Council of the European Union

Brussels, 10 July 2023
(OR. en)

11697/23

Interinstitutional Files:
2023/0227(COD)
2023/0228(COD)

AGRI 390
AGRILEG 132
SEMENCES 33
PHYTOSAN 45
FORETS 85
CODEC 1338

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	6 July 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2023) 410 final
Subject:	COMMISSION STAFF WORKING DOCUMENT Subsidiarity Grid *Accompanying the documents* 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 (Regulation on plant reproductive material) and Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of forest reproductive material in the Union, amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of the Council, and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material)

Delegations will find attached document SWD(2023) 410 final.

Encl.: SWD(2023) 410 final

EUROPEAN
COMMISSION

Brussels, 5.7.2023
SWD(2023) 410 final

COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the documents

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 (Regulation on plant reproductive material)

and

Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of forest reproductive material in the Union, amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of the Council, and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material)

{COM(2023) 414 final} - {SEC(2023) 414 final} - {SWD(2023) 414 final} -
{SWD(2023) 415 final} - {COM(2023) 415 final}

Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
The legal basis for these proposals is Article 43(2) of the Treaty of the Functioning of the European Union (TFEU). This provides the legal basis for adopting the provisions necessary for the pursuit of the objectives of the common agricultural policy.
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In the area of agriculture, the Union's competence is shared with the Member States.
*Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU[1]. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU[2] sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU[3] sets out the areas for which the Unions has competence only to support the actions of the Member States.*
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[4]: - Has there been a wide consultation before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?
To collect all relevant views and engage with stakeholders as much as possible, different consultation methods were combined. The Commission services consulted stakeholders by means of the publication of the inception impact assessment for feedback, the open public consultation, targeted surveys, working groups with national competent authorities and stakeholders, and bilateral meetings with stakeholder organisations. The inception impact assessment was open for feedback between 15 June and 13 July 2021 on the 'Have your say' portal[5] and was addressed to any interested citizen or stakeholder. Feedback was provided in a free text format, while respondents also had the possibility to submit position papers. The feedback collected was taken into account for adjusting the problem description and options, the design of further consultation activities, as well as for the impact assessment. The Commission services also organised two targeted online consultations on EUSurvey, one addressed to national competent authorities responsible for FRM, held from 5 April to 30

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN
[3] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN
[5] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13083-Plant-and-forest-reproductive-material-revised-rules-_en

May 2022 and one addressed to SMEs, held from 2 May to 13 July 2022. Furthermore, the Commission services held meetings of working groups (online due to Covid-19 restrictions) with the national competent authorities and with stakeholders to discuss specific aspects of the revision. At the request of a number of stakeholders, the Commission services held bilateral meetings and also attended relevant events of stakeholders. Finally, some stakeholders and national competent authorities submitted opinions to the Commission services on specific matters outside the framework of the inception impact assessment and the open public consultation. A summary of all these activities and their outcomes is provided in the Annex 2 – Synopsis report, of the Impact Assessment Staff working document.

The explanatory memorandum and the impact assessment Staff working document (chapter 3) contain a section on the principle of subsidiarity (see also question 2.2 below).

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The legislation on the marketing of PRM/FRM has, from the 1960s onwards, been the major contributor for the creation of the internal market of PRM/FRM. The established EU rules have had a positive impact on the free movement, the availability and the quality of PRM/FRM. Without the EU legislation, 27 different systems at Member State level would be in place for PRM/FRM marketing causing fragmentation of the internal market. Despite the existence of EU legislation, divergent implementation in Member States has been observed over the years, whereby national approaches are more and more compensating for the EU legislation not being up to date with the current scientific and technical developments (e.g. innovative processes for the production of PRM/FRM, digitalisation of procedures and documents). Approaches also differ between Member States as regards sustainability considerations in the registration of new varieties (PRM) and of basic material (FRM) and on aspects related to the conservation and sustainable use of plant genetic resources (e.g. market access for conservation varieties). EU action is thus required to modernise that legislation, harmonise its implementation, ensure a level playing field for the operators, as well as to help meet the objectives of transboundary EU policies in relation to the European Green Deal (Farm to Fork, EU Adaptation, EU Forest and Biodiversity Strategies) and the EU Digital Strategy.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

