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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Genetic Resources and Innovation in Agriculture (Seeds, Propagating and Planting Materials)
Subject:	Regulation on plant reproductive material - Request for contributions on non-concluded elements - Comments from RO

Delegations will find in the annex comments/drafting suggestions submitted by Romania on those parts of the proposal for a Regulation on the production and marketing of plant reproductive material in the Union, which have been put in square brackets by previous Presidencies (non-concluded elements).

Consultation on non-concluded elements – PRM Deadline: ***15 August 2025 cob***

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General guidelines to be followed

Please kindly provide your contributions in the table below.

Drafting suggestions: you may use '**track changes**' or formatting **in a different colour**.

Name of document: please add the **two initials** of your delegation's country followed by a space (to the MS Word document name), followed by any optional text, for example, for Austria: **AT comments on … .docx**

Detailed guidelines from the Presidency

For the purpose of the upcoming meeting in October of the Working Party on Genetic Resources and Innovation in Agriculture (PRM) the Danish Presidency would like to give opportunity to delegations to submit written comments on certain articles of the text that has not been concluded during the meetings under the Polish Presidency.

The Presidency has prepared a table with the articles in question and also this note to indicate what we would like delegations to focus on in their comments. Delegations are kindly asked only to comment on the text provided in the table as the Presidency considers the rest of the text to be agreed upon.

Delegations are invited to note that the articles indicated in the consultation document are based on the Polish Presidency final revised text (9647/25).

Article 2(4), point (i)

This addition shall be read in connection with Article 29. Do you support this addition and thus the deletion of Article 29? If you support this addition, do you have any drafting suggestions on the text?

Article 3, point (32a)

Do you agree with the definition of 'true potato seed'?

Article 6(2), points (f) and (g)

Do you agree with the exclusion of commercial seed and preservation mixtures from the category requirement?

Article 17a(4) and (5) (former Article 23)

This article was discussed during the Working Party meeting in March 2025.

Keeping in mind the discussion on traceability (Article 42) at the Working Party meeting in July, do you agree with the wording of Article 17a(4) and (5)?

Article 28

Do you support this derogation and would you like to keep it in the proposal?

If yes, do you agree with the latest changes to the article?

Article 29

This deletion shall be read in connection with Article 2(4), point (i). Do you support the deletion of Article 29 and thus the addition of Article 2(4), point (i)?

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Article 30
Do you agree with the deletion of this derogation?
If not, meaning that you would like to keep this article, do you agree with the latest wording?
Article 32(1a), point (c), and (2a)
Do you agree with the addition of point (c) to paragraph 1a?
Would you like to keep paragraph 2a and, if yes, do you agree with its latest wording?
Article 32a
Do you agree with having this article on the production and marketing of commercial seed?
If yes, do you agree with the latest changes to the article?
Article 36a
This is a new article proposed by the Polish Presidency and discussed during the Working Party meeting in May.
Do you support the addition of this article to the proposal?
Article 39(1a)
Do you support the addition of the second subparagraph to paragraph 1a?
Article 40a
This is a new Article, proposed by the Polish Presidency, that has not been discussed so far by the Working Party. The article contains elements moved from the Article 40.
Do you support the addition of this article to the proposal?

Revised Presidency text	Drafting Suggestions	Comments
Article 2		
Scope and objectives		
4. This Regulation does not apply to:		
[(i) PRM marketed by non-profit organisations and networks other than gene banks, with a purpose defined in their articles of association or other equivalent document of conserving plant genetic resources, to any natural or legal person, under the condition that those organisations and networks have notified their activity to the competent authority and the respective PRM is identified as such through appropriate labelling;]		
Article 3		
Definitions		

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Revised Presidency text	Drafting Suggestions	Comments
[(32a) 'true potato seed' means seed of *Solanum tuberosum* L.]		
Article 6		
Belonging to certain categories of PRM		
2. By way of derogation from paragraph 1, PRM may be produced and marketed without belonging to a category listed in points (a) to (~~c~~**d**) of that paragraph in the following cases:		
[(f) PRM as commercial seed in accordance with Article 32a;~~.~~]		
[(g) preservation mixtures produced in accordance with Article 22.]		
Article 17a (former Article 23)		
Re-packaging, re-sealing and re-labelling of ~~seed lots~~ PRM		

