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CAJ-AG/07/2/4
ORIGINAL: English
DATE: September 28, 2007

UPOV

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE ADVISORY GROUP

Second Session
Geneva, October 26, 2007

ARTICLE 14(5) OF THE 1991 ACT: ESSENTIALLY DERIVED AND CERTAIN OTHER VARIETIES

Document prepared by the Office of the Union

1. At its first session held in Geneva on October 20, 2006, the Administrative and Legal Committee Advisory Group ("CAJ-AG") discussed the provisions related to essentially derived varieties of Article 14 (5) of the 1991 Act of the UPOV Convention on the basis of the information provided on paragraphs 42 to 47 of document CAJ-AG/06/1/2. The CAJ-AG agreed that the issues raised in document CAJ-AG/06/1/2 should be discussed in its following session on the basis of the existing text in document CAJ-AG/06/1/2.

2. Document CAJ-AG/06/1/2 listed the following issues to be addressed in relation to essentially derived varieties (see paragraph 47 of document CAJ-AG/06/1/2):

1. An explanation of the relationship between the Initial Variety and Essentially Derived Varieties (EDVs) (as explained in the UPOV Distance Learning Course (DL-205), with specific consideration of the notion of "Initial Variety");

2. The rights of the breeder of an Initial Variety and of an EDV (as explained in DL-205);

3. Implications of the provisions under Article 14(5) of the 1991 Act for licensing agreements.

4. Determination of whether a variety is essentially derived (the existence of a relationship of essential derivation):

(a) whether it would be appropriate to develop guidance on EDVs;

(b) if so, possible guidance on, e.g.

(i) whether "derived from" requires physical use of an Initial Variety;

(ii) clear examples of what might constitute "predominantly derived" and clear examples of what might not constitute "predominantly derived", to avoid basic misunderstandings; and

(iii) clear examples of what might constitute "essential characteristics" and clear examples of what might not constitute "essential characteristics" to avoid basic misunderstandings.

5. Provisions for Essentially Derived Varieties in the transition from the 1978 Act to the 1991 Act of the UPOV Convention (see documents CAJ/31/4, paragraphs 15 to 23, and CAJ/32/10-TC/29/9, paragraph 29).

3. On May 8, 2007 the Office of the Union (the Office) issued Circular E-475 to invite non-governmental organizations with observer status in the CAJ to provide any materials which they had on guidance or recommendations concerning essentially derived varieties (see Article 14(5) of the 1991 Act of the UPOV Convention). Contributions were received from the International Seed Federation (ISF) and from the International Association of Horticultural Producers (AIPH) and are included in Annexes I and II to this document, respectively.

4. On the basis of existing material, the Office has prepared document UPOV/EXN/EDV Draft 1 "Explanatory Notes on Essential Derived Varieties under the UPOV Convention", in order to address points 1, 2 and 5 in paragraph 2 to this document.

5. The CAJ-AG is requested to:

(a) comment on the draft explanatory notes contained in document UPOV/EXN/EDV Draft 1;

(b) consider the information provided in the Annex to this document; and

(c) consider if explanatory notes should be developed to address matters raised points 3 and 4 of paragraph 2 above.

[Annexes follows]

ANNEX I

INTERNATIONAL SEED FEDERATION (ISF)

ISF View on Intellectual Property
(Bangalore, June 2003)

Excerpt on Essential Derivation

1.4 Essential Derivation

1.4.1 Definition of essential derivation

Article 14.5(b) of the 1991 Act of the UPOV Convention states that 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.

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

1.4.2 ISF consideration on essential derivation

ISF strongly supports this concept of essentially derived varieties (e.d.v.) which allows the new technological developments to be taken into account. It has also the potential to drastically decrease the risk of plagiarism in plant breeding. ISF also considers that this principle, whilst appropriately strengthening Breeder's Right, does not restrict the breeder's exception, a key feature of the UPOV Convention.

ISF notes that even if there are not yet international agreed-upon professional rules and usages for assessing essential derivation and for solving disputes, the concept has already greatly contributed to avoid infringement, breeders being more careful in their breeding programs.

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. ISF stresses that the determination of essential derivation is not part of the procedure of the granting of the Breeder's Right. However, registration data of the varieties based on UPOV guidelines should be available after granting of rights.

1.4.3 ISF interpretation of article 14.5 of the 1991 Act of the UPOV Convention

i) The **technical aspect**

For a variety to be considered as essentially derived, it must fulfill three requirements in relation to the initial variety while retaining the expression of the essential characteristics of the initial variety:

- clear distinctness in the sense of the UPOV Convention;

- conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety;

- predominant derivation from an initial variety.

If one of these requirements is not fulfilled, there is no essential derivation.

ii) The **legal aspect**

The principle of dependence only exists in favor of a non essentially derived protected variety. This means that:

- the initial variety must be a protected one;

- dependence can only exist from one protected variety alone;

- an essentially derived variety can be directly derived from the initial variety or from a variety that is itself predominantly derived from the initial variety. It is possible to have a "cascade" of derivation. However, each essentially derived variety shall only be dependent on one, the protected initial variety. A cascade of dependence shall not exist, the principle having been introduced to better protect the breeder of the initial variety and not those having made derivations from his work.

Essential derivation is a matter of fact whereas dependency resulting therefrom 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. forever. 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., but not dependent of that no longer protected variety. The reason for this lies in the spirit of the concept of dependency. This principle has mainly been introduced to protect more efficiently the initial breeder and not those who make derivations from his work.

1.4.4 Assessment of essential derivation

The assessment of essential derivation takes place after establishing that a variety is clearly distinguishable from all varieties which are a matter of common knowledge and should consider the following requirements:

- conformity to the initial variety in the expression of the essential characteristics that result from the genotype or the combination of genotypes of the initial variety;

- predominant derivation from the initial variety.

The first requirement could be based on reliable phenotypic characteristics: either close relationship in general which could lead to a "conformity threshold" parallel to the minimum distance threshold used for distinctness or only small differences in some simply inherited characteristics. If this requirement is considered as fulfilled, then, we have to assess the second one, which is "predominant derivation from the initial variety".

Predominant derivation from the initial variety implies that the initial variety or products essentially derived there from have been used in the breeding process.

In order to prove that use, various criteria or a combination thereof may be used:

- combining ability
- phenotypic characteristics
- molecular characteristics
- breeding records.

1.4.5 Burden of Proof

According to the general rule of burden of proof**,** it is to the owner of the initial variety to prove essential derivation and then claim dependency. However if the owner of the i.v. can give reasonable evidence of essential derivation (*prima facie* proof), ISF is in favor of the reversal of the burden of proof. For *prima facie* proof, the following elements should be sufficient:

- strong phenotypic similarity;
- only small differences in some simply inherited characteristics;
- strong genetic similarity.

If the owner of the i.v. has fulfilled one of the above requirements, then the second breeder would have to prove that there is no predominant derivation, or that he had not used the i.v., or a variety essentially derived from that i.v.. The use of distance coefficients to define a threshold which would be a trigger point for the reversal of the burden of proof is another interesting approach. Up to now, ISF has mainly worked on thresholds based on distances measured by molecular markers. Geneticists and statisticians consider that technically it is equally possible to measure distance coefficients using morphological markers but that these distances are not always reflective of genetic distances or of pedigree relationships. Additionally, use of morphological characteristics would probably be more difficult due to environmental factors, and much more expensive.

The threshold would divide the scale of conformity into two parts: below the threshold there would be no presumption of essential derivation, above the threshold there would be presumption of essential derivation and the burden of proof of non predominant derivation would fall on the breeder of the putative e.d.v.

The threshold will certainly vary from species to species, depending on the existing genetic variability within the species and the established breeding procedures[1]. ISF recommends to its members, in any case of dispute, to first enter into a conciliation or arbitration procedure according to ISF Conciliation and Arbitration Procedure Rules before resorting to legal action.

