

PROPOSED REPLACEMENT EU ACT INITIAL ASSESSMENT OF IMPACT

DSC REF: DSC/18a/2025

Proposed Replacement EU Act

[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 \(Regulation on plant reproductive material\)](#)

This proposed Regulation COM(2023) 414 on the production and marketing of plant reproductive material (PRM) amends and consolidates ten EU Marketing Directives on the production and marketing of PRM. These relate to agriculture crops, vegetables, vine and fruit plants, in place since the 1960's.

- Council Directive 66/401/EEC on the marketing of fodder plant seed,
- Council Directive 66/402/EEC on the marketing of cereal seed,
- Council Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine,
- Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species,
- Council Directive 2002/54/EC on the marketing of beet seed,
- Council Directive 2002/55/EC on the marketing of vegetable seed,
- Council Directive 2002/56/EC on the marketing of seed potatoes,
- Council Directive 2002/57/EC on the marketing of seed of oil and fibre plants,
- Council Directive 2008/72 on the marketing of vegetable propagating and planting material, other than seeds, and
- Council Directive 2008/90/EC on the marketing of fruit plant propagating material and fruit plants intended for fruit production.

Eight of the Regulations being consolidated are listed in the Northern Ireland Protocol at Annex 2, Heading 42, on Plant reproductive material (now Windsor Framework).

Two of the Directives listed above were added, to the Protocol, in December 2020 by agreement with the EU and UK:-

- Council Directive 66/401/EEC on the marketing of fodder plant seed,

- Council Directive 2008/72 on the marketing of vegetable propagating and planting material, other than seeds.

EU Summary of the Act

This proposal introduces a new approach, with a single regulation replacing all PRM marketing Directives. The proposed regulation on plant reproductive material aims to harmonise implementation, increase efficiency, reduce administrative burden and support innovation. In particular, it takes account of the need to ensure that production of PRM can adapt to evolving agricultural, horticultural and environmental conditions, face the challenges of climate change, to foster the protection of agro-biodiversity, and to meet increasing farmer and consumer expectations related to the quality and sustainability of PRM.

This regulation retains all of the existing rules which relate to the production and marketing of PRM and applies to PRM produced in and moving into Northern Ireland (NI). It retains the two primary pillars of PRM, registration of varieties and certification including:

- The marketing of agriculture crops, vegetables, and fruit plants ensuring their standards and PRM certification
- The availability of high quality and diverse PRM that is adapted to current and future climatic conditions
- Simplified administrative procedures and a more flexible decision-making process
- Streamlined rules for organic and conservation varieties
- Increased harmonisation with the Plant Health Regulation

The final Regulation has not yet been agreed within the EU and the papers available do not represent the final regulatory requirements to be contained within this Regulation.

Department(s) Responsible

The Department for Agriculture, Environment and Rural Affairs (DAERA).

Initial Assessment of Impact

It appears likely that applying these amendments would not have a significant impact specific to everyday life of communities in NI, as the amendments being introduced are primarily to consolidate existing EU legislation which already applies in NI. The proposal also introduces less stringent rules for conservation varieties, heterogeneous material and PRM sold to final user.

It appears likely that not applying the amendments would not have a significant impact on the everyday life of communities in NI. However, it should be noted that non-application would mean that NI would not benefit from the advantages introduced by the amendments.

It should also be noted that the EU anticipates costs to businesses in its assessment. For example, professional operators will have to register and fulfil basic requirements on knowledge and handling of PRM. Marketed varieties must be included on at least one Member State's national catalogue of varieties (to be listed on the EU's Common Catalogue) or be listed on the NI Variety List. The principles of official controls will apply to the marketing of PRM and to the competent authorities. However, it is anticipated that this will have a minor impact in NI due to the very limited number of NI businesses engaging in the testing and registration of PRM.

The Assessment of Impact has not yet been finalised and is in progress due to the relevant Delegated and Implementing Acts not yet being finalised in the EU.

UK Government Explanatory Memorandum

The UKG EM ([EM_COM_23_414_and_415.pdf](#)) provides a high-level summary of the perceived impact of the proposed regulation and notes that a fuller assessment will be completed once the EU has finalised and made the series of implementing and delegated acts, which will contain the detail of how the regulation should be implemented in practice. UKG's initial review suggests that the proposal does not seek to significantly overhaul PRM legislative provisions, but to update the current system to suit the modern world and accommodate the impact of climate change.

UKG has indicated that without the EU's implementing and delegated acts, it is unable to state with certainty the level of regulatory divergence between NI and GB, however, the existing EU directives for PRM, which the proposal aims to replace, was transposed and retained in GB law prior to EU exit. The UKG also stated that it is unlikely there will be divergence between certification standards as these are largely based on international standards.

UKG concluded that the PRM proposal is not expected to affect the current equivalence decision of the EU, as the proposal states that for countries to be equivalent, they must participate in the OECD Scheme for the Certification of PRM Moving in International Trade, of which the UK is a member.

Analysis by the European Commission on its Impact Assessment

This proposal is based on an impact assessment (Annex A) which received a positive opinion with reservations from the Regulatory Scrutiny Board on 17 February 2023.

There are two main problems that this proposal aims to address, as identified with the current PRM legal framework. For more information see Annex A.

