

POSITION

Access to Plant Genetic Resources and Intellectual Property in the European Union

Plant Variety Protection based on the UPOV Convention

and

**Protection of Biotechnological Inventions based on
Directive 98/44/EC**

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ESA Mission Statement

ESA is the voice of the European seed industry, representing the interests of those active in research, breeding, production and marketing of seeds of agricultural, horticultural and ornamental plant species.

Plants from seed are the origin of all food, provide innovative and environmentally friendly industrial products and beautify our landscape.

ESA's mission is to work for:

- ◆ effective protection of intellectual property rights relating to plants and seeds;
- ◆ fair and proportionate regulation of the European seed industry;
- ◆ freedom of choice for customers (farmers, growers, industry, consumers) in supplying seeds as a result of innovative, diverse technologies and production methods

Content

| | |
|--|--------------|
| Part A - Introduction | P. 3 |
| Part B - Plant Variety Protection under UPOV | P. 4 |
| 1. International Union for the Protection of New Varieties of Plants (UPOV) | |
| 2. UPOV 1991 Act | |
| 2.1. Main features | |
| 2.2. Protection of hybrids | |
| 2.2.1. Protection of hybrids through protection of lines | |
| 2.2.2. Access to parental lines | |
| 2.3. Molecular markers in testing for DUS | |
| Part C - Plant Variety Protection in the European Union | P. 7 |
| 1. National Plant Variety Protection | |
| General | |
| Specific remarks | |
| Scope | |
| Duration | |
| Farm saved seed | |
| 2. Community plant variety protection | |
| 2.1. General | |
| 2.2. Main features | |
| Part D - Protection of Biotechnological Inventions | P. 11 |
| 1. Patents for biotechnological inventions | |
| 2. EU Directive for the legal protection of biotechnological inventions | |
| 2.1. General | |
| 2.2. Specific remarks | |
| 2.2.1. Research exemption | |
| 2.2.2. Farm saved seed exemption | |
| 2.2.3. Compulsory cross licenses | |
| 2.2.4. Protection of sequences | |
| 2.2.5. Broad claims | |
| Part E – Summary and Conclusions | P. 14 |

Part A

Introduction

ESA represents the European seed industry and covers the areas of research and development, plant breeding, seed production and marketing. ESA aims to initiate and assure the framework necessary to carry out all these activities. This framework is required to respond to the challenges that the seed industry faces as the basic deliverer of genetic progress in seeds and propagating material of improved plant varieties for food/feed production and non-food uses and to improve food value throughout the subsequent food chain.

For centuries the development and creation of improved plant varieties has responded to the increasing needs of mankind. To meet future society expectations plant breeding as a highly innovative activity is one of the key factors that will contribute to the development of sustainable agriculture. In fact, the Research and Development investment of the plant breeding industry is more than 15% of the annual turnover, which is extremely high in comparison to other industries.

Plant breeding results in biological material, which is particularly easy to copy being generally self-reproducing. Therefore plant breeders require an effective intellectual property protection system.

At the same time, access to all forms of plant material including commercially available protected plant varieties is indispensable for a successful plant breeding industry thus ensuring that it will always be based on as much genetic diversity as possible.

The World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights of 1994 (TRIPS) provides certain criteria concerning the availability, scope and use of Intellectual Property Rights and requires Members to set up a legal framework complying with such criteria. For the protection of plant varieties, Art 27.3b of the TRIPS Agreement provides the choice between patents, an effective sui generis protection system or a combination thereof.

For ESA the UPOV 1991 Convention is the most suitable existing sui generis intellectual property system for the protection of plant varieties per se¹. It is a balanced system providing for the

- a) effective protection of plant varieties of all species,
- b) access to genetic variability by the free use of protected commercialised plant varieties for further breeding work,
- c) compulsory exception of the right for acts done privately and for non-commercial purposes allowing subsistence farmers to save and use seed.

The European Patent Convention (EPC) of 1973 and the EU-Directive on the Legal Protection of Biotechnological Inventions of 1998 clearly specify the exception to patentability for plant varieties and essentially biological processes for the production of plants. ESA fully supports this exception.