Without action at EU level, 27 Member State systems on registration of varieties and certification/control of PRM and related technical requirements to ensure quality of PRM would be in place. Similarly, there would be 27 Member State systems for certification/control of FRM. Such situation would create barriers for the internal market and significant costs and administrative burden for both authorities and operators. Opportunities for more consistent approaches to help address the challenges in relation to sustainable agricultural and food production, climate change and biodiversity would be missed.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?
While common EU rules on PRM/FRM have been in place since the 1960s, there has been margin for their interpretation by the Member States that resulted in different conditions for operators between Member States. Absence of common rules on recent scientific and technical developments have exacerbated those differences. However, the unrestricted marketing of PRM and FRM throughout the EU territory is imperative for the functioning of the common market. It is also important for addressing transboundary issues such as the climate and biodiversity crises, the sustainability of agricultural and food production, food security and sustainable afforestation/reforestation to secure multi-functional forests for future generations. For example, on average EUR 4.8 billion/year of crop losses are caused by drought in the EU. These losses can be partly mitigated through the use of PRM better adapted to drought. The current geopolitical situation and energy crisis have also elevated the importance of securing agricultural and food production.
(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[6] or significantly damage the interests of other Member States?
National policies alone cannot achieve a better access to, and availability of, high-quality PRM/FRM for its users in comparison to EU level action. Absence of EU level action would compromise, the functioning of the internal market, the integration of the EU system with the global trade system, as well as the opportunities to help meet the objectives of the EU policies on sustainability, climate change and biodiversity.
(c) To what extent do Member States have the ability or possibility to enact appropriate measures?
Member States have in certain cases, and under certain conditions, the possibility to adopt more stringent national technical requirements for the marketing of PRM/FRM, so as to meet national agro-ecological production conditions. In certain cases, they are allowed to derogate or to be exempted from Union rules.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
The problem of non-uniform application of the EU legislation and divergence of national transposition has been noted in the majority of Member States. Further divergence between Member States arises as they seek solutions for aspects where the legislation is not up to date with the current scientific and technical developments. This has an impact on the internal market and the open and fair competition between the professional operators concerned. Other spill-over effects are due to sustainability, climate change and biodiversity aspects not being consistently addressed. These include increased risks of losses in agricultural production and forestry, as well as losses in genetic diversity of cultivated plants and forestry species. The impacts vary across national, regional and local levels due to specific agro-climatic conditions. The proposals provide appropriate flexibility for Member

[6] https://europa.eu/european-union/about-eu/eu-in-brief_en

States to address these aspects.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problems are affecting all Member States, but to different degrees.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

The proposed measures are based on an assessment of different policy options and their respective impacts. Most measures do not result in significant costs for the Member States. Costs for the Member States mainly result from the new requirements necessary to achieve the sustainability objectives of the proposals. These are nevertheless proportionate to the expected benefits, while the cost of inaction would be even higher, especially in terms of increased losses in agricultural production and forestry.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

The Council requested in 2019[7] the Commission to submit a study on the options to update the existing legislation, as it considered that the concerns which the Commission aimed to address in 2013 through a legal proposal on the production and marketing of plant reproductive material were still relevant. Furthermore, the Council requested the Commission to submit a proposal, if appropriate in view of the outcomes of the requested study. National competent authorities of most Member States also contributed to the consultations in preparation of the current proposals. Overall, Member States are supportive of the objectives of the proposals but ask to avoid additional administrative burden and to maintain a sufficient level of flexibility for implementation adjusted to national conditions. Only very few regional and local authorities have expressed their views.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

The key added value of action at EU level is the common legal framework on production and marketing of PRM/FRM and related technical requirements instead of 27 different systems at Member State level. The common legal framework establishes a level playing field for operators and a more consistent approach for addressing the transboundary challenges of sustainability, climate change and loss of biodiversity.

(a) Are there clear benefits from EU level action?

