



Seeds and other plant reproductive material Towards new EU rules

SUMMARY *The European Commission (EC) has proposed a Regulation aimed at simplifying and updating the existing body of EU legislation on the production and marketing of plant reproductive material (PRM), including seeds. It forms part of a wider legislative package on controls of plant and animal health.*

At present, in order to be sold in the EU, PRM is subject to a regulatory framework which requires the testing and registration of plant varieties before they can be marketed and the certification, for quality assurance purposes, of individual lots of seeds or other forms of PRM.

While proposing to retain many aspects of the current control regimes, the EC hopes to provide operators in the industry with a wider choice of options for producing and marketing different types of PRM.

Lighter or more flexible rules are foreseen for traditional plant varieties which can play an important role in ensuring biodiversity and environmental sustainability. However, some stakeholder bodies active in these sectors have questioned whether these provisions will sufficiently meet the needs of small-scale breeders and farmers.

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Glossary

Plant reproductive material (PRM): Plants or parts of plants (including seeds) capable of and intended for producing or reproducing entire plants. May also be referred to as plant propagating material (PPM), or seed and plant propagating material (S&PM).

Plant variety: Subdivisions of plant species which are identifiable and distinguishable by individual characteristics. Almost 40 000 different plant varieties are registered in the EU.

Farm saved seed: Seeds saved by farmers from material harvested on their holdings for propagating purposes on their holdings.

Background

The wider policy context

On 6 May 2013, the EC adopted a proposal for a [Regulation](#) providing for a comprehensive overhaul of EU legislation on plant reproductive material, including seeds. It forms one element of a broader [package of legislative proposals](#) introduced on the same day, with the objective of updating and simplifying EU rules on health and safety standards in the agri-food industry and guaranteeing better adherence to these standards. The proposals set out new measures on food chain inspections and controls and on stricter financial penalties for food fraud. They also aim to strengthen,



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modernise and streamline the existing EU legal framework on plant and animal health and on the marketing of seeds and other types of plant reproductive material. About 70 individual items of legislation, dating in some cases back to the early 1960s, regulate these sectors at EU level; it is proposed to reduce this to five principal pieces of legislation (on animal health, plant health, plant reproductive material, official controls and management of expenditure).

PRM - a crucial element of the food chain

Seeds and other types of plant reproductive material are at the basis of crop cultivation and have a fundamental impact upon the productivity, diversity, quality and security of agricultural output, whether used for food, feed or other purposes. According to the FAO, agricultural production will have to almost double by 2050 in order to meet rising global demand for food and feed; most of the increased output will have to come from higher crop yields¹.

The EU seed industry

The EU is a net exporter of seeds, with the value of the EU commercial seed market estimated at €6.8 billion. In Europe, according to the [European Seed Association](#) (ESA), over 7 000 companies, many of them small or medium-sized, are active in the sector, which accounts for some 50 000 jobs and is a major investor in R&D.

PRM - the current regulatory framework

EU-level rules on the marketing of seeds or other PRM have been in place since 1966. At that time, the stated objectives of the system were to increase agricultural productivity (thus contributing to security of food supply), improve competitiveness in the sectors concerned, and harmonise legislation at Community level with a view to achieving more open markets. An extensive body of legislation in this sector has subsequently evolved, consisting of:

- A 'horizontal' Directive ([2002/53/EC](#)) on a common catalogue for varieties of agricultural plant species;

- Eleven 'vertical' or sectoral Directives governing specific categories of crop species and their PRM (seeds for beet, oil and fibre plants, cereals, fodder plants, vegetables and seed potatoes, as well as PRM for vegetables (other than seeds), wine, fruit plants, ornamental plants and forest material)².

These are complemented by numerous implementing acts.

The different sets of rules build on a similar approach and establish a two-pillar framework which requires both the testing and registration of any plant variety before it can be marketed, and the certification, for quality assurance purposes, of individual lots of seeds or other forms of PRM.