¹ ESA Position Paper ESA_02.0085.4

Part B

Plant Variety Protection under UPOV

1. International Union for the Protection of New Varieties of Plants (UPOV)

The International Convention for the Protection of New Varieties of Plants, Act of 1961/1972, Act of 1978 and Act of 1991 as concluded by the Contracting Parties of UPOV, provides for Plant Breeder's Rights (PBRs).

2. UPOV 1991 Act

2.1. Main features

The system is based on the following main features:

- it is specific to the very nature of the living matter to become protected – the plant variety – as to any preconditions, scope of protection, specific exceptions;
- it offers protection for all plant genera and species and extends the scope of protection under specific circumstances to harvested material and - optionally - to products made directly from harvested material;
- it is based on the testing of phenotypical characteristics for the assessment of Distinctness, Uniformity and Stability (DUS);
- it does not cover techniques for the creation of plant varieties or genetic components of a variety as such;
- it allows access to protected genetic variability by exempting from infringement the use of commercially available material of a protected variety as an initial source of variation for plant breeding and, with exception of essentially derived varieties, the subsequent commercial acts in respect of such new varieties;
- it addresses the problem of plagiarism by virtue of the concept of essential derivation;
- it provides for the possibility to use farm saved seed within reasonable limits and subject to the safeguarding of the legitimate interests of the breeders.

2.2. Protection of hybrids

According to the definition of a variety in Art. 1 (vi) UPOV 1991, UPOV provides for the protection of all types of varieties, including hybrids as such. In addition, the protection of hybrids can be covered through the protection of parental lines.

2.2.1. Protection of hybrids through protection of parental lines

UPOV 1991 extends the scope of the PBR on protected varieties to other varieties whose production requires the repeated use of a protected variety (e.g. hybrids). Therefore the production and exploitation of hybrid varieties falls under the scope of protection of its parental lines.

As a result of this it is established that, regardless of whether the seed of the non-protected hybrid is produced in another territory, even without PBR, seed of the hybrid can only be imported, marketed or sold in a country where a parent line of the hybrid is protected, with the prior authorisation of the holder of the right.

On the other hand the scope of protection of a hybrid protected through the protection of parental lines does not extend to the use of that hybrid for the production of other hybrids.

Whether vegetative multiplication of a hybrid falls within the scope of protection of its parental lines depends on national law. Anyhow, the protection against vegetative reproduction of hybrids can be achieved by protecting the hybrid itself in addition to the protection of its parents.

2.2.2. Access to parental lines

Following the concept of Art. 15 (1) (iii) UPOV 1991 regarding the exception of the Breeder's Right, it is clear, that the PBR does not extend to acts done for the purpose of breeding other varieties and acts like the production or selling of propagating material of such other varieties with the exception of essentially derived varieties. Following this, it can be stated, that there is no positive right that might provide for access to protected parental lines of the marketed hybrid.

2.3. Molecular markers in testing for Distinctness, Uniformity and Stability

UPOV is based on testing of phenotypic characteristics for Distinctness, Uniformity and Stability (DUS). ESA considers that, rather than the possible use of molecular markers in DUS testing, the current system based on phenotypical assessment is the most appropriate method to determine whether a new variety fulfils the technical criteria for the granting of PBR.

The use of molecular markers in DUS testing is not considered to be acceptable for the following reasons:

- DNA marker profiles are not reliably accurate for many phenotypic characteristics due to lack of genetic linkage information or the relatively complex genetic control of many phenotypic traits.
- The use of molecular markers in assessing distinctness, if based only on one band of difference in a molecular pattern could lead to a decrease of minimum distance between varieties and by this would jeopardise the value of Plant Breeder's Rights.
- DUS testing based on DNA markers cannot be restricted to distinctness but by necessity would have to be used for uniformity and stability as well. This could have important consequences for the whole concept of plant breeding.

ESA therefore proposes alternative solutions to improve the handling of reference collections to limit the costs of DUS testing instead of the use of markers, e.g. closer cooperation between all Plant Variety Offices and further cooperation with breeders. In this respect, ESA supports the setting up of a database of variety descriptions that could be used for grouping or pre-screening and the organisation of reference collections for use in the field.