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Revised Presidency text	Drafting Suggestions	Comments
[4. **In addition to the provision of Article 42,** ~~T~~the professional operators shall keep records, when re-packaging, re-sealing and re-labelling ~~seed lots~~, for 3 years after the respective re-labelling, re-sealing and re-packaging. The information contained in the records shall include:		
(a) the reference number of the original ~~seed~~ lot;		
(b) the reference number of the repackaged or relabeled ~~seed~~ lot;		
(c) the weight of the original ~~seed~~ lot;		
(d) the weight of the re-packaged or relabeled ~~seed~~ lot;		
(e) the most recent date of re-sealing of the lot.		
Those records shall be kept in a form allowing identification and verification of the authenticity of the original ~~seed~~ lot which is subject to re-		

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Revised Presidency text	Drafting Suggestions	Comments
packaging and re-labelling. They shall be made available to the competent authority on request.]		
5. The original seals and labels shall be removed [from the original ~~seed~~ lot. The professional operator shall also keep the replaced label, its content or digital equivalent of each original seed lot for at least 3 years after the respective re-sealing. In the case the professional operator chooses to keep the content of the replaced label instead of the label itself, the retainment may take the form of storage of the information contained in the official label in a computerised database, provided that this includes the information that is needed to guarantee the traceability.]		
Article 28		
[PRM produced for and marketed to non-professional users		

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Revised Presidency text	Drafting Suggestions	Comments
1. By way of derogation from Articles 5~~(1) –~~ **to** 12~~,~~ **and 14** ~~15~~ **to 17a** ~~and 20~~, PRM with the exception of seed potatoes **and mixtures of seed**, intended to be used **exclusively** by non-professional users may be produced~~,~~ and marketed ~~to non-professional users,~~ if it complies with all of the following requirements:		
(a) ~~to~~ bear an operator's label ~~as referred to in Article 16(2), second subparagraph,~~ with the denomination of the PRM and the indication '~~Plant reproductive material~~ **PRM** for non-professional user **– not certified'** ~~or, in the case of seed, 'Seed for non-professional user~~;		
(b) in case not belonging to a variety registered in a national ~~or in the Union~~ variety register referred to in Article 44 ~~and 45~~:		
(i) ~~to~~ use a denomination **complying with Article 54 and** ~~[starting with the Prefix "Art. 28~~ **followed by the indication 'variety not registered**		

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Revised Presidency text	Drafting Suggestions	Comments
pursuant to Article 44 of Regulation (EU) .../… of the European Parliament and of the Council'[1]~~, and complying with Article 54 followed by any given denomination in order to clearly differentiate] from varieties registered in national or Union variety registers~~; and		
(ii) ~~to~~ have a description made publicly available, on the basis of a private documentation, kept by the professional operator~~.~~, ~~This~~ **and that** ~~private~~ documentation ~~shall be~~ **is** made available by the professional operator ~~upon request~~ to the competent authority **upon request**;	have a description made publicly available, on the basis of a ~~private~~ documentation, kept by the professional operator **and that** documentation **is** made available by the professional operator to the competent authority **upon request**;	Without "private", that is already deleted down in first column (revised Presidency text- (ii))
(c) ~~to~~ be practically free from quality pests and any defects likely to impair its quality as reproductive material, and**:**		

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[1] 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.

Revised Presidency text	Drafting Suggestions	Comments
(i) **in the case of PRM other than seed,** ~~shall~~ have ~~satisfactory~~ **sufficient** vigour and dimensions ~~in respect of its usefulness as PRM~~**;** and~~,~~		
(ii) in the case of seed, ~~shall~~ have ~~satisfactory~~ **minimum sufficient** germination **as applicable for the lowest possible category of the respective species** ~~capacity~~;		
~~(ca) to be kept separate and identifiable from the PRM not intended for non-professional user during the production and marketing process; and~~		
(d) ~~to~~ be marketed as individual plants**,** ~~or trays, or in the case of seed and tubers,~~ **or** in small packages**,** clearly ~~distinct~~ **distinguishable** from ~~those~~ **packages** used for ~~any~~ pre-basic, basic, certified and standard ~~seed~~ **PRM**.		
A professional operator ~~producing or repackaging PRM intended for non-professional users~~ who uses this derogation shall annually notify this activity**, as**		

