketing of PRM, for the production of food, feed and other products.</p>	<p><del>that could have undesirable agronomic effects</del> the category 2 NGT according to the Regulation no. (), including the cultivation for purposes beyond the production and marketing of PRM, for the production of food, feed and other products.</p>	<p>This paragraph refers to plants obtained by category 2 NGT, this should be clearly specified.</p> <p>We believe that NGT definitions 1 and 2 should also be added to this Regulation, in article 3.</p>
<p><b>Article 2</b> <b>Scope</b></p>		
<p>1. This Regulation applies to the genera and species listed for the respective uses referred to in Parts A to E of Annex I.</p> <p>Its requirements concern, respectively, all types of PRM, only seeds, or only material other than seeds.</p> <p>The requirements concerning production of PRM shall apply only to production with a view to its marketing.</p>		



2. The objectives of this Regulation are the following:		
(a) to ensure quality and diversity of choice for PRM, and its availability for professional operators and final users;		
(b) to ensure a equal conditions for the competition of the professional operators across the Union and the functioning of the internal market in PRM;		
(c) to support innovation and competitiveness of the PRM sector in the Union;		
(d) to contribute to conservation and sustainable use of plant genetic resources and agro-biodiversity;		
(e) to contribute to sustainable agricultural production, adapted to current and future projected climatic conditions;		
(f) to contribute to food security		
3. The Commission is empowered in		

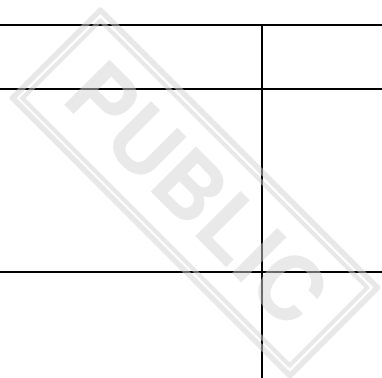


<p>accordance with Article 75 to adopt delegated acts, amend Annex I, in order to adapt it to the developments of technical and scientific knowledge, and the economic data concerning production and marketing of genera and species, by adding genera and species to or removing them from the list that Annex.</p> <p>The delegated act referred to in the first subparagraph shall add genera or species to the list in Annex I if they fulfil at least two of the following elements:</p>		
<p>(a) represent a significant area of production of PRM and a significant value of marketed PRM in the Union.</p>	<p>represent a significant area of production of PRM and a significant value of marketed PRM in the Union <u>or in a certain MS</u>.</p>	<p>Different requirements and particularities of each Member State should be respected.</p>
<p>(b) are of substantial importance for security of food and feed production in the Union, compared to other genera and species not listed in that Annex; and</p>	<p>are of substantial importance for security of food and feed production in the Union, <u>or in a certain MS</u> compared to other genera and species not listed in that Annex;</p>	<p>Different requirements and particularities of each Member State should be respected.</p>
<p>(c) are marketed in at least two Member States.</p>	<p>are marketed in at least <del>two</del> <u>one</u> Member States</p>	<p>The requirements and specificities of each Member State must be taken into account and</p>

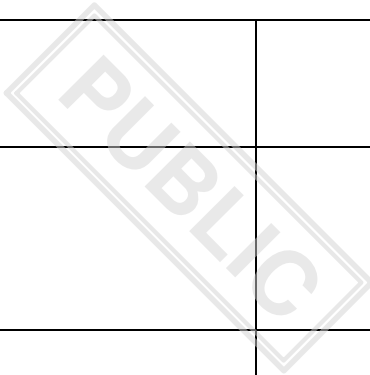


		should not be conditioned.
The delegated act referred to in the first subparagraph shall remove genera or species from the list in Annex I if they no longer fulfil at least two of the elements set out in the second subparagraph.		
4. This Regulation does not apply to:		
(a) propagating material of ornamental plants as defined in Article 2 of Directive 98/56/EC;		
(b) forest reproductive material as defined in Article 3 of Regulation (EU) .../... of the European Parliament and of the Council <sup>1+</sup> ;		
(c) PRM produced for export to third countries;		
(d) PRM sold or transferred in any way, whether free of charge or not, between final users for their own private use and outside their		

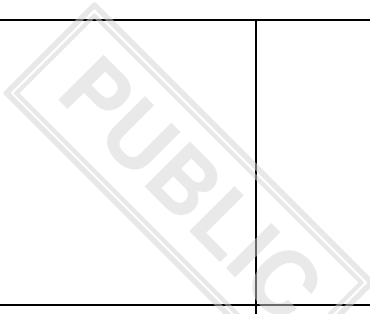
<sup>1</sup> Regulation (EU) .../... of the European Parliament and of the Council .... (OJ..., p....).  
+ OJ: Please insert in the text the number of the Regulation contained in document (... (COD)) and insert the number, date, title and OJ reference of that Regulation in the footnote.



