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ADMINISTRATIVE AND LEGAL COMMITTEE

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Geneva, October 21, 1996

QUESTIONS RAISED BY THE TECHNICAL COMMITTEE

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Introduction

1. At its thirty-second session, held from October 18 to 20, 1995, the Technical Committee decided to ask the Administrative and Legal Committee a series of questions. These questions are described and, where necessary, analyzed below.

Interpretation of "the expression of the characteristics resulting from a given genotype or combination of genotypes"

The Work of the Technical Committee

2. Following upon the presentation of the report on the activities of the Working Group on Biochemical and Molecular Techniques, and DNA Profiles in Particular, the Technical Committee embarked upon a discussion on the notion of the expression of characteristics resulting from a given genotype or combination of genotypes which appears in Article 1(vi) of the 1991 Act of the Convention. This discussion was recorded in the report of the session (document TC/32/7) as follows:

"54. Expressed Versus Non Expressed DNA: The expert from ASSINSEL raised the question of the difficulty of using these techniques in relation to the notion of expressed characteristics used in the definition of a variety under Article 1(vi) of the 1991 Act of the UPOV Convention. He noted that a particular DNA profile showed a combination of characteristics of the genotype itself, but gave no information about its expression. A discussion arose on what had to be understood by the term "expressed." Several experts considered it to mean an expression in the plant grown in the field. One expert was of the opinion that that definition was too strict. He took the view that the non-expressed part of the genome could participate in some form of genetic control and that it could therefore be considered expressed. Other experts pointed out that when the genetic base of a particular DNA profile was available, the use of these techniques should be acceptable as additional or complementary information for DUS testing purposes. Other experts noted that the level of expression of determined genes and its influence in the final result at a morphological level was in many cases the result of interactions with factors external to the variety and that the expression could thus largely be modified including through the use of artificial conditions. Therefore, information obtained from DNA profiles, even in cases where knowledge of the genetic map of a particular species was available and a correlation between a morphological trait and a DNA marker could be established, should have to be taken cautiously. At this point, an expert argued that if on the one hand there was some confusion about what should be meant by the term "expression" in the definition of variety under Article 1(vi) of the 1991 Act and, on the other hand, there were new sophisticated techniques that could not be ignored, an evolution of the Convention might be considered and the definition of a variety might have to be changed. The Administrative and Legal Committee should therefore be consulted to provide guidance on how the term "characteristics that result from the expression of a genotype or combination of genotypes" in Article 1(vi) of the 1991 Act of the UPOV Convention should be interpreted in order to help in analyzing the results obtained with molecular techniques and DNA profiling in particular."

Previous Consideration of the Subject

3. The question whether varieties should be distinguished, for the purposes of the grant of a breeder's right, solely by means of phenotypic characteristics (that is to say by the expression of the genotype) was examined in a joint session of the Administrative and Legal Committee and the Technical Committee, which was held on April 21 and 22, 1993.

4. The Office of the Union had prepared a background document (document CAJ/32/3-TC/29/3) of which an extract is set out below:

"7. Discussion of this question involves first the notion of "characteristic" for the purposes of the UPOV Convention and, secondly, the notion of "phenotype":

(i) Characteristic is not defined in any Act of the Convention. The nature of a characteristic for the purposes of the UPOV Convention was discussed in the context of multivariate analysis in document CAJ/30/2 at paragraph 5. The discussion suggests that a "characteristic" is any feature of the material of a variety which is able to be described. The language of both the 1961 and 1978 Acts requires, however, that such features, in order to be taken into account for distinctness purposes, must "permit a variety to be defined and distinguished" and must "be capable of precise recognition and description." Clearly, the draftsmen of the 1978 Act of the Convention may have had at the front of

their minds the familiar morphological or physiological and other characteristics which are descriptive of the phenotype of a plant variety, but no express or implied limitation to phenotypic characteristics appears in the Convention.

(ii) The Concise Oxford Dictionary defines phenotype as a "set of observable characteristics of an individual or group as determined by genotype and environment." However, the concept of phenotype depends in practice upon the approach adopted by the observer and the method of observation used: the characteristics determined by genotype (i.e. phenotype) can be observed at the level of the final result (for example at the level of the morphological characteristic) or at an intermediate level (for example by an analysis of the molecules that are involved), while in the light of modern biotechnological discoveries, the first observable characteristic resulting from a gene is the messenger RNA which represents the transcription of the gene. There accordingly exists between the concepts of genotype and phenotype such continuity that the question whether varieties must be defined exclusively upon the basis of phenotypic characteristics hardly makes sense.