Registration and certification procedures

In order to be marketed in the EU, a plant variety must be listed (or registered) in a national catalogue. Two [EU Common Catalogues](#), covering agricultural plant species (such as beet, potatoes, wheat, barley or grasses) and vegetable species, collate information on the plant varieties registered at the MS level.

The registration process involves the carrying out of obligatory 'DUS' tests, in order to confirm that the variety is:

- Distinct (clearly distinguishable on one or more important characteristics from any other registered variety)
- Uniform (composed of identical plants)
- Stable (can conserve its essential characteristics over successive generations).

A general distinction is drawn between varieties of agricultural plant species and vegetable species. Both are subject to DUS tests but agricultural varieties are additionally subject to VCU (Value for Cultivation and Use) trials, which test agronomic performance such as, for example, yield capacity. To be registered in a national catalogue, it must be demonstrated that they offer improved

results *vis a vis* other varieties on the market in terms of cultivation or potential uses.

Certification of seed lots and other PRM is also required before PRM can be legally sold. This procedure entails verification of their identity, health and quality (e.g. in terms of purity, disease resistance or germination capacity). It is generally carried out by official bodies in the MS.

Further specific requirements are set out in the 11 vertical directives depending on the plant species concerned and their marketing categories, which can fall under four different headings: pre-basic, basic, certified and standard material. Some variations or exemptions exist on individual species; ornamental plants, for example, are not subject to cataloguing or certification. More recent Directives have required the registration of suppliers, since most of the PRM concerned is marketed under a supplier's label.

Three Directives on conservation of plant genetic resources ([2008/62/EC](#), [2009/145/EC](#) and [2010/60/EU](#)) have introduced various derogations on registration and marketing of traditional plant varieties which are threatened by genetic erosion (i.e. loss of genetic diversity). They are generally grown in, and adapted to, a specific locality or region and are known as 'conservation varieties' in the Common Catalogues.

The EU's framework has been drawn up in the wider context of the international establishment of rules and standards in this sector, by, among other bodies, the [International Seed Testing Association](#), the

[International Union for the Protection of New Varieties of Plants](#) and the [OECD](#).

Revising the system

In recent years the EU rules on PRM have been subject to a comprehensive review. An [evaluation study](#) was carried out in 2007-08, on the basis of which an [Action Plan](#) for review of the relevant legislation was published in 2009. In 2011, a [stakeholder survey](#) outlining different scenarios for future regulation of the sector generated

more than 250 [responses](#) from a wide range of entities. The EC concluded that stakeholders found the framework generally satisfactory in terms of quality, productivity, efficiency and industry competitiveness. However, a number of shortcomings or problems were also identified:

- The legislation was perceived as complex and inaccessible, making life difficult for operators;
- A high administrative burden for public authorities, as the required tests were almost exclusively carried out by them;
- The registration process was seen as too lengthy, delaying the entry of new products onto the market. Non-harmonised implementation of the legislation was also a problem for operators – e.g., no standard rules on cost sharing (for the testing procedures) had been introduced;
- The rules were not sufficiently integrated with EU policies on biodiversity, climate change and sustainability, or food security and safety.

In the latter context, many smaller operators or those involved in conservation activities argued that the rules on plant variety registration were not suitable for

GM crops

The current proposal on PRM does not alter the rules on genetically modified organisms (GMOs), which are regulated by a separate EU legal framework.

The draft Regulation sets out that plant varieties containing GMOs can only be registered in a national catalogue if they are authorised for cultivation in the EU pursuant to [Directive 2001/18](#) (which regulates the release of GMOs into the environment) or [Regulation 1829/2003](#) (which lays down evaluation and authorisation procedures for GM food and feed). Currently, only two GM crops are authorised for cultivation in the EU.

conservation or amateur varieties, many of which do not fulfil the criteria on uniformity which form part of the DUS tests. The cost of certifying local varieties produced on smaller scales was also seen as prohibitive³.