Establishing an EU system and minimum standards of PRM/FRM quality brings significant efficiencies for Member States and operators by avoiding the multiplication of systems and potential barriers to the internal market. By providing a framework and related technical requirements, the EU-level measures are best placed to effectively ensure minimum quality

[7] Council Decision (EU) 2019/1905 of 8 November 2019 requesting the Commission to submit a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material, and a proposal, if appropriate in view of the outcomes of the study (OJ L293, 14.11.2019, p.105).

of PRM/FRM for its users, a functioning internal market and a level playing field for operators while contributing to open and fair competition. Moreover, temporary supply difficulties in Member States can be overcome by action at EU level. Furthermore, common requirements for sustainability and the conservation and sustainable use of plant and forest genetic resources ensure a more consistent approach. Action at EU level also brings efficiency by common import rules and consistency with relevant agreements at international level.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

Common EU rules on the production and marketing of PRM/FRM are in place since the 1960s. These have contributed to the development of world-wide competitive PRM and FRM sectors in the EU. The EU market has an annual value of about 15 billion EUR, accounting for about 20% of the global market, while the EU is one of the top three exporting regions globally. The proposals will further improve the functioning of the internal market by increasing the clarity and coherence of the legal framework.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

The proposals do not replace different national policies, since EU common rules are in place since the 1960s, but address the shortcomings identified in these common rules.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

Member States will not lose competences as the proposals keep the main aspects of the current framework in place, as already set out by Directives since the 1960s.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes, the proposed Regulations will resolve the ambiguities of the existing Directives that have led to differences between the national transposition by Member States. 11 Directives will be replaced by two Regulations (one on PRM and another one on FRM) that will be directly applicable in all Member States.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The measures proposed are limited to actions that need to be taken at an EU level in order

to achieve the intended objectives. They balance the need for harmonised rules on certain aspects (e.g. variety registration and certification of PRM) and for flexibility on other aspects (e.g. implementation of sustainability requirements according to local agro-ecological conditions).

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed action takes the form of 2 new Regulations repealing 11 existing Directives. This type of instrument is considered most suitable, considering that a key element of the proposal is to establish harmonised rules for the production and marketing of PRM/FRM. Uniform requirements for PRM/FRM are the only way to ensure a high level of quality for users, the proper functioning of the internal market and a level playing field for the operators as well as to consistently contribute to the sustainability of agricultural and food production and forestry.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

Yes, in all aspects where Member States could achieve better or equal results, on the basis of their own national legislation, the initiative allows them to do so. This concerns, for instance, PRM excluded from the scope of the legislation or aspects for which Member States are allowed to apply more or less stringent national standards, if they consider this appropriate. Member States are also given the necessary flexibility to implement the sustainability requirements in a way adapted to their local agro-ecological conditions.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

The instrument chosen is that of a Regulation, one Regulation on PRM replacing 10 existing Directives and one Regulation on FRM replacing one existing Directive. This choice is coherent with the objectives pursued, in particular to ensure a level playing field for operators across the EU and to increase the clarity and coherence in relation to the current legal framework. Differences in the transposition of the current Directives have contributed to divergent conditions for operators across Member States.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

Yes, the proposed action sets minimum technical requirements for marketing of PRM and FRM. It also allows, in certain cases and under certain conditions, Member States to apply stricter national technical requirements. To increase transparency, Member States are required to notify these requirements to the Commission and the other Member States.

Moreover, in order to meet temporary supply difficulties of seed Member States may apply lower requirements subject to certain conditions. Member States are also given the necessary flexibility to implement the sustainability requirements in a way adapted to their local agro-ecological conditions.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

Most of the proposed measures entail marginal changes in administrative costs, as existing administrative procedures remain in place (e.g. application for registration of a new variety) and no financial costs, as new possibilities are introduced without imposing new obligations (e.g. option to use digital solutions). The main costs resulting from these proposals relate to the strengthened sustainability requirements for the examination of new varieties. Member States will have to increase their capacity for such examinations, with total costs in the range of 43 to 98 million EUR per year. Plant breeders will face increased costs for registration of new varieties (estimated at 6 million EUR annually). They will also have increased breeding costs that are expected to be transferred to farmers in terms of increased price of PRM, in total estimated at 400 million EUR per year. This amount however corresponds to an increase of costs of inputs for farmers by only 0.15%. These costs are considered commensurate with the objective of ensuring availability of PRM suitable for future challenges. The strengthened sustainability requirements for the examination of new varieties are expected to result in improved varieties (e.g. more tolerant to plant pests or drought) that is expected to reduce crop losses by 622 to 2487 million EUR annually and more broadly can help achieve increased food security.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

No special circumstances in individual Member States were identified that would require a particular territorial variation in the measures to be applied. However, and in certain policy areas, Member States will have the possibility to derogate from EU standards, if so justified by the national circumstances and if authorised by the Commission to do so.