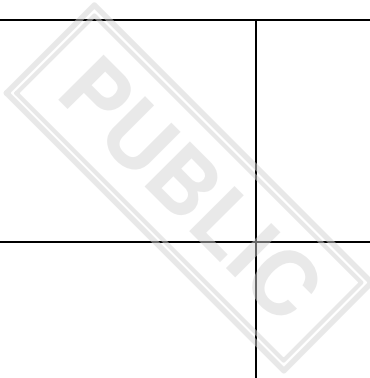
commercial activities;		
(e) PRM used solely for official testing, breeding, inspections, exhibitions or scientific purposes.		
<b>Article 3</b> <b>Definitions</b>		
For the purposes of this Regulation, the following definitions apply:		
(1) ‘plant reproductive material’ (‘PRM’) means plants as defined in Article 2(1) of Regulation (EU) 2016/2031, capable of, and intended for, producing entire plants;		
(2) ‘professional operator’ means any natural or legal person, involved professionally in one or more of the following activities in the Union concerning PRM:		
(a) production;		
(b) marketing;		
(c) maintenance of varieties;		



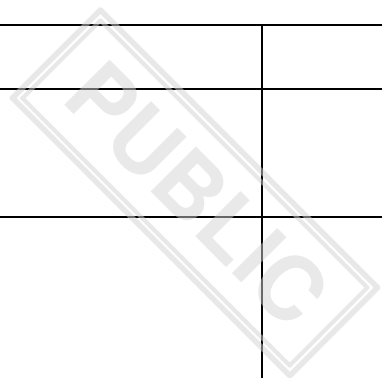
(d) provision of services for identity and quality;		
(e) preservation, storage, drying, processing, treating, packaging, sealing, labelling, sampling or testing;		
(3) ‘marketing’ means the following actions conducted by a professional operator: sale, holding, transfer for free, or offering for sale or any other way of transferring or distribution within, or import into, the Union		
(4) ‘variety’ means a variety as defined in Article 5(2) of Regulation (EC) No 2100/94;		
(5) ‘clone’ means an individual plant progeny, originally derived from another single plant by vegetative reproduction, remaining genetically identical to that plant;		
(6) ‘selected clone’ means a clone that has been selected and chosen for some special intravarietal phenotypic traits and its phytosanitary status that give the selected clone		



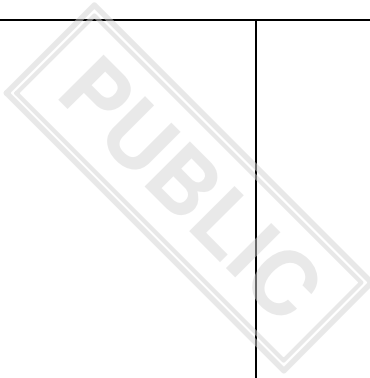
<p>a better performance, is true to the description of the variety to which it belongs and, in the case of selected clones not belonging to a variety, it is true to the description of the species to which it belongs;</p>		
<p>(7) ‘polyclonal plant reproductive material’ means a group of several distinct individual plant progenies derived from different genotypes, each of which is true to the description of the variety to which it belongs;</p>		<p>Polyclonal plant reproductive material for <b>wine grapes</b> cannot be marketed to set-up vineyards.</p>
<p>(8) ‘multiclonal mixture’ means a mixture of selected clones, all belonging to the same variety or species, as appropriate, whereby each of them has been obtained through independent selection;</p>		<p>This definition is not clear. A clone blend for wine grapes cannot be marketed to set-up vineyards (it affects the quality of wine).</p>
<p>(9) ‘competent authority’ means the central or regional authority of a Member State, or, where applicable, the corresponding authority of a third country, responsible for the organisation of official controls, registration, certification</p>		



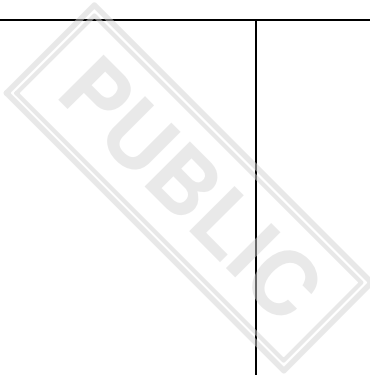
and other official activities concerning the production and marketing of PRM, or any other authority to which that responsibility has been conferred in accordance with Union law;		
(10) ‘official description’ means a description that has been established by a competent authority, includes the relevant characteristics of the variety and makes the variety identifiable as a result of the examination on its distinctness, uniformity and stability;		
(11) ‘officially recognised description’ means a written description of a conservation variety, which has been recognised by a competent authority, includes the specific characteristics of the variety, and has been obtained by other means than the examination of its distinctness, uniformity and stability;		
(12) ‘variety maintenance’ means the actions taken for controlling varietal purity and identity with the aim to ensure that a variety remains in accordance with its description over subsequent		



