



Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material

SANTE Advisory Group, 19 May 2021

Outline

- Background and aims of the study;
- Overview of 5 problems identified in report;
- Key results on FRM;
- Objectives and Policy options;
- Timeline.

Background

- In November 2019, the Council requested the Commission ‘to submit, by 31 December 2020, a study on the options to update the existing legislation on the production and marketing of plant reproductive material’ (‘PRM study’)
- The request and this PRM study are the most recent steps of a process that started more than a decade ago:
 - Evaluation of the legislation in 2007-8
 - Impact assessment in 2012
 - PRM proposal in 2013
 - Withdrawal of the PRM proposal in 2015

Aims of the study

- To provide an updated PRM legislation problem analysis, identifying current issues, their drivers and implications;
- To explore how recent developments, such as technical developments, new regulations (Official Controls Regulation, Plant Health Regulation) and increasing concerns around climate change, biodiversity and food security, impact on PRM issues; and
- To address criticisms of previous proposals, by filling gaps in knowledge on the amateur gardener market and addressing Forest Reproductive Material (FRM).

The work was carried out in-house and by an external contractor (ICF).

Problem 1

Complex, incoherent and fragmented legal framework

- 12 Directives, developed since the 1960s, reflecting different political objectives and applied within a constantly evolving scientific-technical context;
- No harmonised conditions for exemptions;
- The definition of marketing covers any supply or transfer of seed for commercial exploitation creating uncertainties for the “informal seed sector” (seed savers, community seed banks, exchange between farmers...);
- The withdrawal of the 2013 PRM proposal caused a lack of coherence between the PRM and FRM marketing legislation and the plant health legislation.

Problem 2

Complexity and rigidity of procedures

- Efficiency and efficacy of the variety registration and certification system can be improved (more tasks to be done by operators, modern tools);
- Rules too burdensome for some types of varieties (conservation varieties, organic varieties, varieties exclusively marketed to amateur gardeners);
- Limitations for varietal mixtures and heterogeneous material limited to organic agriculture;
- Complex procedures for adding species to the scope of the legislation or for incorporating the results of temporary experiments;
- Inconsistent and complex procedure for granting of equivalence.

Marketing to amateur gardeners

ICF carried out two surveys with regard to amateur gardeners: one survey on producers and one survey on individual gardeners. The objectives were

- To assess market structure and varieties aimed exclusively at amateur gardeners and the extent to which operators target amateur gardeners;
- To assess amateur gardener motivations, preferences and any issues encountered related to the diversity, availability and quality of seeds and PRM available.

Conservation, amateur varieties and preservation seed mixtures

ICF explored

- The extent to which Directives 2008/62/EC, 2009/145/EC and 2010/60/EU have facilitated the acceptance of conservation varieties, varieties with no intrinsic value for crop commercial production but developed for growing under particular conditions (amateur varieties) and preservation seed mixtures;
- Whether the Directives have contributed to the conservation *in situ* and sustainable use of plant genetic resources and the preservation of the natural environment;
- Conservation and amateur varieties market size and growth.

Results are based on evidence from literature, the National Competent Authority (NCA) survey, interviews with stakeholders at EU and national level, including civil society organisations (CSOs), farmer's associations, NCAs and experts, as well as written input provided by researchers and experts.

Problem 3

Internal market problem/non-level playing field

There are differences between nationally transposed rules with regard to:

- Fees and requirements for the registration of conservation and amateur varieties;
- VCU trials;
- Requirements for the registration of organic varieties;
- The information provided to the end users that will be planting the forest seedlings and forest plants.

Problem 4

Lack of harmonised rules on official controls

- Differences in the costs, extent and nature of control and enforcement across Member States;
- As plant health controls for the same PRM and FRM are covered by the Official Controls Regulation, plant inspection services are confronted with two different control regimes;
- Tools included in the Official Controls Regulation such as training and IT support systems can currently not be used in the PRM and FRM sectors;
- There is a lack of a secure IT system to exchange information on seed fraud in relation to the voluntary EU Seed Fraud Network.

