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ADMINISTRATIVE AND LEGAL COMMITTEE

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CHARACTERISTICS USED IN DISTINCTNESS TESTING

Document presented by the Office of the Union

Introduction

1. At its thirty-seventh session, held on October 27, 1997, the Administrative and Legal Committee examined the interpretation of the words “expression of the characteristics resulting from a given genotype or combination of genotypes” in Articles 1(vi) and 14(5)(b) of the 1991 Act of the UPOV Convention. It did so essentially as part of a study on the use of biochemical and molecular tools, especially those permitting DNA analysis. The record of the discussions appears in paragraphs 14 to 23 of document CAJ/37/6.
2. The Committee decided to convene a Working Group to establish a basis for discussion for the present session. The Working Group met on February 12, 1998. It was composed of John V. Carvill (Ireland), Georg Fuchs (Germany), Huib Ghijsen (Netherlands), Joël Guiard (France), Yasuhiro Hamura (Japan), Raimundo Lavignolle (Argentina), Johan Pieter Pluim Mentz (Netherlands), Richard J. Staward (United Kingdom) and Katsumi Yamaguchi (Japan).
3. This document has been drawn up on the basis of the Working Group’s discussions.

Legal Background

The Convention Texts

4. Article 1(vi) of the 1991 Act of the UPOV Convention reads as follows (italics added):

“For the purposes of this Act:

[...]

(vi) “Variety” means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder’s right are fully met, can be

- defined by *the expression of the characteristics resulting from a given genotype or combination of genotypes*,
- distinguished from any other plant grouping by *the expression of at least one of the said characteristics* and
- considered as a unit with regard to its suitability for being propagated unchanged.”

5. Article 7 reads as follows:

“The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. In particular, the filing of an application for the granting of a breeders’ right or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to the granting of a breeder’s right or to the entering of the said other variety in the official register of varieties, as the case may be.”

6. The protection given to a variety extends, when the relevant conditions are met, to varieties essentially derived from the protected variety, which are defined as follows in Article 14(5)(b) (italics added):

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

(i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining *the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety*;

(ii) it is clearly distinguishable from the initial variety and

(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in *the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety*.”

Interpretation of the Texts

7. The Working Group regarded the present provisions as being an adequate working base.

8. The Working Group considered two propositions concerning the function of “the expression of the characteristics resulting from a given genotype or combination of genotypes” in the 1991 Act:

- (a) The words could refer to inheritable (and actually inherited) characteristics;
- (b) The words could refer to characteristics that had to be characteristics of the phenotype.

The majority of the Working Group preferred the second proposition, but on the understanding that the intention had been to exclude from the definition any descriptors that might be the result of environmental influences. For instance, genetically uniform material that showed different characteristics depending on the latitude at which it was grown (notably due to photoperiodic sensitivity) did not give rise to different varieties.

9. There follows a set of definitions translated from the *Dictionnaire de génétique* (Conseil international de la langue française, 1991):

Genic expression: 1. Set of mechanisms that, through transcription of DNA and translation of messenger RNA into proteins, effects the decoding of the genetic information contained in hereditary material. 2. Set of changes set in motion by a gene and leading to the phenotype.

Characteristic: descriptor of the phenotype of a living being that is more or less arbitrarily demarcated by the observer.

Genotype: set of genes of an individual revealed by genetic or molecular analysis within the genome, whether expressed or not.

Gene: nucleotide sequence constituting a unit of genetic information and capable of determining, directly for a structural gene or indirectly for a regulatory gene, the expression of a characteristic.

Phenotype: set of visible characteristics resulting from the expression of the genotype in a given environment. *The actual concept of the phenotype depends on the observation methods and procedures used.*

10. The Working Group finally agreed that, in the practical management of the plant variety protection system, Articles 1(vi) and 7 should be applied separately and in succession to each “plant grouping within a single botanical taxon of the lowest known rank.” Two questions arose as a result:

- (a) Does the grouping constitute a variety, that is, can it in particular be “defined by the expression of the characteristics resulting from a given genotype or combination of genotypes” and “distinguished [...] by the expression of at least one of the said characteristics”? The difference required by the above distinctness condition does not necessarily have to relate to a characteristic noted in the examination of varieties for the purpose of plant variety protection, and does not have to be established with the accuracy required of the examination.