Departmental Engagement

No consultations or impact assessments have been undertaken by DAERA for this proposal. Defra has indicated that as the proposal is developed and proceeds through the EU legislative procedure, it will continue to engage with industry, including through regular meetings with key stakeholders.

DAERA will remain engaged with Defra as the proposal progresses.

Annex A - EU Impact assessment

This proposal is based on an impact assessment which received a positive opinion with reservations from the Regulatory Scrutiny Board on 17 February 2023.

There are two main problems that this proposal aims to address, as identified with the current PRM legal framework:

1. There is a non-harmonised internal market characterised by divergent conditions for operators and marketed plant reproductive material across Member States. The implementation of various aspects of the legislation differs among Member States, because (i) the legislation leaves room for interpretation, (ii) Member States try to find practical solutions to overcome rigid provisions and (iii) the legislation has not followed the new developments in science and technology in good time.

2. The legislation is not aligned with the objectives of the European Green Deal and the related strategies. In particular, and under the current legislation, genetically diverse varieties, PRM subject to activities of seed conservation networks and seed exchanged by farmers are still subject to requirements for variety registration. This is rather disproportionate as such varieties, seed and material cannot always meet those requirements. Moreover, the increasing occurrence of extreme weather events, in combination with insufficient assessment of sustainability characteristics in the registration of new varieties, puts pressure on the stability of yields and thus on the resilience of agri-food production.

The general objective of this initiative is thus to ensure, for all types of users, the availability of PRM of high quality and diversity of choice that is adapted to current and future projected climatic conditions.

The impact assessment compiled all possible measures for analysis. This was based on: (i) an external data gathering study supporting a Commission study on the Union's options to update the legislation on plant reproductive material, (ii) a study in support of the impact assessment conducted by an external consultant, (iii) various stakeholder consultation activities, (iv) an online public consultation and (v) in-depth interviews.

The diverse, complex and often interrelated measures were grouped under three policy options, which are compared against a 'no-policy-change' scenario. Three options were assessed. Option 1 offered the most flexibility, while Option 3 offered the most harmonisation, so as to minimise differences in how the legislation is implemented. Option 2 balanced the need for flexibility with a higher

degree of harmonisation to overcome the problems stemming from differences in interpretation.

All options contained a number of common elements: (i) simplified administrative procedures and a more flexible decision-making process; (ii) streamlined rules for organic and conservation varieties; and (iii) harmonisation with the plant health legislation.

1.Option 1 - Highest degree of flexibility: Option 1 would lay down minimum requirements for official controls on plant reproductive material, but without linking them to the Official Controls Regulation. Guidelines on the use of innovative production processes, bio-molecular techniques and digital solutions would be adopted. The existing assessment of new varieties of agricultural plant species for characteristics contributing to sustainable production would be strengthened. A voluntary assessment would be introduced for vegetables and fruit plants. The activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of PRM between farmers would be exempted from the legislation's scope.

2.Option 2 - Balancing flexibility and harmonisation (preferred option): Option 2 would bring the official controls on plant reproductive material under the scope of the Official Controls Regulation, but with simplified import controls at appropriate places within the Union to ensure a more targeted and efficient enforcement of the existing rules. Basic principles for the use of innovative production processes, bio-molecular techniques and digital solutions would be included in the legislation. The assessment of new varieties for characteristics contributing to sustainable production would become a requirement for all crop groups, but with flexibility for Member States to implement it according to their own agro-ecological conditions. The activities of seed conservation networks, marketing to amateur gardeners and exchanges in kind between farmers would be subject to lighter rules to stimulate the increase in genetic diversity of PRM but also to guarantee a minimum quality.

3.Option 3 - Highest degree of harmonisation: Option 3 would bring the official controls on PRM/FRM under the scope of the Official Controls Regulation, with stricter import controls at border control posts requiring special import documentation to strengthen and fully harmonise enforcement. Detailed and binding rules for the use of innovative production processes, bio-molecular techniques and digital solutions would be included in the legislation. The assessment of new varieties for characteristics contributing to sustainable production would become a requirement for all crops, with detailed and harmonised requirements and methodologies for all Member States. The activities of seed conservation networks, marketing to amateur gardeners and

exchanges in kind between farmers would be subject to the general requirements of the PRM legislation to achieve homogenous rules for all market segments.

Based on the outcome of the impact assessment, the Commission concluded that Option 2 is the best option to effectively address all the objectives of the revision of the PRM legislation in an efficient and consistent manner.

The preferred option will bring efficiency gains for operators and competent national authorities through; (i) extended possibilities for operators to undertake activities under official supervision, (ii) harmonisation with the plant health legislation, (iii) the introduction of risk-based official controls and (iv) the possibility to use bio-molecular techniques and digital solutions in the variety registration and PRM certification systems. Mandatory strengthened sustainability requirements combined with flexibility to adapt to local agro-ecological conditions will contribute to more sustainable agri-food production and food security, as varieties which are more suitable for the changing agro-climatic conditions will have a more stable yield.

The preferred option presents considerable economic costs for operators and competent national authorities due to the need for additional investments to conduct additional sustainability assessments for varieties of vegetables and fruit. These are, however, proportionate to the objectives and will be balanced in the medium term by the benefits coming from the sustainability of agri-food production. They will also be balanced with the adaptation to climate changes in relation to e.g. the reduced use of resources or higher yield stability. Other measures do not result in new obligations for operators but provide them with new options or lighter conditions for accessing the market.