1.4.6 Entry into force

After careful consideration of the economic, legal and technical aspects involved, the following is concluded:

In the case of implementation of the 1991 Convention (see chapter IX of the 1991 revised text of the UPOV Convention), the national laws should include the following:

i) All existing Breeder's Right before implementation should be regarded as independent and should enjoy all the rights given by the revised Convention.

ii) Nevertheless, only where such a protected plant variety is not itself an essentially derived variety (e.d.v.) should the holder enjoy the rights under article 14, par. 5 of the revised Convention.

iii) All e.d.v. for which an application for Breeder's Right has been filed or acts mentioned in article 14, par. 1 of the revised Convention have been done first on or after the implementation date should be subject to the new concept of e.d. and dependency.

iv) The date of filing an application for Breeder's Right should be decisive and not the date of granting Breeder's Right.

v) There should be no difference between the date of application and acts with the plant variety because at the date of application it can be imputed that acts have already been done with this variety (e.g. production of propagating material).

[1] ISF sections/members are working on the definition of a possible threshold for various species, in order to put this legal concept into practice. Studies have been carried out on tomato, rye grass, maize, and results have been published. Studies are going on on lettuce and oilseed rape.
In addition some maize breeders are working on a contractual solution for implementation of the e.d.v. concept by defining a free "green" zone without dependency, a "red" zone with automatic dependency and an "orange" zone in between where a possible dispute should preferably be settled through arbitration. Such "agreement", which balances the interest of a free "green" zone with a systematic dependency "red" one, will be binding only on the signatories.

INTERNATIONAL SEED FEDERATION (ISF)

**Principles of a Code of Conduct in
Essentially Derived Varieties of Perennial Ryegrass**
(Adopted in Chicago, May 2002)

1. The 1991 Act of the UPOV Convention entered into force in 1998 and introduced the concepts of essential derivation and dependency from an initial variety (i.v.).

2. The Forage Plants Section of ASSINSEL conducted in 1997 and 1998 a model study to evaluate tools and to determine possible thresholds for assessing putative essential derivation.

3. Based on the results of the study, the Section proposed during its meeting in Melle in January 1999 to adopt a provisional threshold, 7 for the squared Euclidean distance between pairs, using 60 plants per variety and a 5 primer combination. (The testing protocol, as annexed to this present code of conduct, should be followed precisely for assessing the distance). That proposal was confirmed by the section during its meeting in Melle in March 2002 and the following principles for a Code of Conduct were agreed upon.

4. In case of doubt a new variety is essentially derived from an i.v., doubt based on the fact that the new variety presents the essential characteristics of that i.v., the breeder of the i.v. will have, very likely, the squared Euclidean distance between the two varieties measured.

If the distance is 7 or lower, the breeder of the i.v. may ask for ISF arbitration and the arbitrator may ask for the reversal of the burden of proof. The breeder of the putative essential derived variety (e.d.v.) will have to show that he has not practiced essential derivation from the i.v.. The arbitrators also have the right to ensure that the putative i.v. is not itself an e.d.v. from a preexisting variety.

5. The Code of Conduct would only apply to varieties commercialized or registered for the first time after its entry into force.

6. In order to encourage companies to adopt the code of conduct so that it could be possible to refine the threshold based on new molecular data, a transitional period of 5 years will be established after the entry into force of the code of conduct. During the transitional period the companies adhering to the code shall commit themselves:

   - Not to claim any dependency rights for essentially derived varieties commercialized or registered for the first time during the first two years after adoption of the code of conduct.

   - To agree on compulsory licensing of the e.d.v. by the owner of the i.v. at a level of 50% of royalties obtained in normal commercial practices for essentially derived varieties commercialized or registered for the first time during the following 3 years.

7. After the period of 5 years the threshold will be reviewed and, if necessary revised. Then the code will continue to apply and the owner of the i.v. will have the freedom to exercise his full rights as provided for in the applicable laws.

INTERNATIONAL SEED FEDERATION (ISF)

GUIDELINES FOR THE HANDLING OF A DISPUTE ON EDV IN OILSEED RAPE
(Adopted by the Industrial Crops Section, May 2007)

1. The 1991 Act of the UPOV Convention introduced the concepts of essential derivation and dependency from an initial variety.

2. The ISF Industrial Crops section has conducted, from 2001 to 2006, a study to evaluate the possibility to use molecular markers to assess genetic distances of oilseed rape varieties in using bulk samples and to evaluate the inter-variety genetic diversity of spring and winter varieties presently on the market and also the genetic distance between known pairs of varieties.

3. The results of the study are available in the ISF internal report that can be received on request from the ISF secretariat.

4. Based on the results of the study, the ISF working group has decided to propose a threshold of 0.85 Dice genetic distance for both spring and winter oilseed rape varieties, taking into account the present variability available on the market but also having in mind the need to protect effectively future breeding work.

The assessment of the Dice genetic distance must be done according to a technical protocol available at the ISF secretariat on request.

5. The above-mentioned threshold is a trigger point to initiate a discussion between the breeders of the putative initial and essentially derived varieties. If the Dice coefficient is higher than 0.85, the breeders will try to reach an amicable settlement. If this settlement cannot be reached, one or both parties may ask for the arbitration according to the ISF rules for dispute settlement.

6. The guidelines shall apply on all varieties subject to national laws.

7. After a period of five years the protocol and the threshold shall be reviewed in light of the experience gained and the technical and scientific evolution, as appropriate.

INTERNATIONAL SEED FEDERATION (ISF)

Essential Derivation from a Not-yet Protected Variety and Dependency
(June 2005)

Essential derivation, to be decided upon on a case-by-case basis, according to the following Principles

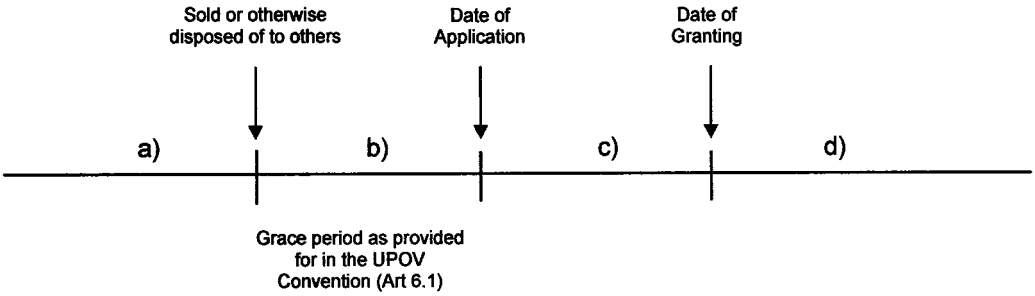
- clear distinctness in the sense of the UPOV Convention
- conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety
- predominant derivation from an initial variety is a fact.

Dependency[2] depends on the status of the initial variety:

1. If the initial variety is not protected, the concept of dependency does not apply

2. If the initial variety is protected, the essentially derived variety shall be dependent from the initial variety

3. If the initial variety was not protected at the time of the act of essential derivation but is granted protection afterwards, according to the following graph, the following conclusions shall apply:



The graph is divided in four periods as regards the initial variety:

a) Before the date of commercialisation (start of the grace period)
b) Between the start of the grace period and the date of application
c) Between the date of application and the date of granting
d) After the date of granting

If the act of derivation is made during the periods b) and c), dependency will start at the date of granting. However, the breeder of the initial variety will, at least, be entitled to an equitable remuneration in line with article 13 on provisional protection of the 1991 Act of the UPOV Convention if the EDV is commercialised during periods b) and c).

Access during period a) needs careful consideration. Access with the consent of the breeder of the initial variety may destroy the novelty of the putative initial variety (ref. article 6 of the UPOV Convention). Any other access may be considered as illegal.

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[2] "Dependency" means, according to article 14(5) of the 1991 Act of the UPOV Convention, that acts as defined by article 14(1) in respect of the propagating material of the essentially derived variety shall require the authorization of the breeder of the initial variety.

INTERNATIONAL SEED FEDERATION (ISF)

GUIDELINES FOR THE HANDLING OF A DISPUTE ON EDV IN LETTUCE
(Adopted by the ISF Vegetable and Ornamental Section, May 2004)

1. The 1991 Act of the UPOV Convention introduced the concepts of essential derivation and dependency from an initial variety (i.v.).

