CIOPORA Position

on

Essentially Derived Varieties

as approved by written procedure in May / June 2016

Key Statements:

- **CIOPORA requests that the EDV concept is clarified through an objective approach and a clear and self-consistent definition, which meets the objective to balance the scope of new breeding techniques and traditional breeding.**

- **CIOPORA maintains that for vegetatively reproduced ornamental and fruit varieties the EDV concept shall establish dependency for varieties, which are phenotypically distinct and predominantly derived from the Initial Variety.**

- **The degree of the phenotypic similarity and the number of phenotypic differences between the EDV and the Initial Variety shall not be taken into consideration for the establishment of dependency, but for the assessment of distinctness.**

- **Predominant derivation is given if material of the Initial Variety has been used for the creation of the EDV and a very high degree of genetic conformity between the Initial Variety and the EDV exists.**

- **The methods and required degrees of genetic conformity should be established crop-by-crop on the basis of state of the art protocols agreed upon by a panel of experts, including representatives of the breeders of the crop concerned, and has to be proven by the title holder of the Initial Variety in case of dispute and litigation.**

- **CIOPORA maintains that mutants and GMOs – as far as they are distinct from the Initial Variety – are EDVs, whenever they retain a very high**

genetic conformity to the Initial Variety as established by the panel of experts, because mutants and GMOs per definition are predominantly derived from the Initial Variety.

- **CIOPORA maintains that the outcomes of repeated back-crossing – as far as they are distinct from the Initial Variety – are EDVs in case they retain a very high genetic conformity to the Initial Variety as established by the panel of experts.**

- **CIOPORA recognizes that there is a realistic possibility that with advancing technologies it might become possible to create independent varieties by new methods, in particular genetic engineering.**

Full Text:

1. Essentially Derived Varieties

According to Article 14 (5) (a) of the UPOV 1991 Act, varieties, which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety, fall under the protection of the protected variety.

According to Article 14 (5) (b), 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[1], 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[2],

[1] Predominant derivation means that the variety can only be essentially derived from one variety.
[2] The expression of the essential characteristics that result from the genotype or combination of genotypes is not a synonym for "phenotype", because phenotype is to a high degree influenced by the environment. The expression of genotype is in fact a chemical process in the cell, through which a part of the genotype ("gene") codifies a certain trait. Such trait is the direct expression of the genotype.

(ii) it is clearly distinguishable from the initial variety[3] 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[4].

(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[5].

2. The current EDV-concept under the UPOV 1991 Act

Very reason for the introduction of the EDV concept in the UPOV 1991 Act was to strengthen the breeders´ right, particularly by creating a balance between biotechnology inventors and traditional breeders and by bringing mutations under the scope of protection of their Initial Variety. The wording of the EDV provision (14 (5) (a) of the UPOV 1991 Act) gives room for interpretation as to what are the requirements of an EDV.

CIOPORA has tried to clarify the current EDV concept by establishing a detailed position on EDV in January 2008.

CIOPORA notes that some want to limit the EDV concept to varieties, which can be distinguished from the Initial Variety by a very limited number of characteristics (typically by one). Such interpretation limits the EDV concept as far as even possible and does not achieve UPOV´s objective to create a balance between biotechnology inventors and traditional breeders and to bring mutations under the scope of protection of their Initial Variety. Taking into consideration that an EDV per definition must be clearly distinguishable from the Initial Variety, which requires as a minimum a difference in one characteristic, under such interpretation only varieties which have exactly one difference compared to their Initial Variety could be considered to be an EDV. This approach does not support innovation.

[3] For the concept of “clearly distinguishable / distinct” refer to the Position Paper on Minimum Distance.
[4] This sentence does not add to clarity, but is superfluous.
[5] This list indicates the intention of the authors that mutations and GMOs and varieties resulting from backcrossing (where the Initial Variety is obviously used as recurrent parent) are typical examples of EDV.

3. The desired EDV concept

CIOPORA requests that the EDV concept is clarified through an objective approach and a clear and self-consistent definition, which meets the objective to balance the scope of new breeding techniques and traditional breeding.

Such objective approach shall be based on the genetic conformity of the varieties concerned. Phenotypic components shall be taken into consideration only as far as the distinctness of the respective varieties is concerned.