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Revised Presidency text	Drafting Suggestions	Comments
well as the quantities produced and marketed, to the competent authority in accordance with the instructions of ~~the~~ **that** ~~competent~~ authority, with regard to the species ~~[and denomination]~~ concerned.		
2. The Commission ~~shall~~ **may**, by means of implementing acts, adopt rules concerning the size, form, sealing and handling requirements concerning **individual plants and** the small packages referred to in paragraph 1, point (d**), and size, form, colour and content of the operator's label.**		
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).**]**		

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Revised Presidency text	Drafting Suggestions	Comments
Article 29	To keep this article	We would like this article to be kept, as this is comprehesive and more appropriate for this moment. We also support the Belgian proposal for art. 29 made before WP of 8th of July, with the amendments made with blue color in the text attached here (the reference to gene banks).
[~~PRM marketed by organisations and networks for the conservation of plant genetic resources~~		
~~1. By way of derogation from Articles 5~~ **~~to~~** ~~15 and 19 - 25, PRM may be marketed, for~~ **~~by~~** ~~non-profit purposes, by organisations and networks~~ **~~other than gene banks, having a purpose defined in their articles of association or other equivalent document~~** ~~with a statutory objective, of ensuring the conservation~~ **~~conserving~~** ~~of plant genetic resources~~**~~, to any natural or legal~~** ~~persons who carry~~**~~ies~~** ~~out conservation of that PRM and to farmers or non-professional users.~~		

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Revised Presidency text	Drafting Suggestions	Comments
~~In these cases, this **Such** PRM shall fulfil the following requirements:~~		
~~(aa) bear an operator's label as referred to in Article 16(2), point (g), with the indication 'Plant reproductive material **PRM** for the conservation of plant genetic resources';~~		
~~(a) be listed in a register kept by those organisations and networks with appropriate related information of that PRM;~~		
~~(b) be conserved by those organisations and networks, and samples of that PRM be made available by them to the competent authorities upon request; and~~		
~~(c) be practically free from quality pests and any defects likely to impair its quality as a reproductive material.~~		
~~2. The organisations and networks shall notify the competent authority of the use of the derogation~~		

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Revised Presidency text	Drafting Suggestions	Comments
~~referred to in paragraph 1 and the species, if listed in Annex I, concerned.~~		
~~**3. The Commission may, by means of implementing acts, adopt rules concerning size, form and content of the operator's label.**~~		
~~**Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).]**~~		
Article 30		
[~~Seed exchanged in kind between farmers~~	To keep this article	We want this ~~-~~article to be kept, as this is more completely explained and wwe think is more appropriate for this moment.
~~1. By way of derogation from Articles 5 to 25 farmers may exchange seed in kind, if such seed fulfil all of the following conditions:~~		

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Revised Presidency text	Drafting Suggestions	Comments
~~(a) are produced in the respective farmer's own premises;~~		
~~(b) are derived from the respective farmer's own harvest; and~~		
~~(c) are not subject to a service contract between the farmer and a professional operator for multiplication of seed.~~		
~~(4) […]~~		
~~2. Such seed shall fulfil all of the following requirements:~~		
~~(a) they do not belong to a variety for which plant variety rights have been granted either in accordance with Regulation (EU) 2100/94 or with the national rules on plant variety rights of the Member State of production;~~		

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Revised Presidency text	Drafting Suggestions	Comments
~~(b) they are limited to small quantities, defined by the competent authorities for specific species per year and per farmer;~~		
~~(ba) they are exchanged at a local level, defined by the competent authories, without using commercial intermediaries or public offer of marketing; and~~		
~~(c) they are practically free from quality pests and any defects likely to impact their quality as seed.~~		
~~3. Member States shall notify to the Commission and the other Member States the defined limitation concerning small quantities per species defined in accordance with paragraph 2, point (b), and any subsequent changes to those quantities.~~		

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Revised Presidency text	Drafting Suggestions	Comments
Article 32		
PRM of varieties <u>under registration</u> ~~for which an application for registration has been submitted~~		
<u>1a. By way of derogation from Articles 5, 9a and 9b, and pursuant to the paragraphs below, a competent authority may authorise professional operators to produce and market PRM of a variety for which the competent authority has confirmed the successful submission of the application for variety registration in accordance with Article 58 for the following purposes:</u>		
<u>[c) production and marketing of fruit plants and vine in accordance with paragraph 2a.]</u>		
<u>[</u>2a. By way of derogation from Article 5, professional operators may produce and market standard material of fruit plants and vine belonging		