2. The ISF Vegetable and Ornamental section has conducted, in 2001 – 2002, a study to evaluate the inter-variety genetic diversity based on the use of AFLP. Three groups of varieties were used: 35 Butter Head Greenhouse heated (short-day butterhead varieties for heated glasshouse production), 21 Butter Head Field Summer (long day butterhead varieties for outdoor production) and 27 Iceberg varieties of the Salinas-type.

3. The results of the study are available in the ISF internal report posted on the ISF website and in the following publication (Statistical Aspects of Essential Derivation, with illustrations based on Lettuce and Barley, F.A. van Eeuwijk and J.R. Law, Euphytica, 2004), to which it is recommended to look at for further details.

4. Based on the results of the study the ISF working group has decided to propose a threshold of 0.96 Jaccard similarity for the three cultigroups, taking into account the present diversity available on the market but also having in mind the need to protect effectively future breeding work[3][1].

The technical protocol is annexed to the present guidelines. It has to be followed precisely for assessing the genetic distance.

5. The above-mentioned threshold is a trigger point to initiate a discussion between the breeders of the putative initial and essentially derived varieties. If the Jaccard coefficient is higher than 0.96, the breeders will try to reach an amicable settlement. If this settlement cannot be reached, the breeder of the i.v. may ask for the arbitration, according to the ISF rules for disputes settlement and the mediators/conciliators or arbitrators may ask for the reversal of the burden of proof. The breeders of the putative EDV will have to provide the information that is relevant to determining the status of his variety. They may be asked to open their breeding records to an independent neutral expert. (See the ISF arbitration rules for further details)

6. The guidelines shall apply on all varieties subject to national laws.

7. After a period of 5 years the protocol and the threshold shall be reviewed in the light of the experience gained and the technical and scientific evolution.

[3] Thresholds for other lettuce cultigroups (and possibly other species) could probably be determined using the same molecular and statistical approach as for the three lettuce cultigroups of the study.

INTERNATIONAL SEED FEDERATION (ISF)

TECHNICAL PROTOCOL FOR IMPLEMENTATION OF THE ISF GUIDELINES FOR THE HANDLING OF A DISPUTE ON EDV IN LETTUCE
(Adopted by ISF Vegetable and Ornamental Section, May 2004)

Plant material

Three types of lettuce were included in the study, in order to establish this PROTOCOL:

• Butter head for long day outdoor production (acronym FS; 21 varieties)
• Butter head for short day greenhouse production (acronym GH; 35 varieties)
• Crisp head lettuce, USA Salinas type (acronym IC; 27 varieties)

Seed lots

When a seed sample has been sent in an official office for protection purpose, that sample, or a sample of the same seed lot, has to be the reference for marker studies in arbitration process.

DNA samples

A leaf disc will be taken of 10 different plants of each variety and the discs will be pooled. The DNA preparation protocol that is used is described in CJ Steward Jr and LE Via, 1993, Biotechniques 14: 748-750.

Primer combinations

The following 10 AFLP primer combinations will be used: E33/M59, E35/M48, E35/M49, E35/M59, E35/M60, E38/M54, E44/M48, E44/M49, E45/M48, E45/M49.

Genetic similarity

Markers will be scored as present or absent, where presence is represented by a score of 1, while absence is scored as 0. All bands, whether monomorphic or polymorphic, will be used to calculate genetic conformity. Conformity between varieties will be calculated by the Jaccard coefficient. This means that for a pair of varieties the similarity will be given by the ratio of the number of markers with bands in both varieties (1,1) on the number of markers for which at least one band appears in either of both varieties (1,1; 1,0; 0,1).

Precision of estimates for genetic similarity

Standard error for similarity estimates will be obtained by the following procedure. Calculate Jaccard similarity estimates between varieties for each of the 10 sets of markers corresponding to the different primer combinations. In this way, for each pair of varieties, 10 similarity estimates will be obtained. Next, calculate standard deviations across the 10 similarity estimates per variety pair. Finally, calculate standard errors by dividing the standard deviations by $\sqrt{10}$.

The use of 10 primer combinations leads to standard errors of about 0.007 and confidence intervals of +/- 0.014 for the similarities in the upper tail of the distribution of similarity

estimates. This is accepted by the study group as representing a sufficiently high level of precision.

Threshold

A threshold for potential essential derivation cases is set at a value of 0.96 Jaccard similarity by means of the tail principle. (1)

New marker systems

Whenever a new marker system is going to be introduced for essential derivation purposes in butter head or crisp head lettuce, the new system should be calibrated on the AFLP system described in this annex. This means that the rank order of the similarity coefficients between current and new system should be high for the collection (or a representative subset thereof) of FS and GH varieties used in the present lettuce study. In addition, standard errors for individual similarities should be within the same order of magnitude as found in the present study, i.e., be around 1% of the similarity estimate.

(1) Specific remarks :
(This principle works as follows. First define the reference set of varieties for the particular problem. As for the lettuce study, there existed a clear separation between the three types (FS, GH, IC) on the basis of cluster-analyses and multidimensional scaling on Jaccard similarities, it was decided to treat initially each lettuce type separately. Next, within a reference set of varieties, order the similarities from low to high. Finally, choose a cut-off point, or threshold, in the ordered series of similarities above which variety pairs will classify as being suspect. Such a threshold will typically be placed somewhere in the highest 5% of similarities. A threshold is well chosen when for variety pairs above the threshold arguments can be given why these varieties are so similar. Simultaneously, no variety pairs known to be closely related should end up clearly below the threshold.

The lettuce study group has placed the threshold at 0.96 similarity for all three lettuce types included in the study. This threshold was chosen on the basis of the position of 95 percentiles in butter head groups, FS and GH. The 95 percentile is the similarity value for which it holds that only 5% of the variety pairs has higher similarity. For a number of the variety pairs in the upper 5% tail of the distribution of Jaccard similarities for FS and GH convincing reasons could be given for their inclusion in the upper tail.

The crisp head group, IC, had less genetic variation than the butter head groups and its 95 percentile corresponded to a similarity value of 0.98. Still, the lettuce study group argued that the amount of genetic variation found in the butter head groups should serve as a standard to be complied with and for that reason also for crisp head lettuce, a threshold similarity value of 0.96 was installed. Further support for this threshold in the crisp head group was given by the breeding history of many variety pairs with similarities larger than 0.96. Many of such variety pairs might be considered to present examples of derivation.)

INTERNATIONAL SEED FEDERATION (ISF)

Regulation for the Arbitration of Disputes concerning Essential Derivation (RED)[4]

General

ARTICLE 1

1. This Regulation, designated here as RED is constituted within the framework of the general *ISF Arbitration Procedure Rules*, designated here as 'APR', and the *ISF Rules for Mediation, conciliation and arbitration for disputes between professionals concerning the management of intellectual property rights in the field of plant breeding*, designated here as 'MCA'. Where necessary the articles hereunder refer to APR and/or MCA.

   This RED also takes into account the relevant paragraphs concerning essential derivation from the position paper *ISF view on Intellectual Property*.

2. In the case of any doubt, this RED for arbitration on essential derivation overrules the APR/MCA. For issues not ruled by this RED, APR and MCA apply or the Arbitral Tribunal will decide at its discretion.

3. These rules apply to parties who have agreed to ISF arbitration through an arbitration clause or agreement. In the case of a contract between the involved parties or an ISF code of conduct to which the parties are signatories, the provisions of the contract or code of conduct that are different from this RED will overrule the relevant provisions of this regulation.

Definitions

ARTICLE 2

For this RED the following definitions apply:

a. Essentially derived variety (EDV)

A variety that has been predominantly derived from a particular initial variety or an EDV there from and which fulfils the definition of Article 14 paragraph 5(b) of the UPOV Convention 1991.

b. Putative essentially derived variety (PEDV)

The variety in question that may be an EDV of a particular initial variety.

c. Initial variety (INV)

The variety from which the PEDV might have or has been derived.

d. Variety of common knowledge

Any variety which is protected, or listed, or described and published, or used, or sold in the market, or maintained in the public domain or is otherwise publicly known, including varieties applied for protection or listing, from the moment of the filing of this application, if the application results in the protection or listing of the said variety.