(b) If the grouping is a commonly known existing variety, can the variety for which an application for protection is filed be clearly distinguished from it? If the grouping (variety) is the subject of an application for protection, can it be clearly distinguished from commonly known existing varieties?

11. One might be tempted to amalgamate Articles 1(vi) and 7.

(a) One might wish to write the concept of clear distinctness clearly into Article 1(vi). Such an interpretation is clearly ruled out by the very structure of the Convention text. It is also ruled out by its meaning. It need only be mentioned, for instance, that it clashes with the expression “irrespective of whether the conditions for the grant of a breeder’s right are fully met,” or that it would remove all substance from Article 14(5)(a)(ii), which extends breeders’ rights to “varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety [...]”

(b) One might equally wish to do the reverse, and introduce the concept of expression of characteristics in the first sentence of Article 7, as is done in Article 7(1) of the EU Council Regulation on Community plant variety rights. It should be noted at this stage that such a transposition of the Convention into national or regional law should be undertaken with the utmost care. The European Community opted for the formulation: “*by reference* to the expression of the characteristics that results from a particular genotype or combination of genotypes.”

(c) The actual word “variety” could be replaced in Article 7 by its definition, indeed it is the only correct way of using the definition. As a result, the plant grouping in respect of which the application for protection is made—and which among other things can be distinguished from any other plant grouping by the expression of at least one of the characteristics resulting from a given genotype or combination of genotypes—will in addition have to be *clearly* distinguishable from the other groupings. This exercise does not in any way narrow down the meaning of Article 7, particularly from the point of view of the requirement of clear distinctness. What it does is show that nothing in Article 7 requires clear distinctness to be established *solely* on the basis of “the expression of the characteristics resulting from a given genotype or combination of genotypes” of the variety concerned, still less solely on the basis of any special interpretation of that phrase (on the understanding that this observation does not carry an *implicit* obligation to recognize that the same distinctness can be established on another basis).

12. On account of its general character, Article 7 of the 1991 Act needs to be supplemented by a set of principles and practical rules, in general terms first and species by species thereafter, in order to create a system of protection that is transparent and cohesive (in both botanical and geographic terms). Article 7 is no different in that respect from Article 6(1)(a) of the 1978 Act, on which were based on the one hand the General Introduction to the Test Guidelines and on the other hand the actual Test Guidelines drawn up for some 160 taxa. However, while the concepts of clear distinctness and importance had to be developed in the case of Article 6(1)(a) of the 1978 Act, Article 7 of the 1991 Act has retained only a reference to the requirement of clear distinctness.

13. And yet the situation has not changed fundamentally between the 1978 Act and the 1991 Act with respect to those rules. This can be demonstrated by rewriting Article 6(1)(a) of the 1978 Act in the light of Article 1(vi) of the 1991 Act:

“[...] The variety must be clearly distinguishable by the expression of one or more important characteristics resulting from its genotype or combination of genotypes [...]”

14. Indeed the continuity of the Convention texts extends to the 1961 Act as well, which contained the following rider:

“A new variety may be defined and distinguished by morphological or physiological characteristics. In all cases, such characteristics must be capable of precise description and recognition.”

15. The extension of protection to essentially-derived varieties—which are also defined with the words “the expression of the [...] characteristics that result from the genotype or combination of genotypes”—does on the other hand impose a limitation: the interpretation of the above expression (or of the phenotype concept) for the purposes of the provisions on distinctness should not prejudice the application of the provisions on essentially-derived varieties. And yet it is generally accepted that extensive use will be made of DNA analysis tools for that application.

16. Overall, subject to the limitation mentioned, the question of the choice of the characteristics used in the testing of distinctness does not differ fundamentally whether one considers it from the angle of the 1978 Act or from that of the 1991 Act.