As a consequence, ESA considers that UPOV should focus on the approach of molecular markers for predicting phenotypic characteristics only in the situation where characteristics are directly linked to the marker. This link between the marker and the trait should also be able to determine the type of the trait. The marker must be able to reveal the allelic variability that can be seen with phenotypic characteristics.

This might be useful for the examination of phenotypic characteristics that cannot be consistently seen in the field or which require additional special procedures (e.g. disease resistance).

ESA does not generally object to the use of markers for grouping, i.e. an organisation of the reference collection under normal growing conditions and practice, but considers it necessary to take into account the technical knowledge specific to each species.

Furthermore ESA considers that molecular markers could be used in areas other than DUS testing, for instance as a tool in the assessment of essential derivation as well as for variety identification.

Part C

Plant Variety Protection under UPOV in the European Union

1. National Plant Variety Protection

1.1 General

National Plant Breeder's Rights in EU Member States are offered on the basis of the different Acts of 1961/1972, 1978 or 1991 of the UPOV Convention.

EU Member States^{*}
Party to the International Union for the Protection of New Varieties of Plants
-UPOV-

| 1961/72 Act | 1978 Act | 1991 Act |
|------------------|---|---|
| Belgium Spain | Austria France Ireland Italy Portugal Slovakia | Czech Republic Denmark Estonia Finland Germany Hungary Latvia Lithuania Netherlands Poland Slovenia Sweden United Kingdom |

| EU Member States* Not Party to UPOV |
|--|
| Luxemburg Greece Malta Cyprus |

1.2 Specific remarks

The situation as described leads to a lack of consistency especially in view of the availability of protection, the scope and the duration of the right as well as in view of the farm saved seed situation in the different national Member States.

ESA urges all EU Member States to assure harmonisation by implementing the UPOV 1991Act.

* EU 25, i.e. including accession countries as of 01.05.2004

1.2.1 Scope

Protection based on UPOV Acts 1961/1972 and 1978 only covers the acts of production for purposes of commercial marketing, the offering for sale and the marketing of the reproductive or vegetative propagating material as such of the variety.

A more extensive right might be granted to breeders in respect of certain genera or species as provided for in some Member States.

The 1991 Act covers the acts of production or reproduction, conditioning, offering for sale, selling or other marketing, exporting, importing and stocking for any of these purposes in respect of the propagating material.

In certain cases the right extends to harvested material.

The scope of protection as described above extends to varieties which are essentially derived from the protected variety where the protected variety is not itself an essentially derived variety.

1.2.2. Duration

The UPOV system provides for minimum duration of protection of the PBR which leads to important differences in the national PBRs in the European Union. The national protection periods vary from 15/18 years following the minimum period as defined in UPOV Acts 1961/1972 and 1978 to 20/25 years following the minimum period defined by the UPOV 1991 Act up to 25/30 years.

1.2.3. Farm saved seed

With the exception of France, all national PBRs, based on UPOV 1961/1972 and 1978 Act, allow the possibility of making use of farm saved seed (FSS) without a specific regulatory provision. This results from the scope of the right being restricted to the act of production for purposes of commercial marketing.

The national PBRs in the EU based on UPOV 1991 provide for the possibility to use farm saved seed, either directly by law or by implementing measures.

Where this is implemented, the parameters of UPOV, i.e. the restriction to the use for propagating purposes on the own holding within reasonable limits safeguarding the legitimate interest of the breeder, are formulated following the concept as laid down in the Community Plant Variety Right (CPVR).

Following this, only well defined agricultural species, where the use of FSS was traditional, fall under the scope of the regime and the breeders have to be compensated by a financial remuneration as a percentage of the royalty fixed by the breeder.

Small farmers are exempted from the obligation to pay remuneration.

Some Member States have decided on other interpretations as to the definition of small farmers than those laid down in CPVR.

2. Community Plant Variety Protection

2.1. General

The Community Plant Variety Rights' (CPVR) system, based on the UPOV 1991 Act, grants protection of plant varieties of all species in the whole territory of the EU as an alternative to the national PBRs of the EU Member States.