[4] Parties may also apply for mediation or conciliation, in which case the rules of MCA as well as the ISF guidelines on conciliation and mediation apply.

e. EDV Threshold

The value of the genetic conformity or distance point that forms, according to a code of conduct or a guideline as adopted by ISF or by another agreement between parties, the trigger point for the reversal of the burden of proof.

f. Breeder

Titleholder of the plant breeder's rights of an INV or EDV concerned, or his mandated agent.

g. Operator

Person or company exploiting the variety concerned.

h. Applicable territories

The territories in which a Plant Variety Protection law is in force which complies with UPOV 1991 or contains a similar provision of essential derivation.

Application for Arbitration, the Deposit Requirement and the Nomination of the Arbitral Tribunal

ARTICLE 3

1. A breeder who suspects that another variety has been derived from his protected INV may apply for an arbitration procedure according to Article 2 APR in combination with Article 3 MCA, with the exception of the requirement of 30 working days, in the country of his choice with an ISF Arbitration Chamber.

   In addition to Article 2 APR in combination with Article 3 MCA, the application shall contain phenotypic and molecular data of his variety compared to the PEDV showing that the PEDV and the INV are genetically and phenotypically very similar so that the PEDV differs from the INV by only one or a few simply inherited characteristics.

   In the case of parent lines of hybrids, data on the lawfully accessible parent line(s) concerned and, if necessary, on the hybrids, which have been produced by the PEDV parent line(s) may be included.

2. The phenotypic analysis or description should preferably meet the requirements of the appropriate UPOV Technical Guideline for the crop concerned and may include additional characteristics. The molecular analysis must be performed by using the agreed methods, as mentioned in the crop specific scheme of this RED. If there is no agreed-upon molecular marker method available for the crop concerned, the method to be used and the EDV threshold as mentioned in Article 2e may be decided upon between the parties.

3. Each molecular method used in this RED must conform to the ISF paper *Issues to be addressed by technical experts to define molecular markers sets for establishing threshold for ISF EDV arbitration.*

4. The breeder or operator of the PEDV may, according to Article 9 APR, within 30 days after the receipt of the copy of the application for arbitration, file the counter claim that the INV is itself an EDV. This claim should be followed within one year after the said 30 days with a clear justification using phenotypic and molecular data. This period of one year may be reduced by the Arbitral Tribunal taking into account the time period

that the breeder or operator of the PEDV had clear knowledge of the fact that his variety was considered to be an EDV by the breeder of the INV. Not fulfilling these time limits may result in dismissal of the counter claim at the discretion of the arbitrators. Paragraphs 2 and 3 of this article are similarly applicable

5. In case the breeder or operator of a variety is in any way accused of infringing the rights of another party by exploiting a variety, which is considered by the other party as essentially derived from his protected variety, the breeder or operator of the PEDV may apply for an arbitration procedure in order to obtain a decision whether his variety has been derived from the said protected variety or not. The application for the arbitration procedure must be according to Article 2 APR in combination with Article 3 MCA, with the exception of the requirement of 30 working days, in the country of his choice with an ISF Arbitration Chamber.

ARTICLE 4

1. For the application for arbitration, the required financial deposit and nomination of the Arbitral Tribunal, Articles 2, 3, 4 and 5 APR in combination with Articles 3, 4 and 5 MCA shall apply.

2. The application for arbitration shall contain the claims, which may include financial damages concerning the alleged infringement acts with the PEDV.

3. Failing the requirements laid down in Articles 3 and 4 with respect to time limits and required documentation may result in a dismissal of the case by the decision of the Arbitral Tribunal. However, before the Arbitral Tribunal decides, parties will have the opportunity to complete their files within 45 days after a written request to do so.

The Arbitration Procedure

ARTICLE 5

Notwithstanding the provisions of Articles 6, 7 and 8 APR in combination with Articles 6, 8, 9, 10 and 11 MCA, the following additional rules of Articles 6, 7, 8, 9 and 10 of this RED shall apply.

ARTICLE 6

1. If the Arbitral Tribunal is convinced that the genetic conformity of the PEDV with the INV is above the EDV threshold, it determines that the breeder or operator of the PEDV has to prove that the PEDV has not been predominantly derived from the INV.

2. If an EDV threshold has not been established for the crop concerned and no agreement concerning a threshold is reached between the parties, the Arbitral Tribunal will decide at its own discretion whether the breeder or operator of the PEDV has to prove that the PEDV has not been derived from the INV.

3. In the case the INV has been counter claimed to be an EDV itself and the Arbitral Tribunal is convinced that the genetic conformity of the INV with another variety is above the EDV threshold, the breeder of the INV has to prove that his INV has not been predominantly derived from that other variety.

ARTICLE 7

1. Before the Arbitral Tribunal takes a decision, both parties will have the opportunity to deposit their arguments in writing, and to comment once in writing on these arguments within 6 weeks of their receipt. It is at the discretion of the Arbitral Tribunal to allow additional cycle(s) of written comments. The Arbitral Tribunal will send copies of the documents immediately and directly to the parties. The Arbitral Tribunal will organise at least one hearing, taking into account the provisions of Article 6, paragraph 1 APR.
2. The Arbitral Tribunal may at any time request the parties to disclose all relevant information concerning the breeding history of the INV and the PEDV.
3. Confidential information or parts thereof, clearly designated as such by the party concerned, will not be provided to any other party, unless the said party gives his consent in writing.
4. For the purpose of this article confidential information shall mean any information that is in the possession of a party, is not accessible to the public, is of commercial, financial or technical significance and is treated and declared as confidential by the party possessing it.
5. Any confidential information affecting one of the parties will be provided to the Arbitral Tribunal under a confidentiality agreement or other appropriate means.
6. Both parties may supply additional phenotypic, biochemical or molecular information, which will be taken into account by the Arbitral Tribunal.

ARTICLE 8

1. The Arbitral Tribunal may decide to have the varieties concerned tested with molecular, biochemical or phenotypic methods or a combination thereof by an independent third party.
2. If the data concerning the parents of a hybrid variety shows a high probability that the hybrid was produced by a PEDV parent line, the Arbitral Tribunal can decide to have the PEDV parent line tested by an independent third party in comparison with the INV parent line.
3. Paragraphs 2 and 3 of Article 3 are similarly applicable.
4. To implement Paragraphs 1 and 2 of this article, both parties shall authorise, the Arbitral Tribunal, at its request, to apply for and receive an official sample of the deposited seeds of the varieties concerned and/or ancestors thereof, if applicable, from the competent authorities or other relevant independent bodies.
5. In the case the said authorities or bodies do not acknowledge such a request from the Arbitral Tribunal, the parties shall arrange to have the seed sent, on their behalf, by this authority or body to the Arbitral Tribunal. If no seed of a variety can be obtained from an independent source, the Arbitral Tribunal will decide how to proceed.

ARTICLE 9

1. The Arbitral Tribunal may, on request of one party, admit this party to bring witnesses or experts. The Arbitral Tribunal may designate one of its members to hear the witnesses or experts.

2. The Arbitral Tribunal may for reasons of confidentiality, at its own initiative or at the request of one party, agree to hear one party in the absence of its opponent. It will inform the other party at least 7 days before such a hearing. An extract of the report of this hearing will be sent to the other party within 15 days of the session.

3. The Arbitral Tribunal may appoint, in consultation with the parties, one or more expert(s) to formulate and provide technical advice. After its decision on such a matter the Arbitral Tribunal will send a copy of the nomination and the assigned task of the expert(s) to both parties directly, with the time frame for the task as determined by the Tribunal.

4. The parties may only once challenge the nomination of an expert through a reasoned written argument sent to the Arbitral Tribunal by registered mail within 8 working days of the receipt of the aforementioned nomination. If the Arbitral Tribunal decides the reasons for the challenge to be justified, it will appoint another expert according to paragraph 3 of this article.