The Concept of the Expression of Characteristics Resulting from a Given Genotype or Combination of Genotypes and DNA Analysis Tools

The Two Major Categories of DNA Analysis Tools

17. The identification methods based on molecular technology were described in document BMT/3/2, dated July 5, 1995; in spite of technical progress, it is still a reliable source of information. DNA analysis tools can be arranged in two broad categories for the purposes of plant variety protection:

(a) the first category is that of “global tools.” These involve the cutting of DNA in precise locations with restriction enzymes and the analysis of the resulting fragments (for instance as for the presence or absence of strands corresponding to a probe). Such tools generally provide information that we are not able to interpret in genetic terms and which has no intrinsic value in determining the genetic make-up of the organism under consideration and especially its phenotype (this is, for instance, true of the study of microsatellites, which belong to the non-coding part of the DNA).

(b) The second category is that of “specific tools,” which enable the presence of a gene or group of specific genes to be determined.

Possible Uses of Global Tools

18. The basic question that arises is whether global tools produce information descriptive of the “expression of the characteristics resulting from a given genotype or combination of genotypes,” or of the phenotype (that is to say, characteristics that are “important” for the purpose of Article 6(1)(a) of the 1978 Act). The concepts of characteristic and phenotype derive essentially from agricultural botany and classical Mendelian genetics respectively; to the knowledge of the Office of the Union, there is no authoritative work that redefines the concepts in the light of the latest progress in molecular genetics. The dictionary mentioned earlier, while essentially devoted to molecular genetics, nevertheless confines itself to classical definitions, at the same time emphasizing the important part played by the observer (or examiner, in the case of plant variety protection) and by observation methods and procedures.

19. There are thus two possible answers to the question:

(a) The concepts of characteristic and phenotype refer to the result of the reading and transcription of the genes; they therefore do not apply to the actual structure of the DNA, and so global tools tell us nothing of the phenotype.

(b) The concepts of characteristic and phenotype need to be brought up to date and in future to include the descriptors of the DNA itself; on this basis, the global tools would allow phenotypical characteristics to be defined.

20. The second question that arises is whether the legal texts allow the use of global tools. Combining of these two questions produces four options (for the sake of simplicity, we shall refer from here on to the shorter term expression of characteristics).

21. First option: global tools do not impart information on the expression of characteristics, and the texts do not allow their use. – The Working Group did not consider this option, which is patently inappropriate: it amounts to denying the plant variety protection system any development in line with technological progress, both in plant improvement and in variety examination.

22. It could be added that it also, in effect, denies the possibility of using global tools in the application of the provisions on essentially-derived varieties.

23. Second option: global tools do not impart information on the expression of characteristics, but the texts do allow them to be used as a complement to other techniques. – The Working Group concentrated on this option.

24. Under this option, the observer must first note the existence of a difference at the level of the phenotype, in the restricted classical sense, to establish the existence of a “variety”; the difference can relate to any characteristic, and does not necessarily have to be established with the same strictness as a difference leading to a grant of breeders’ rights. If the examiner is convinced of the existence of a sufficient difference at phenotype level, still in the restricted classical sense, but without being able to establish it on the basis of the characteristics

normally used for the purpose (essentially the characteristics defined in the Test Guidelines). global tools could then be used to confirm (or prove) the difference.

25. This would be the case, for example, where the new variety showed a visible difference in yield compared with an existing variety, but without the difference being attributable to one characteristic or another, or where it showed a resistance to a biotic or an abiotic factor, such as cold, which can only be assessed with great difficulty.

26. The global tools that one might use would have to meet a certain number of criteria, as electrophoresis does: they should be generally available (and not covered by a patent which is liable to restrict their use); they must be easy to use, and at reasonable cost; they must have good distinguishing power; and they must be covered by accurate protocols and produce repeatable results. As for the varieties, they must be homogeneous in relation to the result produced by the tool, and the breeder must be able to ensure the variety's stability in relation to that result.

27. The main difference compared with electrophoresis is that, for electrophoresis, it has been decided within UPOV that it will not be applied for plant variety protection purposes otherwise than to bands corresponding to characteristics of known genetic control, whereas global tools, by definition, give only a general view of genetic structure. The use of global tools, even for complementary proof, will probably mean that decisions will have to be taken on the minimum genetic distance to be maintained between varieties before they can be used.