The CPVR and national PBRs are the exclusive intellectual property rights available in the European Union for the protection of plant varieties, since the European Patent Convention (EPC) of October 1973 excludes in Art. 53b plant varieties and essentially biological processes for the production of plants from patentability.

2.2. Specific remarks

The principal features of the CPVR are highlighted in the following:

- CPVR is granted on one application by the Community Plant Variety Office (CPVO) and has direct and uniform effect throughout the European Union.
- Examinations of plants/varieties under normal growing conditions are the basis for the establishment of the requirements for protection namely Distinctness, Uniformity, Stability (DUS). They are carried out by CPVO-agreed Offices using the EU Technical Protocols as a guideline for DUS tests including appropriate reference collections of varieties of common knowledge.
- The maintenance of the protected variety in a state of confirmed unaltered existence is assessed.
- The breeder's exception confirming the free access to protected, commercially available varieties for the development there-from and exploitation of new varieties is integral part of the CPVR.
- In order to avoid plagiarism, the concept of essentially derived varieties has been included in the system.
- A Farm Saved Seed Exemption provided for as 'Agricultural Exemption' allows farmers to use the product of their harvest of certain well-defined species under certain conditions and with the obligation to pay an equitable remuneration to the holder of the right of the protected variety.
In this respect there is a need for the legislators to clarify the extent of the legal obligation for farmers and processors to supply information as to the use of farm saved seed to the breeders.
Without an extensive obligation for the delivery of information that is not dependent on concrete evidence of farm saved seed use, the holders of the rights are not able to enforce their rights in view of the remuneration based on concrete invoices.

- The term of the CPVR runs until the end of the 25th calendar year, or in the case of potatoes, vine and tree species, until the end of the 30th calendar year following the year of granting.
- The scope of the CPVR covers variety constituents and harvested material and extends in certain cases to products obtained directly through unauthorised use of material of the protected variety.
- Following Art. 17 UPOV, a compulsory exploitation right may be granted only on grounds of public interest.
- The introduction of the new concept of compulsory cross licensing following Art. 12 Directive 98/44/EC on the Legal Protection of Biotechnological Inventions in the Regulation on Community Plant Variety Rights provides for coherence of the system in both sets of legislation.

Part D

The Protection of Biotechnological Inventions

1. Patents for Biotechnological Inventions

ESA has always supported the co-existence of all Intellectual Property Rights offering adequate protection for each kind of inventive activities in living matter and results thereof. Whilst supporting the exclusion from patentability of plant varieties per se, ESA is of the opinion, that the patent system is the most appropriate system for protection of biotechnological inventions in general. This is valid more specifically for plants having non-indigenous DNA incorporated into their genome, vectors, plasmids, inventive processes for transformation of plants, processes resulting in an improved useful quality of plant material found in nature, methods, uses etc., provided the criteria for patentability are met.

2. EU-Directive on the Legal Protection of Biotechnological Inventions

2.1. General

Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions provides for an obligation of the Member States to adjust their laws to take account of the provisions of the Directive.

Currently, implementation of the Directive into National law has only been accomplished in DK, FIN, UK, IE, E and GR.

In January 2003, the Commission has opened official proceedings against the nine other Member States for not having complied with the obligation to adopt national legislation by 20. July 2000.

- Object

Biotechnological inventions, which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable.

Plants can be patented as long as plant varieties are not individually claimed. Thus, inventions that concern plants are patentable if the technical feasibility of the invention is not confined to particular plant varieties. This conclusion follows the respective decision of the enlarged Board of Appeal of the European Patent Office in the Novartis case in 2000.

- Exclusion

Plant varieties as well as essentially biological processes for the production of plants are excluded from patentability. According to the definition of the CPVR system, a 'plant variety' is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties. A plant grouping, however, which is characterised by a particular gene and not by its whole genome, is not covered by the CPVR and therefore not excluded from patentability, even if it comprises new varieties of plants.

- Processes

A process for the production of plants and animals is legally defined as being essentially biological, and therefore excluded from patentability, if it consists entirely of natural phenomena such as crossing or selection.

2.2 Specific remarks

2.2.1 Research exemption

With respect to the research exemption provided for in the national patent laws, ESA is of the opinion, that in view of the needs of the plant breeding industry this legal exemption (so far as it is provided for) is frequently unclear and/or far too narrow.