5. The Arbitral Tribunal may require one or both parties to supply all relevant information and to render the necessary assistance to the expert(s).

6. The Arbitral Tribunal will send the draft expert-report that may contain confidential information for review to the party concerned. This party will send his comments within 15 days after the receipt of this document.

7. Directly after the finalisation of the expert-report, the Arbitral Tribunal will send a copy to both parties without the confidential information, unless the owner of that information agrees in writing to its inclusion. A party may, within 15 days after the receipt of the said copy, request to hear the expert(s) in a session of the Arbitral Tribunal. The Arbitral Tribunal will provide parties the opportunity to hear the expert(s) and to bring their own experts. The session will be announced to the parties 15 days before it is held.

8. The Arbitral Tribunal may, through a full or part representation, visit the relevant trials at the premises of one or both parties or a third party. The Tribunal will inform both parties of this visit at least 5 days before. Paragraph 6 of Article 9 RED is similarly applicable.

ARTICLE 10

Each session of the Arbitral Tribunal will be recorded in a written report. Unless agreed otherwise between the parties and the Tribunal, a copy of the full report, accompanied with the productions of the parties that have not already been distributed, will be sent to both parties within 6 weeks after the session.

Withdrawal, Settlement or Award

ARTICLE 11

1. If the claimant or claimants withdraw(s) the case from arbitration according to the rules of Art 10 APR, the status of the contested PEDV or INV will remain unchanged with respect to third parties as before the application for arbitration.

2. If a settlement without an award contains the decision to consider the disputed variety or varieties as being essentially derived, paragraph 1 of this article is similarly applicable.

ARTICLE 12

1. The award is subject to the rules of Article 11 APR. The decision shall contain a clear and well-motivated statement whether the disputed variety is an EDV or not. The Arbitral Tribunal shall deliver the award within 3 months of its last meeting with both parties.

2. The Arbitral Tribunal will decide on the claims as laid down at the application for arbitration according to Article 5 paragraph 1 RED. The allocated compensation should not cover financial damages for more than 5 years before the date of application for arbitration, unless otherwise determined by the Arbitral Tribunal with a motivated decision.

Appeal

ARTICLE 13

1. Each party may lodge an appeal against the award by registered mail to the Secretary General of ISF, no later than one month after the acknowledged receipt of the award as controlled by the postmark, and by fulfilling the financial requirements of Article 12 paragraph 3 APR.

2. The appeal lodged shall contain a clear description of the grievances.

3. The Secretary General of ISF will inform the other party that an appeal has been lodged and will organise the appeal in accordance with Article 13 APR.

4. Articles 2, 6, 10, 11 and 12 and paragraph 1 of Article 7 and paragraphs 1 and 2 of Article 9 of this RED as well as the relevant provisions of Articles 12, 13 and 14 APR are similarly applicable.

5. The Arbitral Tribunal shall make the award, as per to Article 13 APR, within 6 months after the Secretary General of ISF has charged a national organisation with the hearing of the appeal.

6. Except if otherwise decided by the Arbitral Tribunal or the award of first level is reversed, the cost of the appeal shall be at the charge of the appellant.

Entering into force of the Award

ARTICLE 14

1. The award of first instance shall enter into force the day one month after the acknowledged receipt of the award by both parties, and if no party has lodged an appeal within this term. The appeal award enters into force the day of its acknowledged receipt by the parties. In accordance with Article 11 paragraph 7 APR, the final award is legally binding on the parties concerned.

2. If the final decision determines that the INV concerned is itself an essentially derived variety, the breeder of this INV will have no rights on any essentially derived variety from the INV in question, based on Article 14 paragraph 5(a) (i) UPOV 1991 in the applicable territories.

3. Both parties shall inform all other parties with an interest in the case, including possible licensees, about the content of the final award.

4. The Secretary General of ISF may publish extracts of awards without revealing the names of the parties and other information considered confidential. In case the Arbitral Tribunal confirms the PEDV to be essentially derived from the INV, this fact including the variety denominations will be published in the interest of concerned third parties.

5. With reference to Article 18 APR and the relevant provisions of the Conventions of Geneva and New York, if the party declared in default does not implement the award, the party that has won the award may claim enforcement of the award before the civil court of the country in which the other party resides.

6. The party declared in default may, according to the law of the country in which the award has been made, claim the annulment of the award for procedural reasons only. Such a claim does not postpone the implementation of the award unless the civil court in the said country decides otherwise.

7. Article 18 paragraph 4 APR shall be similarly applicable.

Arbitration costs

ARTICLE 15

1. In addition to Article 15 APR, the Arbitral Tribunal shall, unless the parties have agreed otherwise, decide the apportionment of the costs caused by the technical tests and expert advice from Article 8 paragraph 1 and Article 9 paragraph 3 of this RED.

2. For the remaining financial issues Articles 15, 16 and 17 APR and paragraph 1 of Article 18 APR shall apply.

Agreement and Liability

ARTICLE 16

1. The provisions of these rules are binding on the parties involved in the arbitration.

2. With reference to Article 20 APR, the Arbitration Chamber, the Arbitral Tribunal, the Secretary General of ISF, the member associations of ISF and the appointed experts shall in no way be liable to the proceeding parties for any damage or any other consequences arising from their decisions or opinions by the application of these rules.

   The parties will refrain from any claims against the persons or bodies mentioned in the first sentence of this paragraph.

3. Any party or person involved who releases untimely information to persons or organisations other than those directly and professionally involved in the proceedings of the case may be liable for any damage caused by but not limited to loss of turnover, profit or good name of the other party or parties in the dispute concerned.

INTERNATIONAL SEED FEDERATION (ISF)

Issues to be Addressed by Technical Experts to Define Molecular Marker Sets for Establishing Thresholds for ISF EDV Arbitration

1) Sampling of individual varieties

How many individuals of a variety should be profiled? Should the molecular profiles of a single variety be examined using individual profiles of DNA extracted from individual plants or can DNA from several plants of the same variety be examined in one bulk extract? If bulks can be used then what is the minimum number of individuals that should form the bulk for each variety? And what is the maximum number of individuals for each bulk? Should tissues from individual plants be bulked before DNA isolation? Or should DNA from individual plants be bulked after extraction from individual plants? How many DNA bulks does a variety need? The breeding system of the crop will need to be taken into account. The error rate of the marker system will likely have to be taken into consideration, i.e. the ability to detect rare alleles in a bulk sample. Is it important to be able to detect rare alleles or is there a threshold of allele frequency below which alleles need not be detected? If so, what is that threshold? Should there be at least an initial study of heterogeneity using a representative sample of varieties? How will data from heterozygous loci (for inbred lines and varieties of self pollinated crops) be dealt with? Should there be minimum standards required for homozygosity?

2) Gauging discrimination power of markers

Which varieties should be used to establish a set of varieties that will be used to gauge the discriminative power of candidate molecular marker loci, the genomic coverage of markers, and the number of markers that should constitute a panel for determining information useful for establishing EDV status? Will related species (germplasm) be included for analysis? Which varieties would constitute a survey of the relevant breadth of genetic diversity likely to be encountered in future EDV determinations? Is it important to use varieties that have already been established as distinct, uniform and stable? Is it important to include some varieties that could be regarded as EDVs due to known close pedigree relationships and/or morphological similarity to other varieties included in the set of “standard” varieties? Is it important to include varieties of well-known pedigree relationships (i.e. publicly bred inbred lines of known pedigree)? Is it necessary to include varieties that represent different eras in the history of breeding of the crop? Is it important to include varieties that are of significant importance to the industry (grown on large area) at different periods although they may not necessarily represent unique germplasm?