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Revised Presidency text	Drafting Suggestions	Comments
to a variety ~~not yet registered in a national variety register as referred to in Article 44~~ **for which an application for variety registration has been accepted pursuant to Article 58** before the PRM has been ~~certified~~ **confirmed** to comply with the requirements referred to in Article 8 concerning varietal identity and varietal purity, if all of the following requirements are fulfilled:		
(a) there is no risk that the marketing will lead to insufficient identification or quality of the marketed PRM;		
(b) that PRM complies with the requirements pursuant to Article 8 concerning varietal identity and varietal purity, which shall be attested by the technical questionnaire provided by the professional operator;		
(c) that PRM bears a denomination deemed suitable pursuant to Article 54~~;~~ ~~and~~		

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Revised Presidency text	Drafting Suggestions	Comments
~~(d) that PRM belongs to a variety for which an application has been submitted for registration in a national variety register pursuant to Article 55~~.		
That PRM shall not be produced and marketed anymore when a decision pursuant to Article 67 is adopted concerning the registration of the respective variety or if the application for registration of the respective variety is withdrawn **or rejected**.**]**		
Article 32a		
[Requirements for the ~~P~~production and marketing of commercial seed		
1. By way of derogation from Articles 5, **6, 6a, 7, 8,** ~~24~~ **9a** and ~~25~~ **9b,** seed of the genera or species included in column ~~7~~ **3** ~~[V]~~ of Annex I may be produced and marketed as commercial seed if ~~the~~		

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Revised Presidency text	Drafting Suggestions	Comments
they comply with the requirements referred to in **Annex III, with the exception of varietal aspects** ~~Article 7 are fulfilled with the exception of the requirement of varietal identity and varietal purity~~.		
~~2. By way of derogation from Article 5, seed of the genera or species newly added to Annex I via a delegated act pursuant to Article 2(3) and for which fewer than [30 varieties] are registered in the Register of Community Plant Variety Rights pursuant to Regulation (EU) 2100/94 when the delegated act enters into force may also be produced and marketed as commercial seed~~.		
~~When seed of the genera or species newly added to Annex I may be produced and marketed as commercial seed pursuant to this paragraph, the Commission shall indicate column 7 of Annex I for these species or genera when adopting the delegated act referred to in the first subparagraph.~~		

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Revised Presidency text	Drafting Suggestions	Comments
3. The Commission is empowered in accordance with Article 75 to adopt delegated acts, amending Annex I**,** ~~to the breeding and economic developments of the~~ **by adding** genera ~~and~~ **or** species **to,** ~~in that Annex by adding~~ or removing genera or species from**,** column ~~7~~ **3 ~~I~~** of that Annex.		
Those delegated acts shall take into account the breeding and economic developments concerning the production and marketing of PRM of the respective genera or species.		
~~The delegated act shall add genera or species to column 7 of Annex I if they fulfil at least one of the two following elements:~~		
~~(a) the number of varieties registered in the Union variety register pursuant to Article 45 does not meet the needs of the operators concerned;~~		

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Revised Presidency text	Drafting Suggestions	Comments
~~(b) the value of the genera or species mainly lies within multifaceted purposes that extend beyond traditional food and feed production.~~		
~~The delegated act referred to in the first subparagraph shall remove genera or species from column 7 of Annex I if they no longer fulfil both of the elements set out in the second subparagraph.~~		
4. Seed~~s~~ referred to in paragraph 1 ~~and 2~~ shall be accompanied by an ~~official~~ **operator's** label ~~pursuant to Article 15,~~ with the indication 'Commercial seed'.		
5. The Commission may, by means of implementing acts, adopt rules concerning size, form, colour and content of the operator's label. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).]		
Article 36a		

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Revised Presidency text	Drafting Suggestions	Comments
[Derogation from the production rules for certain species		
1. By way of derogation from Articles 5 to 22, PRM may be produced in a Member State subject to national rules pursuant to a request from that Member State demonstrating, on the basis of consultations with the professional operators concerned, that the following conditions are fulfilled:		
a) the cultivation of that species in the requesting Member State is insignificant, in terms of economic value and area of cultivation, due to the agro-climatic conditions in that Member State; and		
b) the certification and control of the production of PRM of that species would impose a disproportionate administrative burden on the		