Particularly the entanglement of dependency and plagiarism is a mistake in the conception of the EDV provision. Plagiarism is not a question of derivation or dependency, but rather a question of Minimum Distance and direct infringement. If a variety in its phenotype very much resembles a protected variety, it is not clearly distinguishable from the protected variety, and its commercialization is a direct infringement, irrespective whether the new variety is (essentially) derived from the protected variety or not.

Additionally, phenotype is, by definition, what results from the expression of an organism's genes as well as the influence of environmental factors and the interactions between the two. The degree of phenotypic similarity is the result of a subjective evaluation, strongly influenced by variations based on environmental and judgmental factors.

Finally, the wording of the UPOV 1991 Act with regard to the requirement and level of phenotypic conformity between an Initial Variety and its EDV is unclear and contradictory. In Article 14 (5) (b) (i) a general conformity seems to be required, while Article 14 (5) (b) (iii) provides that the EDV must conform to the Initial Variety in the expression of the essential characteristics, *except for the differences which result from the act of derivation*[6].

CIOPORA, therefore, maintains that Article 14 (5) (b) (i) of the UPOV 1991 Act does not establish phenotypic similarity as a pre-condition for EDV (because the interaction with the environment is not taken into account), but specifically and expressly refers to genotype[7].

[6] Contrary to that, in the PVR law of the European Community (Regulation 2100/94) and some other countries, this contradiction does not exist, since the phrase “while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety” of Art. 14 (5) (b) (i) has not been included in Art. 13 (6) (a) of Regulation 2100/94. Nevertheless, Regulation 2100/94 has been accepted by UPOV as being in line with the UPOV 1991 Act.

[7] Obviously, at the time when the UPOV 1991 Act was drafted, genotype could not been described other than in relation to its expression.

CIOPORA, therefore, is of the opinion that close phenotypic similarity must not be a precondition for a variety to be considered to be an EDV. However, a close phenotypic similarity can be an indication for essential derivation.

Instead, CIOPORA maintains that for vegetatively reproduced ornamental and fruit varieties the EDV concept shall establish dependency for varieties, which are phenotypically distinct and predominantly derived from the Initial Variety.

The degree of phenotypic similarity and the number of phenotypic differences between the dependent and the Initial Variety shall not be taken into consideration for the establishment of dependency, but for the assessment of distinctness.

3.1 Distinctness

An EDV shall be phenotypically distinct from its Initial Variety. For the assessment of Distinctness the Position Paper of CIOPORA on Minimum Distance of 2 April 2014 shall apply.

3.2 Predominant derivation

An EDV shall be predominantly derived from its Initial Variety.

Predominant derivation is given if material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety, **has been used for the creation of the EDV and a very high degree of genetic conformity between the Initial Variety and the EDV exists.**

A variety can only be *predominantly* derived from *one* variety, as Article 14 (5) (b) (i) UPOV 1991 Act stipulates the EDV must be predominantly derived from the Initial Variety.

The methods and required degrees of genetic conformity should be established crop-by-crop on the basis of state of the art protocols agreed upon by a panel of experts, including representatives of the breeders of the crop concerned, and has to be proven by the title holder of the Initial Variety in case of dispute and litigation.

CIOPORA maintains that mutants and GMOs – as far as they are distinct from the Initial Variety – are EDVs, whenever they retain a very high genetic conformity to the

Initial Variety as established by the panel of experts, because mutants and GMOs per definition are predominantly derived from the Initial Variety.

CIOPORA maintains that the outcomes of repeated back-crossing – as far as they are distinct from the Initial Variety – are EDVs in case they retain a very high genetic conformity to the Initial Variety as established by the panel of experts.

4. Burden of proof

For the sake of establishing the existence of an EDV the following requirements are to be fulfilled:

- Distinctness
- Use of Material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety (derivation),
- Very high degree of genetic conformity (predominant derivation)

With regard to the burden of proof it is up to the plaintiff (holder of the Initial Variety) to prove distinctness and the very high degree of genetic conformity, as defined above. Proving the necessary degree of genetic conformity establishes also a prima facie evidence that material of the Initial Variety or of a variety, which itself is predominantly derived from the Initial Variety has been used. Nevertheless, a close phenotypic similarity may also call for an assessment of the degree of genetic conformity by the parties or the court.

An EDV is dependent on its protected Initial Variety. As a consequence, the commercialization of the EDV requires the authorization of the title holder of the Initial Variety during the duration of its protection.