ESA is of the opinion that with respect to the breeder's exception as stated in UPOV, the CPVR and national plant variety protection laws, acts done for the purposes of breeding or discovering and developing other plant varieties should be excluded from the scope of patent protection of biotechnological inventions. Plants containing patented elements should be freely usable for developing new plant varieties.

The commercial use of any new plant variety no longer expressing the function of patented elements should be free.

Consequently, the commercial use of new plant varieties expressing the function of patented elements, such as multiplication of propagating material in view of sale of this propagating material, requires the authorisation of the holder of the patent right. On the other hand ESA considers that in any case acts required for obtaining PBR should not be considered as commercial use in the framework of the research exemption.

2.2.2 Farm Saved Seed Exemption

Art.11 of Directive 98/44/EC provides for derogation from Art.8, 9 of this Directive. By this it overrides the rights of the patent holder and authorises the farmer to use the product of his harvest obtained from planting propagated material sold to him by a patent holder of the patent (or with his consent) for agricultural use. This corresponds to the Farm Saved Seed exemption as mentioned earlier in this paper and as contained in Art.14 Regulation (EC) No. 2100/94 Community Patent Variety Right.

2.2.3. Compulsory cross licences

Art. 12 Directive 98/44/EC provides for the possibility of compulsory cross licences between breeders and patent holders for cases, where the acquisition or exploitation of the PBR or the exploitation of the patented invention would not be possible without infringing a prior patent or a prior plant variety right, subject to payment of an appropriate royalty. As a precondition, the unsuccessful application to obtain a contractual licence must be demonstrated.

The other precondition set out, namely that the plant variety or the invention constitutes "significant technical progress of considerable economic interest" compared with the invention claimed in the patent or the protected variety needs further clarification.

2.2.4. Protection of sequences

ESA considers that DNA Sequences are patentable provided they fulfil all criteria for patentability. In particular, sequences without an identified function and the related industrial applications should not be patentable.

2.2.5. Broad claims

The scope of a patent is defined by the claims. This should not lead to unjustified broad claims. Claims must not go beyond the invention made.

Part E

Conclusions

- The UPOV 1991 Act provides for the most suitable and effective sui generis intellectual property system for the protection of plant varieties per se.
- The UPOV 1991 Act provides free access to genetic variation and contributes to genetic variability.
It allows subsistence farmers to make use of farm saved seed of protected varieties for acts done privately and for non-commercial purposes.
By this it is consistent with the Convention on Biological Diversity (CBD) and the Food and Agricultural Organisation (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA)
- The Community Plant Variety Right (CPVR) offers the best existing protection of plant varieties in the European Union with limited administrative burden.

However, ESA is of the opinion that the CPVR shall be reviewed in particular as concerns the following points:

- the agricultural exemption as provided in the CPVR should be deleted.
If however, for overriding political reasons, this exemption in view of farm saved seed is provided, the following principles must be observed:
 - the legitimate interests of breeders must be safeguarded by providing for an obligation of farmers to pay remuneration at the level of the royalties.
 - Small farmers should not be exempted from the obligation to pay remuneration.
 - The use of farm saved seed only be allowed for species where traditionally farm saved seed has been used.
 - The users of farm saved seed should be obliged to deliver respective information on the use of farm saved seed without any further conditions to be fulfilled by the holder of the right.
 - The duration of protection should be extended to take account of the life span of plant varieties of certain species.
 - The extension of the scope of protection to acts in respect of certain products should not depend on the establishing of implementing rules and should not be restricted to specific cases.
- ESA welcomes the exclusion of plant varieties and biological processes from patentability according to EU Directive 98/44/EC on the Patenting of Biotechnological Inventions and the European Patent Convention.
- ESA is of the opinion that the patent system is the most appropriate system for the protection of biotechnological inventions in general.
- ESA requests that acts done for the purpose of breeding or discovering and developing other plant varieties shall be excluded from the scope of patent protection for biotechnological inventions.
The commercial use of new plant varieties expressing the function of the patented elements requires authorisation of the holder of the patent.