Problem 5

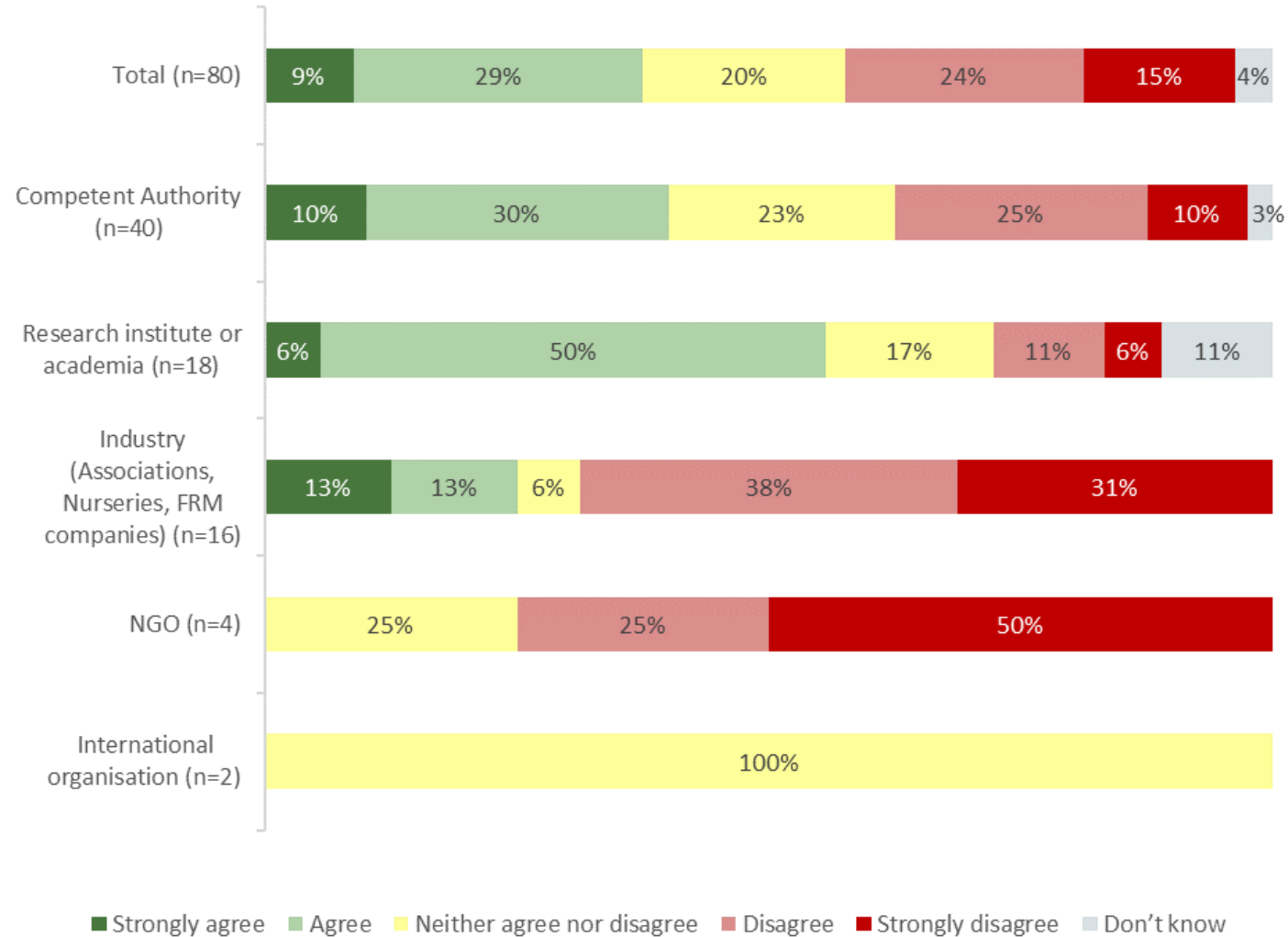
Obstacles to innovation

- The rigidity of the regulatory framework can create barriers for the market access of PRM and FRM obtained through scientific and technical progress (e.g. true potato seed (TPS), *in vitro* propagation of fruit propagating material and somatic embryogenesis to produce FRM);
- The availability of organic seed and of varieties suitable for organic cultivation is insufficient because of the use of untreated non-organic seed and variety registration tests not adapted to the needs of the organic sector.