Towards new EU rules

Scope and general principles

The proposed [Regulation](#) on PRM aims to address the above-mentioned issues and integrate the various legislative instruments detailing specific objectives for different plant varieties. All PRM is included in the scope of the proposed Regulation. In broad terms, the existing registration and certification procedures are maintained. Certain flexibility is, however, introduced for the marketing of different types of material, not least with a view to support for biodiversity. Rules are established for professional operators in the sector, including the requirement to register (in national registers which will also cover operators in the broader plant health sector) in order to guarantee traceability of PRM.

Exemptions and derogations

PRM which is intended for gene bank conservation or solely for breeding or scientific testing purposes is exempt from the scope of the proposed Regulation, as is PRM intended for on-farm conservation or exchanged in kind between seed-savers.

The Regulation sets out derogations from different aspects of the rules which can be granted in specific cases (such as varieties pending registration, temporary shortages of supply, emergency measures etc).

The EC has [underlined](#) that the use of seed in private gardens is not covered by the draft rules. Private individuals can continue to sell seed in small quantities or exchange seed with other non-professional gardeners.

Supporting diversity

Questions were frequently raised during the recent review process as to whether the EU's rules on production and marketing of PRM were suitable for small-scale producers, organic farmers or growers of less commercial or mainstream varieties. The three Directives on the *in situ* conservation and sustainable use of plant genetic resources had been aimed in part at facilitating a lighter regime for marketing of traditional or conservation varieties which are frequently specific to a given region and produced on a limited scale. Such varieties,

being historically adapted to their immediate locality, play an important role in ensuring biodiversity and frequently bring other environmental, cultural and economic benefits. Many of them, however, do not fulfil standard DUS testing criteria. Despite the introduction of a somewhat more flexible approach, the number of conservation varieties listed in the EU Common Catalogues remains relatively small – some 158 agricultural varieties (from a total of 19 500 listed) and 492 vegetable varieties (from 18 500 listed)⁴.

With its latest proposals, the EC introduces a new concept - 'varieties with officially recognised description' - whereby traditional varieties could be registered not on the basis of DUS criteria but instead on the basis of a description indicating their characteristics. It is also indicated that specific rules for testing

Role of the CPVO

Established by [Regulation 2100/94/EC](#), the [Community Plant Variety Office](#) (CPVO, based in Angers, France) is a self-financing decentralised EU agency which is responsible for managing the EU's intellectual property rights system for new plant varieties.

Under the Commission's package of proposals on PRM and on [plant health](#), the CPVO would become the European Agency on Plant Varieties (EAPV). It would have new or expanded responsibilities in terms of auditing national plant variety examination offices, harmonising technical requirements, collating all information on varieties of PRM registered at national or European level and maintaining the relevant EU databases.

plants according to sustainability criteria could be developed.

While some operators in this sector reject the need to register traditional varieties at all, the EC takes the view that users should have access to information about the varieties available. Registration of these varieties would therefore be obligatory, albeit with reduced fees.

A further category of PRM – niche material – is defined as material marketed in small quantities by non-professionals or micro-enterprises. It could be put on the market without having been registered.

Certification and labelling

Under the new proposals, operators would have greater possibilities to carry out certification (an existing possibility under current legislation, but one which has not been taken up to a great extent) and labelling procedures themselves, under supervision from an official body.

Recovery of costs

The annual costs for MS of implementing registration and certification procedures are estimated at €55-60 and €73-79 million respectively⁵. A majority of MS recover these costs either partially or fully from industry operators, but a minority does not. In line with the wider package of proposals on plant and animal health, the PRM Regulation sets out a general principle of recovery of costs for services carried out by responsible public authorities. This would relate not only to testing procedures but also to annual registration fees and fees for the processing applications. Micro-enterprises⁶ would have a general exemption from paying these fees,

and, as noted above, fees for registration of traditional varieties would be reduced.

EP position

Parliament has consistently stressed the important link between EU policies on seed use and plant variety protection on the one

hand and protection of biodiversity in the food chain on the other. In a [resolution](#) of January 2012 on the farm input supply chain it insisted that farmers should continue to have the possibility to use farm-produced and farm-processed seed. In the same resolution, Members called for simplification of the legal framework on plant breeding rights and the use of [farm-saved seed](#) with a view to ensuring a balance between the need for industry innovation and the enhancement and preservation of crop diversity.