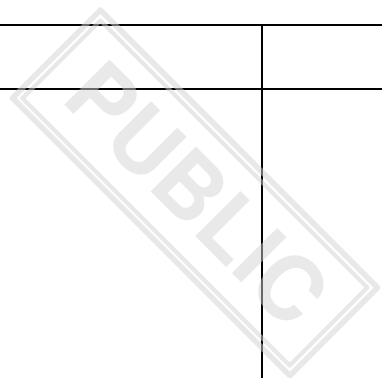
cycles of reproduction;		
(13) ‘seeds’ means seeds in the botanical sense;		
(14) ‘pre-basic seed’ means seed that belongs to a generation preceeding the generation of the basic seed, is intended for the production and certification of basic or certified seed, and has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Part A of Annex II;		
(15) ‘basic seed’ means seed that has been produced from pre-basic seed or preceding generations of basic seed, is intended for the production of further generations of basic seed or certified seed, and which has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Part A of Annex II;		



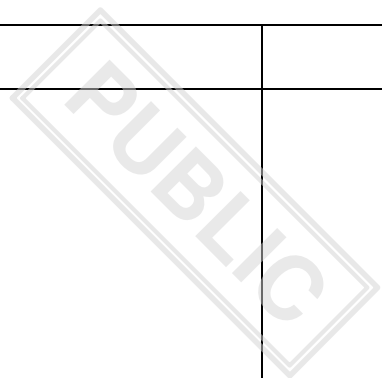
<p>(16) ‘certified seed’ means seed that has been produced from pre-basic, basic or preceding generations of certified seed, and which has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Part A of Annex II;</p>		
<p>(17) ‘standard seed’ means seed, other than pre-basic, basic or certified seed, that is not intended for further multiplication, and satisfies the respective conditions laid down in Part A of Annex III;</p>		
<p>(18) ‘pre-basic material’ means PRM, other than seeds, that belongs to a generation preceding the generation of basic material, is intended for the production and certification of basic or certified material, and has been found by means of official certification or certification under official supervision to satisfy the respective conditions laid down in Part B of Annex II;</p>		



<p>(19) ‘basic material’ means PRM, other than seed, that has been produced from pre-basic material or preceding generations of basic material, is intended for the production and certification of further generations of basic material or certified material, and has been found by means of official certification or certification under official supervision to satisfy the respective conditions laid down in Part B of Annex II;</p>		
<p>(20) ‘certified material’ means PRM, other than seed, that has been produced from pre-basic, basic or preceding generations of certified material, and has been found by means of official certification or certification under official supervision to satisfy the respective conditions laid down in Part B of Annex II;</p>		
<p>(21) ‘standard material’ means PRM other than seed, and other than pre-basic, basic or certified material, that is not intended for further multiplication, and satisfies the respective</p>		

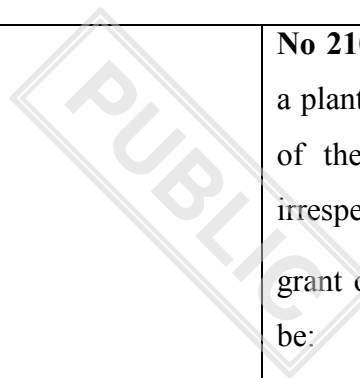


conditions laid down in Part B of Annex III;		
(22) ‘official certification’ means official attestation by the competent authority of the compliance of pre-basic, basic or certified seed or material with the respective requirements of this Regulation, where all relevant inspections on site, sampling and testing including where appropriate control plot testing have been carried out by that authority, and if it has concluded that the seed or material concerned meets those requirements;		
(23) ‘certification under official supervision’ means attestation by a specifically authorised professional operator that pre-basic, basic or certified seed or material complies with the applicable requirements, and where at least one or more of the relevant inspections, sampling, testing or label printing have been carried out by that professional operator, under the official supervision of the competent authority, and if it has concluded that the seed or material		



concerned meets those requirements;		
(24) ‘category’ of PRM means a group or an individual unit of PRM that qualifies as pre-basic, basic, certified or standard seed or material and is identifiable by complying with specific identity and quality requirements;		
(25) ‘genetically modified organism’ means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council <sup>(2)</sup> , excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;		<i>We believe that the NGT 2 definition should also be added.</i>
(26) ‘lot’ means a unit of PRM, identifiable by its homogeneity of composition and origin;		
(27) ‘heterogeneous material’ means a plant grouping within a single botanical taxon of the lowest known rank which:		The definition is not clear and leads to confusion.  According to <b>Article 5(2) of Regulation (EC)</b>

<sup>2</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).



<p>(a) presents common phenotypic characteristics;</p> <p>(b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that plant grouping is represented by the material as a whole, and not by a small number of units;</p> <p>(c) is not a variety; and</p> <p>(d) is not a mixture of varieties;</p>		<p><b>No 2100/94:</b> ...‘<i>variety</i>’ shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:</p> <ul style="list-style-type: none"><li>– defined by the expression of the characteristics that results from a given genotype or combination of genotypes,</li><li>– distinguished from any other plant grouping by the expression of at least one of the said characteristics, and</li><li>– considered as a unit with regard to its suitability for being propagated unchanged</li></ul>
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