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Revised Presidency text	Drafting Suggestions	Comments
competent authority of that Member State.		
That PRM may only be marketed in the territory of that Member State with a label indicating that it is for marketing in that territory only.		
2. The Commission may, by means of implementing acts, temporarily allow PRM belonging to certain species listed in Annex I to be produced in a Member State without being subject to the rules of Articles 5 to 22 as referred to in paragraph 1 of this Article.		
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).]		
Article 39		
Imports on the basis of Union equivalence		

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Revised Presidency text	Drafting Suggestions	Comments
1a. …		
[The ~~EU~~ professional operator responsible for the imported PRM shall provide upon request of the competent authority, information on the conditions under which the multiplication took place, the place of processing, and the varieties to which the seed belongs.]		
Article 40a		
[Information provided for PRM imported from third countries		
3. ~~The professional operator responsible for the imported~~ PRM **may only by imported into the Union after the electronic notification is delivered**~~, shall inform~~ **by the profesional operator** ~~the respective competent authority in advance of the arrival of the consignment and provide the information referred to in paragraph 1 or 2~~ through the information management system		

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Revised Presidency text	Drafting Suggestions	Comments
for official controls (IMSOC) referred to in Article 131 of Regulation (EU) 2017/625. **The rules of the delegated act referred to in Article 45(4) of Regulation (EU) 2017/625 shall apply accordingly.**		
3a. In addition to the information pursuant to paragraph 3, the professional operator responsible for the imported PRM shall immediately and directly inform the competent authority of the place of destination as referred to in Article 44(3), point (e), of Regulation (EU) 2017/625 about the arrival of the consignment.		
~~4. Member States shall immediately notify the Information management system for official controls (IMSOC), referred to in Article 131 of Regulation (EU) 2017/625, of all established non-compliances of the imported PRM concerning the requirements of paragraphs 1 and 2~~.		

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Revised Presidency text	Drafting Suggestions	Comments
~~5. The Commission is empowered in accordance with Article 75 to adopt delegated acts, amending paragraphs 1b and 2, in order to align these provisions to technical and scientific developments of international standards.~~]		

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Article 29

PRM marketed to and between gene banks, organisations and networks for the conservation of plant genetic resources

1. By way of derogation from Articles 5 **- 15 and 19 - 25**, PRM may be marketed~~, **for non-profit purposes**~~ to, or between~~, **by**~~ gene banks~~,~~ organisations and networks with **a purpose of conserving plant genetic resources and a non profit goal defined in their articles of association or other equivalent documenta statutory objective,** ~~or an objective official notified to the competent authority, to conserve~~ **of ensuring the conservation** ~~of plant genetic resources, whereby any of the activities are carried out for non-profit purposes.~~

It can be marketed as well from those ~~gene banks,~~ organisations and networks, for non-profit purposes, to persons who carry out conservation of that PRM **and to**~~as final consumers~~ **farmers or non-professional users**. **Any professional operator may also market this PRM if it is marketed solely to gene banks, networks and organisations with a purpose of conserving plant genetic resources and a non profit goal defined in their statutory objective, articles of association or other equivalent document.**

In the**se** cases ~~provided for in the first and the second subparagraphs~~, **this** PRM shall fulfil the following requirements:

(aa) bear an operator's label ~~as referred to in Article 16(2), point (g),~~ with the indication 'Plant reproductive material for the conservation of plant genetic resources';

(a) be listed in a register or Database kept by those gene banks~~,~~ organisations and networks with ~~an~~ appropriate **related information** ~~description~~ of that PRM;

(b) be conserved by those gene banks, organisations and networks, and samples of that PRM be made available by them to the competent authorities upon request; and

(c) be practically free from quality pests and any defects likely to impair its quality as a reproductive material~~, and have satisfactory vigour and dimensions in~~

~~respect of its usefulness as PRM, and, in the case of seeds, have satisfactory germination capacity~~.

2. The gene banks, organisations and networks shall notify the competent authority of the use of the derogation referred to in paragraph 1 and the species**, if listed in Annex I,** concerned.

2a. The Commission may, by means of an implementing act, adopt rules concerning size, form, colour and content of the operator's label as referred to in paragraph 1, point aa. This implementing act shall be adopted in accordance with the examination procedure referred to in Article 76(2).

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