"8. Today, a large number of observations can be made in relation to the material of a variety which are closely related to the DNA, the genotype itself, and totally uninfluenced by the environment (except that of the laboratory!), but which nonetheless constitute characteristics which result from the genotype itself. The results of laboratory assays using genetic probes of various kinds would seem in most cases to fall into this category. It should be noted in this context that the 1991 Act both in Article 1(vi) and Article 14(5)(b) refers to characteristics which "result from" a genotype. It does not use the term "expression" in relation to the genotype (where it is a term of art with a very specific meaning) but only in relation to characteristics. "Result from" is not a term of art in relation to genotype and does accordingly allow for some latitude in interpretation.

"9. The suggestion that Article 1(vi) of the 1991 Act should not be interpreted so as to base the existence of distinctness solely upon phenotypic characteristics is supported by the historical evolution of the provisions concerned with the distinctness criterion itself. The 1961 Act specified that: "A new variety may be defined and distinguished by morphological or physiological characteristics." From the outset it was questioned whether the adjectives "morphological" or "physiological" really added much to the broad meaning of "characteristics." In practice, the phrase was given the widest possible interpretation so that the word "physiological," for example, was taken to include characteristics which would be described as "cytological, chemical or otherwise" under the provisions of the International Code of Nomenclature for Cultivated Plants. The reference to the morphological and physiological nature of characteristics was finally deleted from the Convention during the 1978 Diplomatic Conference without, in any way, changing the technical basis for the criterion. Today's precise methods of DNA analysis simply establish "cytological" or "chemical" characteristics that are independent of environment.

"10. Further support comes from the fact that for certain species, the first "characteristic" (in the sense in which this word is used in the guidelines) which is observed, is at the level of ploidy. This characteristic is not descriptive of "the expression of a characteristic resulting from a given genotype," but of the genome itself being the observation of its chromosome number. There can presumably be no question of dispensing with this important characteristic.

[...]

"15. The above analysis would seem to support the conclusions that

(i) the 1978 Act of the UPOV Convention uses the concept of characteristics for distinctness purposes but without adopting language which, in practice, limits the nature of the characteristics which can be used, except that a particular characteristic must be capable of precise recognition and description so as to permit a variety to be defined and distinguished; the 1991 Act no longer refers to characteristics for distinction purposes, leaving the expert free to determine the most appropriate technique to establish that a variety is clearly distinguishable;

(ii) the characteristics that can be used to define and/or distinguish a variety were never limited to the phenotype as such;

(iii) the expression "at least one characteristic," when used in the definition of variety in the 1991 Act, simply requires that there be "a difference" between plant groupings in order that they be regarded as separate varieties for the purposes of the Convention; it has no other function and, in particular, imposes no limitation on the examination procedures followed to establish distinctness for the purposes of protection."

5. The discussions of the Committees were recorded in the report of the session (document CAJ/32/10-TC/29/9) as follows:

"15. The Chairman introduced this question by giving an account of the history of the provisions concerned:

(i) The 1978 Act did not contain a definition of the variety, which was because it was not necessary for the assessment of a variety for which a protection application was filed. The variety concept came up only in connection with other varieties, notably in the examination of distinctness or that of variety denominations. It was the discussions within WIPO that gave rise to the definition, in view of the fact that a certain number of States excluded plant varieties from patentability. A joint committee of experts of UPOV and WIPO met from January 29 to February 2, 1990, to discuss questions of mutual concern, and it considered it necessary to devise a general definition that would make for a uniform approach to the variety concept in the field of plant variety protection and in that of patents. That intention was moreover apparent in the fact that the 1991 Diplomatic Conference appointed a representative of the European Patent Organisation to its Working Group on Article 1.

(ii) As far as the discussions of the Plenary of the Conference were concerned, the following should be remembered: Article 1 defined the variety concept, but remained silent on whether or not a variety was eligible for protection; the reference to the genotype was intended to make it clear that the existence of a variety merely presupposed the possibility of defining it according to genetically determined criteria, and not necessarily by characteristics appearing in lists drawn up for the purposes of the grant of breeders' rights. The genotype was neither defined nor even specified in the course of the discussions. There was nevertheless the underlying hypothesis that a variety could not be defined otherwise than by its genes; in that sense, no substantive difference was made between the genotype and the phenotype. Finally, for the variety concept to be satisfied, there needed only to be a difference in one characteristic, even if the difference was not a clear one. It was the Conference's intention to set the lower limit above which

one could speak of a variety, without pronouncing on any other conditions that might have to be met.