28. In the definition of essentially-derived varieties, the two conditions which must be satisfied and are relevant to this study are:

(a) that the variety must be predominantly derived from the initial variety;

(b) that the variety must retain (subject to certain permitted differences) the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety, or (with the same proviso) conform to the initial variety in the expression of those characteristics.

29. Derivation (or non-derivation) may be proved by any means, including global tools, provided that those tools allow it to be shown, or shown to be probable, that one variety derives (or does not derive) from another. On the other hand, the second option would require that there be conformity at phenotype level, in the restricted classical sense. Given such an interpretation, one could be drawn to the conclusion that a climbing variant of a bush rose or a "spur" variant of an apple variety is not an essentially-derived variety, as the differences noted on the basis of the characteristics entered in the relevant Test Guidelines are too numerous for conformity to be spoken of. The same would apply to a genetically altered variety where the gene inserted makes for anomalies in the expression of the initial genotype. Such a consequence is not at all what was intended when the provisions concerned were adopted.

30. Third option: global tools do not impart information on the expression of characteristics, but the 1991 Act allows them to be used as a main technique. – Under this option, the observer must first notice the existence of a difference at the phenotype level, in

the restricted classical sense, to establish the existence of a “variety”; clear distinctness can then be established with the aid of a global tool.

31. At this stage it should be recalled that the purpose of the plant variety protection system is to protect breeders’ rights and to promote the development of agriculture. In order to satisfy this objective, the system should only protect varieties that are clearly distinguished from each other, and should maintain a “minimum distance” between varieties that makes sense for the varieties and seeds industry. Conceptually speaking, the required minimum distance may be either phenotypic or genotypic:

(a) In the first case (the phenotypic minimum distance), a global tool ought not to be used unless one is certain (or at least sufficiently sure) that the difference shown by the tool guarantees clear phenotypic distinctness with respect to the characteristics normally examined. This approach amounts to replacing variety testing in the field with laboratory testing. In the absence of testing in the field, breeders’ rights would be granted on the basis of a DNA profile, and not on the basis of a phenotypic description.

(b) In the second case (the genotypic minimum distance), it is accepted (for the purpose of argument) that two varieties can be phenotypically identical in all but the characteristic on the basis of which the conclusion has been reached pursuant to Article 1(vi) that there is a phenotypic difference between two plant groupings. A global tool may be used only if one is certain (or at least sufficiently sure) that the difference revealed by the tool amounts to clear distinctness at the level of the genotype, in the restricted classical sense: it would indeed be blatantly contrary to the purpose of the plant variety protection system to protect plant groupings that were distinguished from each other only by the characteristics of the non-coding parts of their hereditary material. We saw earlier that the actual concept of the phenotype depends on the observation methods and procedures used. A clear genotypic difference will normally be reflected in the metabolism of the plant, at which level it therefore becomes possible to define “characteristics resulting from a given genotype or combination of genotypes.”

32. It could be maintained that this option is not available under the 1978 Act, as the global tool does not allow the hypothetical definition of (important) characteristics, as a result of the assumption that is the basis for the option considered here; however, under Article 7 of that Act, “protection shall be granted only after examination of the new plant variety *in the light of* the criteria defined in Article 6,” which affords sufficient flexibility for examination by means of indirect proof (at least in connection with the first approach described above). And yet strict interpretation of the 1978 Act does not allow us to rule out the principal use of global tools, as it is sufficient to redefine the concept of characteristic and proceed to the fourth option.

33. It could also be maintained that this option is not available under the 1991 Act either, inasmuch as the intention had not been to introduce an amendment when the words “by one or more important characteristics” were left out of the provision on distinctness (Article 6(1)(a) of the 1978 Act and Article 7 of the 1991 Act). It will be noted that Article 12 of the latter Act is more precise in that it provides that “any decision to grant a breeder’s right shall require an examination *for compliance with* the conditions under Articles 5 to 9”; this wording could be interpreted as being more demanding on the gathering of direct proof (always on the understanding that it does not in any way prejudice the validity of the fourth option).

34. On a practical level, it is for the plant variety protection authorities to ensure that variety testing policy maintains the integrity of the system. The nature of their responsibility does not change according to whether “traditional” morphological or physiological characteristics on the one hand or global tools on the other are used. However, the difficulties to be overcome in exercising that responsibility change with the global tools, because for one thing the application possibilities are practically unlimited, and for another thing the information gathered does not correlate with the phenotype. So, having accepted a tool applied with a particular set of restriction enzymes (or primers), it will probably be difficult to refuse the same tool applied with another set of restriction enzymes (or primers).

