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POSITION

REVISED DRAFT ESA SPO POSITION

ON ESSENTIAL DERIVATION AND DEPENDENCY IN POTATO

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. The ESA Potato Section (SPO) represents more specifically the European potato breeders involved in research, plant breeding, production and marketing of potato varieties.

1. LEGAL FRAMEWORK

The 1991 Act of the UPOV Convention introduced the concepts of essential derivation and dependency from an initial variety. Article 14 (5) (b) (*) defines that a variety shall be deemed to be essentially derived from another variety when:

- i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,
- ii) it is clearly distinguishable from the initial variety and
- iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

Article 14(5) (c) provides that essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

This concept of "essentially derived varieties" (EDV concept) has been transposed into the European legislation on plant variety protection (Regulation (EC) no. 2100/94 – Community PVP Regulation) and into the plant variety protection acts of most of the EU Member States.

(*) The full text of Art 14 of the 1991 UPOV Convention can be found in Annex 1.

2. ESA POSITION ON ESSENTIALLY DERIVED VARIETIES (*)

ESA supports the EDV concept as an instrument for addressing the problem of plagiarism and an important tool for ensuring not only a balanced, but also an efficient protection of plant variety rights.

The selection methods named in Article 14 (5) (c) UPOV 1991 (*selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering*) do indeed very often - in the case of mutants most likely - but not automatically result in an essentially derived variety.

ESA supports the reversal of the burden of proof in favour of the holder of the plant breeders' right of the initial variety once a certain degree of genotypic similarity between the initial variety and a suspected essentially derived variety is reached.

A scientific threshold triggering such reversal of the burden of proof needs to be determined for each species or group of species. Furthermore, such thresholds should not be set at too low a level in order to avoid that derivation is deemed too easily.

The term "essential characteristics" in Art 14 (5) (b) i and iii must not be limited to characteristics relevant for the marketing of the variety. Any such limitation would give rise to a very subjective evaluation and thus legal uncertainty.

(*) The full text of the ESA Position on Essentially Derived Varieties (ESA_11.0043) can be found on the ESA website: http://www.euroseeds.org/publications/position-papers/intellectual-property/esa_11.0043

3. EXAMPLES OF ESSENTIALLY DERIVED POTATO VARIETIES TODAY

Potato is a tetraploid crop ($4n=48$) which is multiplied vegetatively. Certain mutants of existing potato varieties have proven in practice to be of significant economic value. In the past decade several potato varieties have been developed by genetic modification in modifying certain characteristics in existing potato varieties.

The ESA SPO Section notes that both mutants and the use of genetic modification could lead to an essential derived variety provided that all other conditions as defined in Article 14 (5) (b) of the UPOV 1991 Convention are met.

The ESA SPO Section also notes that in case the initial variety is protected by Plant Breeder's Rights the acts as indicated in Article 14(1-4) of the UPOV 1991 Convention in respect of the material of the essential derived variety shall require the authorisation of the title holder of the initial variety. In other words in these cases an Essentially Derived Variety will be dependent from the initial variety.

4. CONFORMITY THRESHOLDS FOR POTATO

The ESA SPO Section acknowledges the results of the study conducted on the “Construction of an integrated microsatellite and key morphological characteristic database of potato varieties in the Common Catalogue. The project was carried out by SASA (UK), BSA (DE, COBORU (PL), Naktuinbouw (NL) and co-financed by the Community Plant Variety Office in Angers. The results of the study are available on the website of the CPVO:

http://www.cpvo.fr/documents/techreports/CPV6608_final_report.pdf.

An additional Research project was carried on behalf of ESA SPO “Determining a threshold for genetic conformity in potato seed lings”. The final report of this study is available on the ESA website:

<http://www.euroseeds.org/publications/position-papers/crop-specific-issues/potatoes/>

Based on the results of this study (*) the ESA SPO section considers a similarity coefficient of 92% and higher as an indication of predominant derivation (Art. 14 (5) (b) ii and iii) and agrees that a similarity coefficient of 92% is appropriate to shift the burden of proof to the breeder of the putative essentially derived variety. In the further assessment additional criteria should be evaluated as morphological characteristics and breeding records.

(*) A description of the DNA sampling technique is attached in Annex 2.

ANNEX 1

ARTICLE 14 (UPOV 1991) – SCOPE OF THE BREEDER’S RIGHT

(1) [*Acts in respect of the propagating material*]

(a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:

- (i) production or reproduction (multiplication),
- (ii) conditioning for the purpose of propagation,
- (iii) offering for sale,
- (iv) selling or other marketing,
- (v) exporting,
- (vi) importing,
- (vii) stocking for any of the purposes mentioned in (i) to (vi), above.

(b) The breeder may make his authorization subject to conditions and limitations.

(2) [*Acts in respect of the harvested material*] Subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1) (a) in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.

(3) [*Acts in respect of certain products*] Each Contracting Party may provide that, subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of products made directly from harvested material of the protected variety falling within the provisions of paragraph (2) through the unauthorized use of the said harvested material shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested material.

(4) [*Possible additional acts*] Each Contracting Party may provide that, subject to Articles 15 and 16, acts other than those referred to in items (i) to (vii) of paragraph (1)(a) shall also require the authorization of the breeder.

(5) [*Essentially derived and certain other varieties*]

(a) The provisions of paragraphs (1) to (4) shall also apply in relation to

- (i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,
- (ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and
- (iii) varieties whose production requires the repeated use of the protected variety.

(b) For the purposes of subparagraph (a) (i), a variety shall be deemed to be essentially derived from another variety (“the initial variety”) when

- i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,
- ii) it is clearly distinguishable from the initial variety and
- iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

(c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

ANNEX 2

DNA SAMPLES

DNA can be extracted from either tuber, leaf or microplant material for profiling purposes. If possible at least two individual plants should be profiled separately. If using tuber material a core equivalent to 1 cm³ should be taken. If leaf material is used it is preferable to use fresh young leaves and to extract from a sample equivalent to around 3-4 cm². One or two leaves with a total area of around 1 cm² from microplant tissue is sufficient. DNA from the plant material to be extracted as described in Reid *et al.* (2008).

PCR CONDITIONS

Amplifications to be carried out using the Qiagen Type-it Microsatellite PCR Kit in 10 mL reactions with 10-20 ng of extracted DNA and 1 mL of the multiplex primer sets in Table 1. PCR profile and sequencer run conditions are those set out in Reid *et al.* (2008).

Multiplex set	Marker	Dye	Concentration in mix (pmol/mL)
1	STM0019	VIC	4
	STM3009	NED	2
	SSR1	6FAM	2
2	STM2005	NED	2
	STM3012	6FAM	4
	STM3023	VIC	1
3	STM2028	NED	4
	STM5136	VIC	1
	STM5148	6FAM	4
4	STM1016	VIC	1
	STM1024	6FAM	1
	STM2022	NED	2

Reid A, Hof L, Esselink D, Vosman B (2008) Potato cultivar genome analysis. In: Burn R (ed) Plant pathology—techniques and protocols. Springer, New York

ESA is the voice of the European seed sector. ESA's members are national associations and individual companies active in research, breeding, production and marketing of seeds of agricultural and ornamental plant species. ESA represents more than 7000 seed businesses in the EU and beyond.

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