



Council of the  
European Union

Brussels, 28 September 2023  
(OR. en)

13484/23

LIMITE

AGRI 561  
AGRILEG 214  
SEMENCES 79  
PHYTOSAN 89  
FORETS 140  
CODEC 1703

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**Interinstitutional File:  
2023/0227(COD)**

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### CONTRIBUTION

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From: General Secretariat of the Council  
To: Delegations

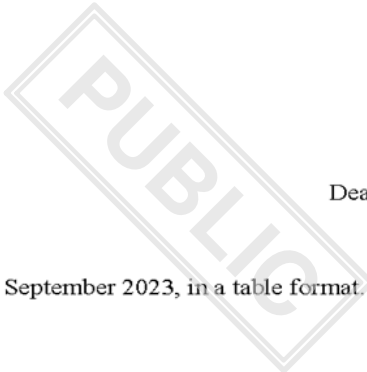
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Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and 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 the Netherlands

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**DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (14.11.2023)**

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



MS Comments on 2023/0227 (COD) – Regulation on plant reproductive material (PRM)

Deadline: 27 September 2023

Dear Delegates,

Please find below the articles of the PRM proposal discussed at the WP meeting on 13 September 2023, in a table format. We kindly ask for your drafting suggestions and comments by **27 September 2023**.

Please follow these points when completing the table:

- Indicate the MS delegation who has filled in the table.
- Do not delete any rows or columns from the table.
- Do not insert any new rows or columns.
- Do not use comments “bubbles”.
- Do not edit the first column.
- Insert your comments into the second and third columns of the table only, corresponding to the provision concerned.
- For drafting suggestions please highlight amendments in underline and deletions in ~~strike through~~.
- Send your comments as a Word document to [redacted] and [redacted]

You are free to change header/footer of the attached file as you wish - but please keep the table intact.

<b>Member State:</b>	<b>The Netherlands</b>
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<b>Commission proposal (PRM)</b>	<b>MS Drafting Suggestions</b>	<b>MS Comments</b>
<b>CHAPTER I 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 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>After last meeting in September, there is confusion about the term 'import', as a part of and in relation to the definition 'marketing' and seeds harvested in third countries. This confusion could – if understood in the wrong way – destroy the business model of European seed companies in many member states and at the same time endanger the availability of sufficient seeds for professional farmers and growers in the EU.</p> <p>If the assumption is that imported 'seeds harvested in bulk' from third countries have to fulfil all the rules of the PRM Regulation at exactly the moment of import, then many seed companies are in big trouble. It is a common business model to produce seeds of their own varieties on their own premises or under contract in bulk in third countries (mainly in the Southern Hemisphere to be able to produce seeds in our winter), transport them as grown (including a phyto-certificate and thus traceable) to the main offices in the EU for further processing.</p> <p>What we therefore would like to see clarified regarding 'import', is that the current practice as described above and in line with the current directives will remain possible, because this is fundamental for the production and the trade. Obliging marketed seeds that were produced in third countries to comply fully would:</p>
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		<ul style="list-style-type: none"> <li>- increase cost of seeds to European users</li> <li>- negatively impact the availability of seeds</li> <li>- negatively impact the EU economy.</li> </ul> <p>We do agree that seeds marketed from third countries and imported directly to the consumer would fall under the scope of the PRM Regulation. That kind of material should only be possible to be imported from countries that have achieved equivalence to the relevant EU standards for the crop.</p> <p>Maybe the issue of ‘seed as grown’, as an important part of the import, could best be added to art 2.4 ((this regulation does not apply to...), see suggestion there.</p> <p>In the second part of the article, the undesirable agro-economic effects are mentioned. The discussion about these effects has not been started in the meetings, we wonder whether these effects should be mentioned in the first article, while it will probably be a relatively small group of varieties.</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>Add an addition to exempt ornamental varieties originating from agricultural, vegetable and fruit varieties (i.e. sunflower, maize, brassica, Cucurbita etc.)</p>

<p>The requirements concerning production of PRM shall apply only to production with a view to its marketing.</p>		<p>The last sentence can be removed. Only when the production requirements are met, material can be used as PRM.</p>
<p>2. The objectives of this Regulation are the following:</p>		
<p>(a) to ensure quality and diversity of choice for PRM, and its availability for professional operators and final users;</p>	<p>Add professional users</p>	<p>The wording of professional operators and final users caused some confusion. In our interpretation, farmers can possibly be part of both professional operator and final user. Therefore we propose to add the professional user in this definition.</p>
<p>(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;</p>		
<p>(c) to support innovation and competitiveness of the PRM sector in the Union;</p>		
<p>(d) to contribute to conservation and sustainable use of plant genetic resources and agro-biodiversity;</p>		
<p>(e) to contribute to sustainable agricultural production, adapted to current and future projected climatic conditions;</p>		
<p>(f) to contribute to food security</p>		
<p>3. The Commission is empowered in 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,</p>		

<p>by adding genera and species to or removing them from the list that Annex. 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 with a minimum turn over of .....</p>	<p>During the meeting on September 13<sup>th</sup> there was some discussion on how to implement the word significant (in both area of production and in value of marketed PRM) To make the definition of significant value of marketed PRM clearer, we propose to add an amount of turnover as significant value.</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>Also here, the use of substantial raises questions. We are also interested in the discussion and procedures to add or delete genera or species from the list and the specific role and responsibilities of the member states.</p>
<p>(c) are marketed in at least two Member States.</p>		
<p>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.</p>		
<p>4. This Regulation does not apply to:</p>		
<p>(a) propagating material of ornamental plants as defined in Article 2 of Directive 98/56/EC;</p>		