In a [resolution](#) of April 2012 on biodiversity strategy up to 2020, the EP expressed alarm at the loss of species diversity

and crop varieties in Europe and underlined the necessity to mainstream biodiversity protection into all relevant EU policies. It called for appropriate legislation and incentives for the maintenance and further development of diversity in farm genetic resources, including with locally adapted breeds and varieties.

In May 2012, the EP adopted a [resolution](#) on the patenting of essential biological processes which called upon the European Patent Office to ensure strict adherence to the rule excluding products derived from conventional breeding from patenting. It also took the view that the so-called 'breeder's privilege' – which in the context of plant variety rights guarantees access to genetic material for further breeding

Forestry

Forest reproductive material (FRM) – which is currently regulated under [Directive 1999/105/EC](#) – is treated under an individual heading of the Regulation. For the EC, this approach allows for basic horizontal principles or administrative measures which are common across all PRM sectors to be applied to FRM, while also respecting the specificities of the forest sector and allowing for alignment of the legislation with the Lisbon Treaty.

However, European forestry industry representatives have [opposed](#) the inclusion of FRM in the Regulation, suggesting that the existing rules meet the needs of forestry stakeholders and that the proposed control regime is not suitable for the sector.

purposes – should be applicable in patent law for plant and animal breeding.

Stakeholder reactions

The Commission proposals have generated a divided reaction from stakeholders in the seed, plant breeding and wider agricultural and environmental sectors. The [European Seed Association](#), which has stressed that the choice of varieties available to farmers and consumers is greater than ever before, [welcomed](#) the efforts to create 'a modern legal framework for seed that is adapted to the competitiveness and vitality of the industry'. [COPA-COGECA](#), representative body for farmers and cooperative organisations, welcomed moves towards simplification of the legislative acquis across the spectrum for plant and animal health, but [urged](#) that the costs for official controls should not be disproportionally imposed on their members.

NGOs and farmers' groups active in areas such as seed-saving, conservation, organic farming or biodiversity have been markedly more critical of the proposals, [suggesting](#) that the rules are too restrictive for smaller producers of niche, traditional and/or less commercial varieties and, far from achieving the stated objective of ensuring biodiversity, are more likely to impact negatively upon the environment, preservation of plant genetic diversity, food security and consumer choice. [Ifoam](#), representing organic farming, said that the proposal had failed to deliver on agro-biodiversity and

would hinder small producers' ability to contribute to conservation.

Next steps

The proposed Regulation, which is subject to the ordinary legislative procedure, has been [referred](#) in the EP to the Committee on Agriculture and Rural Affairs (AGRI) (which has appointed Sergio Silvestris, EPP, Italy as rapporteur), with the Committee on Environment, Public Health and Food Safety (ENVI) to furnish an opinion.

Further reading

[A guide to EU legislation on the marketing of seed and plant propagating material in the context of agricultural biodiversity](#) / Fridtjof Nansen Institute, 2012.

[OECD Seed Schemes: a synthesis of international regulatory aspects that affect seed trade](#) / OECD, 2012

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Endnotes

¹ FAO expert meeting [report](#) 'How to feed the world in 2050', p.10.

² The full list of the Directives concerned is on page 2 of the [draft Regulation](#).

³ In its ruling of 12 July 2012 on the '[Kokopelli](#)' case, the European Court of Justice upheld the validity of Directives 2002/55/EC and 2009/145/EC on the marketing of vegetable seed and said that the rules in force did not breach the principle of proportionality.

⁴ [Minutes](#) of the meeting of 04.03.2012 of the EU Standing Committee on seeds, p. 2

⁵ Estimated figures for 2010. See the [impact assessment](#) accompanying the draft Regulation, p.33.

⁶ Enterprises employing fewer than ten persons, whose annual turnover or balance sheet total does not exceed €2 million.