3) Type of molecular marker system

What are the acceptable types of molecular markers? Is it essential that the marker is co-dominant (detecting both alleles at one locus)? Will non-PCR based markers be excluded? If more than one marker type is potentially usable then what criteria would be used to prioritise the choice of marker type? Is it important to understand the genetic control of the markers? What criteria and standards should be used to determine identity, type, number, and genomic coverage of molecular markers? Should markers come from expressed regions of DNA, from anonymous coding regions, from regions of repeat DNA, or from a combination of chromosomal regions? Is map information needed? Should each chromosome arm be sampled? What density of chromosomal coverage is required?

4) Eligibility of markers

What minimum criteria must markers pass to be considered as candidates for inclusion in the set used for EDV? How to determine? Must profiles be interpretable in terms of alleles? What minimum discrimination power (polymorphic index content) is required? Do certain criteria rule out eligibility, e.g. a certain level of stutter bands? For polyploid crops (such as cotton) will the monomorphic fragment be included in data analysis although polymorphism is revealed by the same primers (at the same or different locus)? Are markers available publicly or against licenses, or not available to third parties?

5) PCR conditions

Should specific PCR conditions be specified? If so, what are these? E.G. addition of +A. Is it possible to use one or a very few PCR conditions for the same type of molecular marker system (e.g. SSR)? Should PCR based markers be amplified singly in individual tubes or wells or can they be amplified in a multiplexed format to increase throughput and provide cost efficiencies? If Yes, then should the, multiplex be carried out before PCR or only after PCR amplification of individual loci?

6) Gel running conditions

Should PCR based markers that require molecular size to be measured be electrophoresed singly in individual gel lanes or capillaries or can they be run in a multiplexed fashion to increase running speed and provide more efficient running costs? If markers can be multiplexed then are there specific criteria that must be observed? If so, what are these criteria?

7) Recording data

What molecular weight standards are needed as a basis from which to measure molecular sizes of amplified fragments? What threshold criteria should be used to determine whether an amplified product is of significant magnitude to warrant recording? What are the procedures and equipment that should be used to objectively record molecular weights? How should data be recorded - as molecular sizes or as discrete binned data? If data should be recorded in terms of discrete bins then what are the criteria for establishing bin sizes? What standards should be used to validate marker identity and to check repeatability of scoring and databasing?

8) Measuring distances

Which statistical methods should be used to measure genetic distances? Should the data be analysed as qualitative data (presence vs. absence) or as genetic data (alleles at specific loci)? How are data used from loci that exhibit two or more (a possibility if varieties are comprised of bulked individuals) alleles per locus as compared to loci where a single amplified product is recorded?

9) Data quality

Will two (or more?) laboratories conduct experiments to ensure the data quality? How will those experiments be planned to ensure there is no bias in data generation, scoring or interpretation? What means (if any) are needed to ensure or to at least evaluate consistency of data generation, scoring and interpretation?

10) Data use and availability

How will the data be used? Will the data be accessible to the public, or only available on a restricted basis, and to whom?

INTERNATIONAL SEED FEDERATION (ISF)

Guidelines for the Handling of a Dispute on EDV in Cotton

(Adopted by the Industrial Crops Section, May 2007)

1. The 1991 Act of the UPOV Convention introduced the concepts of essential derivation and dependency from an initial variety.

2. The ISF Industrial Crops section has conducted a literature review on the use of molecular markers to identify a putative EDV in cotton and survey of industry breeding practices in *Gossypium hirsutum* and *Gossypium barbadense* cotton varieties.

3. The results of this literature review are available at the ISF Secretariat on request. Due to the genetic diversity within individual allotetraploid cotton varieties no EDV threshold based on molecular markers can be assigned at this time. However, considering the global importance of cotton and the advancement in adoption of the 1991 Act of the UPOV convention, the ISF Industrial Crops section desires to establish an EDV threshold based on parentage and continue to assess the scientific progress in the application of molecular markers to cotton variety identification.

4. Based on the results of this review and survey, the ISF Industrial Crops section has decided to propose an EDV threshold in cotton based on parentage. When the phenotypic or genetic characteristics of a variety suggest that its parentage could have been derived from a plant or plants created by two or more backcrosses using the initial variety as the recurrent parent, or has a coefficient of parentage value of 87.5% or more, this second variety can be considered a putative EDV.

5. The above-mentioned threshold is a trigger point to initiate a discussion between the breeders of the initial variety and the breeders of the putative essentially derived varieties. If a settlement cannot be reached, the breeder of the initial variety may ask for the arbitration, according to the ISF rules for disputes settlement and the mediators/conciliators or arbitrators may ask for the reversal of the burden of proof. The breeders of the putative EDV will have to provide the information that is relevant to determining the status of his variety. They may be asked to open their breeding records of the putative EDV to an independent neutral expert. (See the ISF arbitration rules for further details)

6. The guidelines shall apply on all varieties subject to national laws.

7. After a period of 5 years the threshold shall be reviewed in the light of the experience gained and the technical and scientific advancements.

INTERNATIONAL SEED FEDERATION (ISF)

Guidelines for the Handling of a Dispute on Essential Derivation of Maize Lines
(Adopted by the Maize and Sorghum Section, May 2007)

1. The 1991 Act of the UPOV Convention introduced the concepts of essential derivation and dependency from an initial variety (i.v.).

2. The ISF View on Intellectual Property (adopted June 2003) supports the UPOV Convention and clarifies various technical and legal aspects of essentially derived varieties (EDV).

3. There have been several studies conducted to determine if genetic markers systems can be used as a tool to determine the possibility that one variety may have been derived from an initial variety. The key papers are:

   a. Identifying Essentially Derived Varieties with Molecular Markers. Heckenberger et al. 2005 TAG 111:598

   b. Study on Essential Derivation in Corn in North America. Charles W. Stuber. North Carolina State University. 2005

   c. Synthesis of Studies conducted by SEPROMA on the estimate of genetic distances between maize inbred lines. B. Andreau, D. Dubrevil, D. Perret, F. Azanza, A, Charcosset. IRNA Station de Genetique Vegetale Ferme du Moulon F-91190 Gif/Yvette, France. SEPROMA 17 rue du Louvre, F75001 Paris, France December 2003

   An additional study was commissioned using the statistical model used in the Heckenberger et al study and the markers selected for use by the SEPROMA studies. The results are described in a paper ISF EDV Study, May 8, 2006. Martin Bohn, University of Illinois-Crop Science.

   The conclusion of these studies is that molecular marker systems can be used to differentiate between inbred lines of maize. It is further concluded that a threshold can be set that could initiate the discussion as to the derivation of one variety from an initial variety.

4. ISF recognizes that marker systems and specific marker sets will change over time as the technologies develop. As of the date of the adoption of this paper, simple sequence repeat (SSR) systems are the most commonly used. The use of this system is most effective when the following criteria are applied:

   a. A minimum of 150 SSR markers are employed

   b. The SSR markers must be highly polymorphic

   c. The SSR markers should be uniformly distributed across the chromosomes – 80% coverage of the genome (minimum of 75 bins)

      i. Average of 2 markers/bin (minimum = 1, maximum =4)

ii. Distance > 5 Cm

iii. Minimum of 3 alleles/marker

iv. PIC minimum 0.3

v. Average PIC of the set between 0.6 and 0.7

5. The studies suggest that using a marker set as described in point 4 would indicate, with a low error rate, that EDV might be a question if the homology, based on the Rogers distance, is 82% or higher.

6. The ISF Maize and Sorghum Section does not support a central database on the DUS of maize lines as described by the molecular markers. It is the burden of the inventor of the initial variety to determine if there is a question of EDV. Once the threshold of 82% is determined, other criteria should be evaluated including combining ability, phenotypic characteristics, and breeding records. With a sufficient weight of evidence, the burden of proof shifts to the breeder of the putative essentially derived variety in question.

7. In order to help arbitration in a case of dispute, the ISF Maize and Sorghum Section recommends considering a second threshold of 90% using all the markers as a strong indication of predominant derivation.

8. Because of the rapid pace of the technology development, the threshold and measurement technique described in this paper will be reviewed every five years and adjusted as necessary. In case of change in the measurement technique, the new protocol will be tested against a set of lines used for the establishment of the agreed threshold. This set of lines should be kept in a gene bank.