Problems 1 – 5 Key results: FRM

- Identity: harmonisation of information documentation: competent authorities + researchers;
- Traceability: document management system and approach traceability during production and marketing;
- Scope of FRM Directive: uncertainties about applicable rules when species regulated by the FRM Directive are marketed for non-forestry purposes;
- Difficulty to align FRM Directive with new EU policies: Biodiversity, EU Climate Adaptation, European Digital and new EU Forest Strategies.

There is currently a problem with the traceability of forest reproductive material



Objectives of revising the legislation (1)

General objectives:

- To remove any obstacle or barrier in the internal market in order to ensure a level playing field for production with a view to marketing and marketing of PRM and FRM;
- For all types of users a wide diversity of choice of PRM and FRM should be ensured;
- To support innovation and competitiveness of the EU PRM and FRM industry;
- To support adaptation to – and mitigation of – climate change, and to contribute to food security, sustainable production and biodiversity protection.

Objectives of revising the legislation (2)

The specific objectives are:

- To increase coherence of the Directives: simplified and harmonised basic rules and definitions;
- To increase the efficiency/effectiveness of the systems for PRM and FRM sector;
- To establish a harmonised and risk-based framework for official controls;
- To support the conservation and sustainable use of plant and forest genetic resources;
- To clarify the scope of the FRM marketing Directive: marketing for non-forestry purposes;
- To support the development of digital technologies and bio-molecular techniques.

Options to update the legislation (1)

Option 0: Do-nothing

- No new initiative would be taken concerning any revision of the PRM and FRM marketing legislation;
- The use of existing empowerments for adopting specific rules and derogations would take into account the objectives of the European Green Deal and the Farm to Fork Strategy.

Options to update the legislation (2)

Option 1: Improve procedures and coherence of the legislation and introduce specific measures to increase sustainability

- Streamlining decision-making procedures to set and to adapt requirements;
- More tasks to be carried out under official supervision;
- Simplifying decision-making procedures at EU level;
- Improving coherence between the PRM, FRM and the plant health, GMO and organic legislation;
- Clarifying and harmonising information to be provided by operators in FRM documentation;
- Supporting the Green Deal objectives and in particular contributing to the goals of the Farm to Fork Strategy;
- Creating a harmonised and risk-based system for official controls.

Options to update the legislation (3)

Option 2: Flexibility to adapt to technological developments, to improve access to genetic resources and to address the sustainability objectives in a coherent way

- Improving label security, traceability and the integrity of the PRM and FRM production chain by promoting the use of digital technologies;
- Introducing new provisions to enhance the efficiency of the certification/inspection and variety registration system through modern and flexible processes and rules for the use of new technologies.

Options to update the legislation (4)

Sub-option 2A: Balancing flexibility and harmonisation – more guarantees for users

- PRM marketing Directives only apply to the professional sector;
- FRM marketing Directive extended to certain clearly defined non-forestry purposes;
- Streamlining the existing derogations if requirements cannot be met;
- Creating a harmonised and risk-based system for official controls;
- Establishing an *ad hoc* framework for the exchange of seed between farmers;
- Clarifying and extending exemptions to the scope of application of the PRM and FRM legislation.

Options to update the legislation (5)

Sub-option 2B: Full harmonisation – high guarantees for users

- PRM legislation applies to professional and non-professional end users;
- FRM legislation applies exclusively to FRM marketed for forestry purposes;
- Restricting derogations and national measures to a strict minimum;
- Including PRM and FRM Directives into the scope of the Official Controls Regulation;
- Regulating exchange of seed between farmers as ‘marketing’.

Timeline

- Inception Impact Assessment: Q2 2021;
- Launch External Study: Q3 2021;
- Open Public Consultation: Q4 2021 – Q1 2022;
- Finalisation Impact Assessment: Q3 2022;
- Adoption Commission proposal: Q4 2022.

SANTE webpage

- PRM study:
https://ec.europa.eu/food/sites/food/files/plant/docs/prm_leg_future_prm-study_sw-d-2021-90.pdf
- Contractor's findings: <https://doi.org/10.2875/406165>
- Commission reply to Council:
https://ec.europa.eu/food/sites/food/files/plant/docs/prm_leg_review_article-241-tfeu.pdf