35. From the point of view of the integrity of the protection system, “traditional” characteristics and global tools have their strengths and their weaknesses, and it cannot be suggested that one is intrinsically better than the other. Global tools, carefully used, can in fact produce minimum distances that are genetically far superior to those achievable with the present practice, which accepts distinctness based upon a single characteristic. Conversely, one could think that it would be possible to breed (or introduce) differences into that portion of the genetic heritage that is not expressed in order to obtain a difference that is clear at the outset.

36. The Office of the Union suggests that, in the absence of more precise knowledge into the significance of information gathered with the aid of global tools, it is not (yet) possible to consider taking up the third option.

37. In any event, the third option brings with it the same difficulties as the second as far as the definition of essentially-derived varieties is concerned.

38. Fourth option: global tools are capable of defining “important characteristics” within the meaning of Article 6(1)(a) of the 1978 Act or “characteristics resulting from a given genotype or combination of genotypes” within the meaning of Article 1(vi) of the 1991 Act. – Under this option, the genotype is regarded as being not only the genes collectively, but as extending also to the arrangement of the nucleotide sequences, whether coding or non-coding. A given sequence—or a given sequence in a given location in the genetic structure—is regarded as a characteristic whose levels of expression are presence and absence.

39. With this option, therefore, a plant grouping can be regarded as a variety as soon as a difference is noted in the DNA. For the variety to qualify for protection, the difference must in addition be clear, which takes us back to the considerations underlying the third option.

40. This option does however have the advantage of offering greater flexibility for observing whether or not one variety is essentially derived from another.

Possibilities for the Use of Specific Tools

41. These tools make it possible to detect the presence of a gene (or more accurately an allele) or a group of specific genes. Insofar as there is a correlation between the genotype and the phenotype, the tool is just one more tool at the disposal of the examiner for testing the level of expression of the characteristic concerned.

42. The situation is somewhat different for transgenic varieties: the relevant gene (and where appropriate the marker) may be present, but may not be expressed, or may be expressed badly, or again may affect the expression of other genes. The opinion within the Working Group was that it is preferable to examine the characteristic concerned at phenotype level, and to do so by examining either the whole plant or its molecules (for the protein coded by the gene or for a physiological characteristic governed by the gene).

43. At this point too there arises the question whether the minimum distance between varieties should be phenotypic or genotypic—along with the realization that the phenotype concept is determined by the observation methods and procedures used. If one considers two plants that are resistant to a herbicide at whole plant level, they have the same phenotype at that level. If one considers them in physiological or molecular terms, they may have different phenotypes if the resistance is imparted on the one hand by an alteration of the herbicide's target molecule, and on the other hand by a degradation reaction of the herbicide. It will be for the technical authorities of UPOV to decide whether the biochemical difference—which may be revealed at the genetic level—makes for clear distinctness within the meaning of Article 7 of the 1991 Act (or relates to an important characteristic within the meaning of Article 6(1)(a) of the 1978 Act).

Final Comments

44. DNA analysis tools can be used in plant variety protection for various purposes:

- (a) in the case of variety examination, as tools to help reach a decision, for instance:
 - to identify genetically close varieties and improve the organization of testing and the management of reference collections;
 - to compare the candidate variety with a variety that is not included in the tests;
 - to compare the candidate variety with a variety for which only DNA profiles are (still) available;
 - to verify pedigrees;
 - to verify environmental influence on the expression of genotypes.
- (b) in the case of the exercise of breeders' rights:
 - to prove or disprove an allegation of infringement of the protected variety;
 - to determine whether a variety is a hybrid produced from a protected line or is essentially derived from the protected variety.

45. The Office of the Union considers it important that the Working Party on Biochemical and Molecular Techniques, and DNA Profiling in Particular, should continue its work in the light of the whole range of potential uses.

46. The Office of the Union does not regard the foregoing analysis as invalidating the conclusions reached by the Committee at previous sessions.

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