ANNEX II

INTERNATIONAL ASSOCIATION OF HORTICULTURAL PRODUCERS (AIPH)

AIPH recommendations or guidance concerning Essentially Derived Varieties (EDV's)

The International Association of Horticultural Producers (AIPH) is honoured to contribute herewith the enclosed recommendations and guidance's concerning Essentially Derived Varieties (EDV's).

General statement

Innovation and products renewal are the basis for progress in the ornamental sector.

Therefore plant breeding is fundamentally important. The AIPH supports a Plant Breeders Rights system that stimulates breeding. A good working Plant Breeders Rights system is very important. Though the EDV rules seem to favour existing breeders above new breeders by making it more difficult for new breeders to receive a new independent breeder's right.
The AIPH supports rules and regulations that stimulate product renewal.

The UPOV EDV regulation

AIPH makes note of the concept of EDV in the introduction of article 14.5 by UPOV Convention 1991.This paragraph introduces varieties that are essentially derived from another protected variety.

These regulations define that if a breeder brings a new variety onto the market that is not significantly different from its parent (protected) variety, he can apply for a breeder's right but still needs permission from the owner of the parent variety, who can exercise full rights to the breeder of the essentially derived variety. In other words: a mutation can have breeder's right protection but the finder has to ask permission from the breeder of the initial variety if he wants to sell material of this new mutation. In general the intention was that mutation finders who hardly did any breeding work still have to pay a kind of royalty to the breeder who did all the work.

One of the main principles of PBR is the so called breeders exemption. This allows breeders to use protected varieties for their breeding programs. As we all know new varieties obtained by breeding sometimes hardly differ from the parent varieties. AIPH is of the opinion that the rules on EDV may not restrict this breeders exemption in any way and can hardly belief this can be the intention of the breeders organisations either. So in the rest of our comments we will focus on the problems related to mutants.

Since the introduction of article 14.5 Convention 1991, AIPH has raised the question. Can the problem of EDV (or in other words the mutation problem) be solved with a juridical solution? Our opinion is that essentially the EDV mutation issue is not a juridical one for the following reasons:

1. The existing EDV rule as described in article 14.5 of the Convention does not agree with the juridical ground and the essence of the UPOV Plant breeder's right system.

2. The EDV rule complicates the mutation issue instead of simplifying it.

Ad reason 1:
The goal of PBR is to stimulate plant breeding. Conversely it is not the goal to supply monopolies to existing breeders, nor to give certain breeders economical powers through cartels and to benefit someone breeders above other breeders. On the contrary current anti cartel rules, especially in the EU, are strongly enforced by the authorities with the aim to avoid illegal competition and to forbid cartel agreements. The EDV regulation could easily create these scenarios.

As said, the goal of PBR is to stimulate plant breeding by an intellectual property rights system. This ensures that we (the society) except that certain entrepreneurs can for certain products, during a certain period of time and under strict conditions, gain a monopoly. The only reason for this is that we as society have the opinion that it is important that certain intellectual and/or economical activities are stimulated, because these activities contribute to technical and intellectual progress, which subsequently supplies important and useful products to our society.

The existing EDV regulation is difficult to understand in the perspective of the essence of the intellectual property right system. The regulation discourages the breeding activity, as it's difficult to imagine any commercial situation in which the holder of an existing breeder's right would honour someone else's EDV and give that person permission to exploit the EDV in the market. Contrary, this could damage the holder of the first existing breeder's right.

Ad reason 2:
The EVD regulation makes the mutation issue complex instead of simplifying it. Before the enforcement of the UPOV Convention 1991, (in a nutshell) one relevant question had to be answered before there could be a ruling granted on a new PBR. "Is there a new variety or not?" Since the introduction of the EDV in 1991, there became a second question which had to be answered first. "Is this new variety essential derived from another variety, yes or no?" Unsolvable questions arise, for example: the differences between certain tomato, vegetable and cucumber varieties are much more insignificant than the differences between flower varieties, but the regulations make no differences between vegetables and flowers (ornamentals). We believe there are differences that have to be recognized. For the determination of tyres between EDV vegetable varieties and EDV ornamental varieties, different measures for vegetables and ornamentals should be used by the experts. Principles as 'essential characteristics' could be useful in conflicts to determine if there is a new and independent variety, but these principles are rather vague and lead to potential problems in practice. The development of jurisprudence might help to determine the tyres, but until now too few cases have been brought to court for such a development.

One of the criteria for EDV is that the derived variety has to be independent and to be different from the origin. But what is an independent variety from an juridical point of view, as every variety is biological originating from other varieties?

Because of the fact that every new variety, like every living thing in nature, is borne from parents, the only question here is: is the offspring different enough from his parents to grant him/her a new breeder's right. Governments and their controlling bodies should take their responsibilities in setting out a logical, fair and consistent system in their decision-making process when they grant breeder's rights. In addition to this it has been realised during recent decades, how difficult it is for controlling bodies to decide on the question as to whether there is a new variety or not. As said earlier the introduction of an EDV exasperates these problems.

AIPH mentions two other important questions about the correct juridical base of EDV:

What is the exact meaning of UPOV definition in UPOV Convention 1991 in art. 1, iv : "breeder means the person who bred or discovered and developed a variety". Is discovered and developed imperative or does this definition says discovered and / or developed?

We do not fully understand what the UPOV means with "the person who bred". This text suggests UPOV knows.

As farmer, one should think a breeder is a person who makes new varieties.

The legal meaning is that of a person who works out in his mind, a thought that leads to a new variety.

We do not protect a physical plant but the thought bringing process of a new variety.

The legal system of intellectual property rights is to distinguish these property rights from physical properties. An intellectual property is the fruit of the processes of the mind. An abstract thought that can be protected by an intellectual property right, in our case breeder's right.

So a new variety and the exclusive right to apply for a breeders right is conjured up in the mind. Discovered relates to an intellectual spiritual process in the mind, i.e. this has nothing to do with the physical activity of wandering around in a forest and find a new plant by seeing or smelling.

What is the meaning of "and developed" in this definition? Does it mean two separate thinking steps: first you discover in your thought process a new variety and than you develop in your thought process a new variety?

The system of intellectual properties is that new intellectual properties arise, originate in the mind.

It is clear, AIPH has fundamental problems with EDV. Our fear is that in the final analysis this regulation will not stimulate breeding at all but in fact will encourage the opposite. In the example in vegetables, as mentioned before, we see that the differences between existing new tomato or cucumber varieties are extremely small and often concentrate on important but slight improvements, like the introduction of certain resistances. And in general we can see that when you start breeding with a new crop the progress you make with relatively small investments is initially enormous. But the more important the crop becomes, often through that same breeding work, the more investments the breeding requires and the less the degree of progress is made. If you bring that all under an EDV this type of breeding might stop or at the very least, it will reduce healthy competition amongst breeders.

Nevertheless AIPH admit that since the introduction of it in the 1991 Convention the existence of the EDV regulation is a fact. And in the course of time the practise teaches us that for the most part, conflicts are solved between the breeder from the origin variety and the holder of the alleged EDV or the mutant finder.

However AIPH pleads from the juridical point of view for another solution than the now existing EDV regulation in the UPOV Convention (and consequently in all the legal systems which are based on UPOV). We base our opinion on the arguments as written down above.

But concerns regarding the fact it will take some time before Conventions will be changed and knowing until then breeders and growers will have to deal with the now existing EDV regulation, AIPH gives the following recommendations to these rules:

In the UPOV EDV regulation two elements are significant:

- an EDV need not be protected and may therefore entirely elude the attention of the authority granting the holders' rights

- if an EDV exists yes or no, depends on the question if the holder of the right of the original variety and the holder of the alleged EDV come to an agreement on exploitation. If not, they have to go to Court.

Application of the UPOV EDV regulation has resulted in the situation where someone has cultivated an EDV, but that person is unable to exploit that variety without permission from the holder of the right to the original variety. The two holders must therefore come to some agreement on exploitation.