(b) forest reproductive material as defined in Article 3 of Regulation (.../... of the European Parliament and of the Council <sup>23+</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 commercial activities;		
(e) PRM used solely for official testing, breeding, inspections, exhibitions or scientific purposes.		
	f) PRM as grown in bulk (not yet processed for commercial exploitation), imported in the EU, going directly to the seed company for further processing.	Seeds may be imported ‘as grown’ for further processing, to be re-exported outside the EU, but also for marketing in the sense of commercial sale within the EU. The processing within the EU is done by the seed company under accreditation/inspection/supervision of the official inspection services. The seeds that come to the market this way are fully under inspection by the competent authority and comply with the EU standards when they are marketed within the Union. They cannot be marketed as ‘seeds as grown’ directly after import. This is the current standard operation for many vegetable seeds and also for some agricultural seeds. In addition, this is the case for OECD labelled seeds. There is always an additional activity by the seed

<sup>23</sup> Regulation (EU) .../... of the European Parliament and of the Council .... (OJ...., p....).

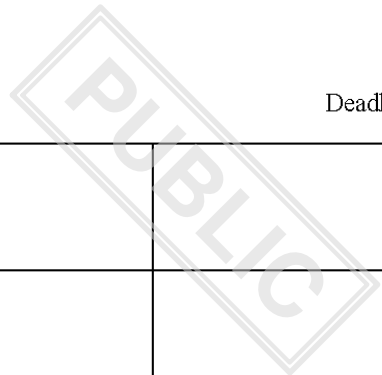
+ OJ: Please insert in the text the number of the Regulation contained in document (... (COD)) and insert the number, date, title and OJ reference of that Regulation in the footnote.

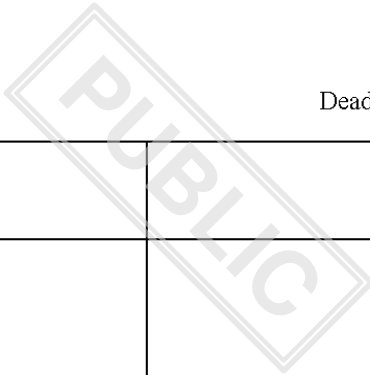
		<p>company under inspection of the competent authority before the seeds can be marketed.</p> <p>It is not possible for technical reasons or lack of inspection capacity or cost for many of the value adding processes that are now done in the EU exclusively to have them done and inspected in the third country. There would be negative economic consequences for the European Union when this kind of high value adding services is moved outside the EU. Therefore we propose to make an exemption in this article for seed as grown.</p>
<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;		

<p>(e) preservation, storage, drying, processing, treating, packaging, sealing, labelling, sampling or testing;</p>		
<p>(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</p>	<p>3) marketing’ means the following actions <del>conducted by a professional operator</del>: sale, holding, transfer for free, or offering for sale or any other way of transferring or distribution within, <b>or imported directly to the final consumer</b> into, the Union <u>aimed at commercial exploitation</u></p> <p><u>‘marketing’ shall mean the sale, holding with a view to sale, offer for sale and any disposal, supply or transfer aimed at commercial exploitation of seed to third parties, whether or not for consideration.</u></p>	<p>The definition of professional operator is too narrow. The definition should apply to everybody who markets PRM for commercial exploitation. We also miss the exceptions in this definition, such as service providers, disinfecting or other treatments and the closed loops.</p> <p>We also notice that other words in the definition are quite prohibitive, such as holding, transfer for free, or any other way of transferring or distribution within. If this means that when companies move their stock within the company (from one location to another) the material has to comply to all PRM criteria, this will generate big problems.</p> <p>Another way to look at the discussion of marketing is to better look at the definition from the current directives. This worked fine for years, thereby proving to be a stable definition.</p>
<p>(4) ‘variety’ means a variety as defined in Article 5(2) of Regulation (EC) No 2100/94;</p>		
<p>(5) ‘clone’ means an individual plant progeny, originally derived from another single plant by vegetative reproduction, remaining genetically identical to that plant;</p>		
<p>(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;		
(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;		
(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;		
(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 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		

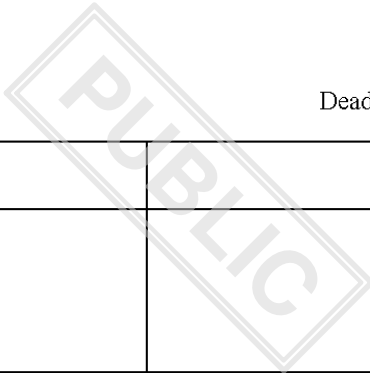
authority, includes the specific characteristics of the variety, and has been obtained by other means than the examination of its distinctness, uniformity and stability;		
(12) ‘variety maintenance’ means the actions taken for controlling varietal purity and identity with the aim to ensure that a variety 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 preceding 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;		
(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		





<p>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</p>		

supervision to satisfy the respective conditions laid down in Part B of Annex II;		
(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 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>(24)</sup> , excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;		
(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: (a) presents common phenotypic characteristics; (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; (c) is not a variety; and (d) is not a mixture of varieties;		

<sup>24</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, 17.4.2011, p. 1).