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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

GENEVA

**SIXTH MEETING
WITH INTERNATIONAL ORGANIZATIONS**

Geneva, October 30, 1992

ESSENTIALLY DERIVED VARIETIES

OBSERVATIONS FROM ASSINSEL

Document prepared by the Office of the Union

The annex to this document contains a position paper adopted by the General Assembly of the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL) in Toronto (Canada) on June 5, 1992. That paper was transmitted to the Office of the Union by letter dated September 15, 1992.

[Annex follows]

ANNEX

ASSINSEL STATEMENT REGARDING THE IMPLEMENTATION OF THE
NEW PRINCIPLE OF ESSENTIALLY DERIVED VARIETIES IN THE UPOV CONVENTION
Adopted by the General Assembly in Toronto on June 5, 1992

No. A. 92. 48b

At the UPOV Diplomatic Conference in Geneva in March 1991, new conditions in relation to essentially derived varieties (e.d.v.) were introduced into a revised convention. The following resolution was adopted:

"The Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants held from March 4 to March 19, 1991, requests the Secretary General of UPOV to set in motion immediately after the closing of the Conference the establishment of draft standard guidelines, for adoption by the Council of UPOV, on essentially derived varieties."

In response ASSINSEL presents the following statement.

After careful consideration of the new text [Article 14(5)] it is concluded that the implementation of this new concept should take the following points into consideration.

Introduction

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In all previous statements ASSINSEL has strongly approved the introduction of the essentially derived varieties (e.d.v.) concept. With respect to the very recent developments in the field of plant breeding and biotechnology and the resulting lack of clarity between the fields respectively covered by patents and plant breeders' rights and the degree of protection which they offer, ASSINSEL considers that the new principle builds a bridge between the two protection systems in the interest of the affected industries. This new principle will also decrease drastically the possibility of plagiarism in plant breeding.

ASSINSEL plant breeders are convinced that this new principle brings about an important strengthening of plant breeders' rights without any real restrictions of the key issue of the so-called breeders' exemption.

It has to be appreciated that the introduction of this new principle into the UPOV Convention represents a step into new territories. As usual with such situations there are uncertainties and doubts. Therefore, at this stage, the national legislators - as well as the UPOV Council - should restrict their statements to general formulation of this new principle and should not go too far into detailed regulations. A too detailed regulation would run the risk that omissions will subsequently become apparent or that future developments will be hampered or not provided for. Furthermore the implementation should be practical and not too complicated.

As will be shown in the following, this principle mainly involves questions of scope of protection and enforcement of the rights of the breeder. It is, therefore, left to the initiative of the breeder to enforce these rights.

A. General Aspects

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1. In its principle, the concept of e.d.v. deals with the genotype rather than with the phenotype. Contrary to the principle of "clear distinctness" of Article 7 of the UPOV Convention being judged on the basis of the expression of certain morphological or physiological characteristics, Article 14(5) has to do with the question whether the essence of the genotype of the initial variety (i.v.) has been taken over - that means whether it retains virtually the totality of the genome of the i.v. - retaining the expression of the essential characteristics. In this respect, "... essential characteristics that result from the genotype..." include only inheritable characteristics.

Furthermore, depending on the given genetic constitution of a given plant species and established breeding technology the required threshold of the quantity of conformity can be different for different species.

2. The "genetic distance/conformity" should be judged on a species-by-species or even within-a-species basis. The methods of derivation may be used as a tool to help to establish or to define an e.d.v.

The given list of examples for methods of derivation [selection of a natural or induced mutant or of a somaclonal variant, selection of variant individual from plants of the i.v., multiple backcrossing, transformation by genetic engineering: see Article 14(5)(c)] is not an exhaustive list.