While the Regulation does not say so in as many words, it is in fact the holder of the original variety, whose right is involved, who must demonstrate that another variety is derived from his variety. There is accordingly no direct role in this for authorities charged with granting holders' rights. In this context, an EDV need not be protected and may therefore entirely elude the attention of the authority granting the holders' rights.

If the owner of the alleged EDV does not deny that status for the variety, the parties will have to agree on how to exploit the EDV.

If the holder of the alleged EDV denies that his variety is an EDV, the Court will have to have the final word.

AIPH mentions the following comments in relation to these two elements.

EDV registration
It is possible that the holder of the alleged EDV can apply for a PBR at one of the official national or international authorities, without the knowledge of the holder of the right of the original variety about this application. If the holder of the existing right is unaware of the application, the applicant could realize meanwhile an independent new PBR. The only option which has left in this case for the holder of the right of the original variety, is to go to Court.
For this reason AIPH pleads for clearness and transparency about the fact that it concerns an EDV in the registrations application for PBR application, but also in the registrations of granted PBR's. For all parties involved, breeders, growers and authorities, it is important to have clearness about the status of the application and of the granted PBR, whether this is a mutation, an EDV or one of the *certain other varieties* as described in article 14 (5) of the 1991 UPOV Convention.

In this respect AIPH mentions the fact that in most licence agreements between breeder and grower for the exploitation of plant varieties, the condition is written down that the grower

has to inform the breeder if he has found a mutant in one of the varieties on which the breeder has PBR. To support transparency AIPH advises the involved parties in her 'Checklist for breeder and grower to make a license agreement for the exploitation of plant varieties' (available on the AIPH-website) to make an agreement about the assignment of each and every mutation from the licensor to the licensee.

Essentially derived from another variety
There are several difficult and vague conceptions and ideas used in the EDV regulations. For example, what is 'predominantly derived from the initial variety' (see UPOV article 14 (5 b, sub (i)), what is 'clearly distinguishable' (see UPOV article 14 (5 b, sub (ii)) and what are 'essential characteristics' (see UPOV article 14 (5 b, sub (i) and (iii)) ?

AIPH again brings in mind the minimal differences between initial and new varieties that can be the result of intensive breeding work and also draws attention to the fact that a mutant can differ significantly from the initial variety. Examples are numerous of completely new types, shapes and colours of the stems, leaves and flowers of ornamentals.

AIPH agrees with the opinion of Mr. B. Kiewiet , President of the CPVO, as mentioned in his speech for Plantum NL in March 2006, where he said: "The answer to this ought to lie within the definition of an EDV. But, as pointed out earlier, this is sufficiently vague as to lead to potential problems in practice. It is, therefore, a wise initiative for ISF and CIOPORA to try and agree on codes of conduct that can be used on a voluntary basis for resolution of an EDV dispute. The courts would not be bound by any such code, but would be inclined to lend their significant weight to whatever had been agreed between growers at an international level".
AIPH doubts however on the idea that codes of conducts will bring the solution. It is a very big job to find codes which foresee in all the theoretical possibilities in the definition there is enough distance between a variety and a derived variety (and as said above in paragraph *ad reason 1:* every variety is biological derived) to be an independent right instead of an EDV. Stronger AIPH asks UPOV if this organisation itself is able to give the right definition of an EDV ?

AIPH has the opinion that the main criteria is that there must be a significant extent of agreement at the morphological and phenotypical level. The District Court in The Hague decided in line with AIPH's opinion in a case between Astée Flowers and Danziger 'Dan' Flower Farm (13 July 2005). This Court made some findings in principle on the expression 'essentially derived variety'. The appeal in this case will be continued on the 6th of September 2007 and AIPH is very interested in the outcome of this case.

AIPH opinion is supported by the authors of the book: European Community Plant Variety Protection, (Oxford University Press 2006, pages 121-126). The authors of paragraph 6.31 mentioned that another important feature of the definition of an EDV has been laid down in article 13 (6) (c) of Council regulation EU 2100/94: it must conform essentially to the initial variety in the expression of its characteristics that result from the genotype or combination of genotypes of the initial variety. There is the exception, of course, of the (presumably very few) differences between the varieties in question. In this context, the term 'genotype' should be interpreted as meaning the entire genetic constitution of individual plants, which belong to a particular variety. The expression 'combination of genotypes' entails the possibility that two or even more genotypes, although distinguishable from each other, can still be regarded as constituting just one variety. Furthermore, in our opinion the words 'in expression of its characteristics' cited above imply that this provision will only be applicable if the breeder's work has resulted in one or more new morphological or physiological characteristics capable

of precise recognition and description. In other words, merely changing the genetic structure of plants, without being able to 'prove' this modification through the expression of morphological or physiological features, will not lead to a novel and distinct variety.

Conclusions

AIPH's contribution to recommendations or guidance concerning Essentially Derived Varieties (EDV's) has been derived logically. AIPH has the following elements in it:

1. AIPH has fundamental problems with EDV from the juridical point of view and therefore pleads for a solution other than the now existing EDV regulation in the UPOV Convention. It does not agree with the juridical basis. The essence of the UPOV Plant breeders right system and on base of our arguments herein, it follows that AIPH wishes to not regulate this issue by law.

2. Accepting the fact that EDV at this moment is regulated by law, AIPH agrees with the explanation as given by the authors of the book 'European Community Plant Variety Protection', here quoted, "*that the provision of EDV will only be applicable if the breeder's work has resulted in one or more new morphological or physiological characteristics capable of precise recognition and description.*" In other words, merely changing the genetic structure of plants, without being able to 'prove' this modification through the expression of morphological or physiological features, will not lead to a novel and distinct variety.

3. The writers of the definition in the book European Plant Variety Protection follow a good line of thinking but these authors too finally have to answer the question how to interpret the differences of morphological and physiological characteristics. The breeders right serves to stimulate the abstract process leading to new varieties. The question of morphological and physiological characteristics comes after that initial process in the mind.

4. Regulations of any kind on EDV may never block the breeders exemption as this is a very important possibility to improve the assortment of any crop, is a basis for fair competition between breeders and opens the possibilities for new breeders.

5. Breeders right serves the general interest of society: stimulating breeding. The general interest of stimulating breeding and the interests of breeders associations are not always equal. Breeders associations work for the interests of their members. AIPH respects breeders associations and organizations and understand that is the goal of these associations to serve the interests of their members. Existing breeders have opposing interests and do not want new competitors. The society in general and the growers in particular have interest in new varieties and do not question themselves as to where these varieties come from: existing breeders or new breeders. AIPH is not in favour of rules that make the entrance to the market for new varieties more difficult or rules that strengthen the position of existing breeders against the position of new breeders.

6. EDV seems to strengthen and benefit the existing breeder above a new breeder by raising the EDV question in two ways. (See paragraph above : ad reason 2, quoted: "Is there a new variety or not?" Since the introduction of the EDV in 1991, there became a second question which had to be answered first. "Is this new variety essential derived from another variety, yes or no?").

7. This EDV question “Is this new variety essential derived from another variety, yes or no?”. will never be asked by the breeder himself. It is not in his best interest. An existing breeder that finds a mutant in his own stock can apply for a full new breeders right on his own mutant. Secondly EDV gives existing breeders a legal weapon to question every new variety of another breeder. The chance that a breeder chooses to use this legal weapon is not unthinkable. Every new variety from another breeder can compete with his existing variety and can damage his commercial interests and market position.

8. AIPH considers it as a disadvantage that questions of proof continuously are mixed up with principal law system questions . First breeders right has to be formulated correctly ie. by answering the following questions. What is a variety, what is a new variety, who is a breeder and when can a breeder apply for a breeders right? It is after these questions are answered that the end set of questions arise regarding proof and evidence, control, demonstration of the right or how can a breeder defends his rights and what he can do about infringement against his claim has to be solved. These are essentially two different types of questions. The answers to the last set of questions has to be given, but on another place than in a PBR-law. AIPH recognizes the sometimes difficult position of breeders right holders and supports initiatives to strengthen the breeders right holders but not by favouring existing breeders right above new breeders.

[End of Annex and of document]