3. Whether or not a plant variety is an e.d.v. may need to be based upon scientifically reliable methods. This may start with the judgement of essential characteristics and be completed by methods of genome identification in so far as adequate methods are available. Depending on the given species, this assessment can vary in relation to different methods of derivation used and also by different genetic distances. Scientific and reliable methods for the proof of genetic distances might be e.g. RFLP (Restricted Fragment Length Polymorphism), RAPD (Random Amplification of Polymorphic DNA), PCR (Polymerase Chain Reaction), combining ability.
4. This assessment should be made by species-specific experts skilled in the art, including breeders, molecular geneticists, etc.
5. The plant variety offices have only a duty to prove whether a plant variety having been entered for protection fulfills the requirements for protection (DUS-test), regardless of the question of whether it is an e.d.v. or not. Thus for ASSINSEL it is important and obvious that the determination of the existence of an e.d.v. should not be a part of the procedure for granting plant breeders' rights. However, registration data of the variety based on UPOV guidelines should be available after granting of rights.
6. The determination as to whether a plant variety is an e.d.v., is mainly a question of whether it has been derived from a given variety (see 2). Where a plant variety has been developed without using that variety, there cannot be essential derivation. However, the general rules of burden of proof have to be considered (see C. below).
- 7) Essential derivation is a matter of fact whereas dependency resulting herefrom is a possible legal consequence. Therefore, if an e.d.v. has been claimed and proved as such with legal validity it remains an e.d.v. On the other hand, one variety which first has been assumed to be independently developed can be later on claimed and proved to be an e.d.v. with all the consequences that that proof implies, for the variety itself and for those essentially derived from it.

An e.d.v. remains an e.d.v. for ever. Even if the protection period of the i.v. has been exhausted, a variety derived from the first variety in a chain of essentially derived varieties remains an e.d.v. and the remaining varieties in the chain will still be essentially derived from the i.v. The reason for this lies in the spirit of the concept of dependency. This very new principle has mainly been introduced to protect more efficiently the initial breeder and not those who make derivations from his work.

B. Special Interpretations of Article 14(5)
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1. The principle of dependency only exists in favour "of the protected variety" [see Article 14(5)(a)(i)].

This means:

- a) The initial variety must be a protected one.
 - b) Dependency can only exist from one protected variety alone.
 - c) A dependent variety can be directly derived from the i.v. or from a variety that is itself predominantly derived from the i.v. [see Article 14(5)(b)(i)]. As already mentioned under A.7, dependency only exists in relation to the i.v.
2. ASSINSEL interprets Article 14(5)(b) ("a variety should be deemed to be essentially derived from the i.v.") in that the e.d.v. effectively has to meet the following three requirements in relation to the initial variety while retaining the expression of its essential characteristics:
 - a) clear distinction in the sense of Article 7;
 - b) predominant derivation;
 - c) genetic conformity.

If one requirement is not fulfilled, there will be no essential derivation.

3. The methods of breeding which can be regarded as leading to an e.d.v. may differ from species to species, or even within a species. This will result in different thresholds being required to characterize dependency.

C. General Rules for Burden of Proof
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- a) According to the general rules of burden of proof, each party has the burden of proof for those requirements of the legal provision which is favourable to him. That means that the owner of the i.v. has to prove all requirements of dependency.
- b) If the owner of the i.v. can prove the requirement of "genetic conformity" his burden of proof regarding "predominant derivation" is facilitated by the so-called "prima facie" proof (proof by evidence). The existence of "genetic conformity" gives the presumption that the second breeder has predominantly derived his variety from the i.v. On the other hand, if the owner of the i.v. can prove the requirements of "predominant derivation", the existence of "genetic conformity" can be also presumed.

For the proof of evidence to justify essential derivation, the following elements should be sufficient:

- genetic conformity or
 - close relationship e.g. in phenotypical characteristics or
 - only small differences in some simply inherited characteristics.
- c) If the owner of the i.v. has fulfilled the above requirements, then the second breeder has to prove:
 - no genetic conformity or
 - no predominant derivation.

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