(iii) Article 7 dealt only—and that was already clear from its inclusion in Chapter III—with the circumstances in which a variety may be protected, in view of the fact that it was not eligible for protection by virtue of the mere fact of its being a variety. Article 7 therefore contained stricter conditions than Article 1. To qualify for protection, a variety had to be "clearly" distinguishable. The word "clearly" had not been defined, and it was important to point out that the Diplomatic Conference did not want to introduce specific restrictions. Article 7 did not refer to the characteristics to be taken into account, not even from the point of view of their importance or their essential nature. It was therefore for the examining authority to determine the characteristics or combinations of characteristics that it would use in examination. The Article also did not specify when a difference was clear, so it was for the authority to decide, for instance, whether a single difference was sufficient, assuming that it was great enough, or alternatively whether one need only note the existence of a number of differences that were not clear, provided that they could be combined to give a clear difference. The Convention left all these options open.

[...]

"16. The Delegation of the United States of America shared the view expressed by the Chairman.

"17. The Delegation of the Netherlands referred to document CAJ/32/3-TC/29/3, drawn up by the Office of the Union as the basis for the discussions on this agenda item. One of its members expressed disagreement with the last sentence of paragraph 7(ii). Another pointed out that the distinctness criterion did not differ in conception between Article 1 and Article 7, even though the requirements were different; there was no need to go further into that question, however, as Article 1(vi) had no functional importance. He then said that the questions raised in paragraph 6 in connection with Article 1(vi) were applicable also to Article 7. In the case of the latter Article, the present practice in the Netherlands was to base distinctness on observable characteristics, in other words the phenotype; a genotypical difference not expressed at phenotype level could not result in the grant of a breeder's right. He wondered whether the 1991 Act required the approach to be reconsidered; yet that was in fact a question that should be dealt with case by case, and possibly left to case law. [...]

"18. It was pointed out that questions concerning the genotype and phenotype concepts, notably DNA profiles, were central to the terms of reference of the Working Group on Biochemical and Molecular Techniques, and that the Technical Committee should also concern itself with them. In that connection, the Delegation of the Netherlands mentioned that the two bodies should not take decisions, but rather assemble facts and arguments on the basis of which national authorities could take decisions that would then be substantiated and uniform within UPOV."

Re-affirmation of Existing Interpretation

6. The Office of the Union suggests that the Administrative and Legal Committee

(a) reaffirm the position set out in paragraph 15 of document CAJ/32/10-TC/29/9,

(b) state that the words "the expression of the characteristics resulting from a given genotype or combination of genotypes" appearing in Article 1(vi) of the 1991 Act do not conflict with the use of characteristics based upon the features of genetic material (in particular "DNA profiles"),

(c) state that the question of deciding whether a characteristic based upon the features of genetic material and resulting from the use of a well-established method of analysis (a "DNA profile") can be used within the framework of the examination of distinctness should be addressed in each particular case by applying the criteria which have already been established in relation to "traditional" characteristics (including characteristics resulting from the use, for example, of electrophoresis), and

(d) underline that the extension of protection to essentially derived varieties ought not to result in a weakening of the criteria for decisions on distinctness (at the above-mentioned joint session, the Committees also examined the relationship between Articles 1(vi) (definition of variety) and 7 (distinctness), on the one hand, and Article 14(5)(b) (definition of essentially derived variety), on the other hand).

A Related Question

7. When discussing the results of the work of the Working Group on Biochemical and Molecular Techniques, and DNA Profiles in Particular, the Technical Committee also embarked upon a discussion of the various categories of characteristics. In the course of the discussion it was stated that the definitions were more of a legal nature than of a technical nature and should therefore also be presented to the next session of the Administrative and Legal Committee for discussion. The following list was produced at the end of the discussion (paragraph 64 of document TC/32/7):

"(a) Asterisked Characteristics

Characteristics recommended by UPOV for use on all varieties in every growing period over which examinations are made and always included in the variety descriptions, except when the state of expression of a preceding characteristic or regional environmental conditions render this impossible.

"(b) Non-Asterisked Characteristics

Characteristics considered useful by UPOV for DUS testing and description, but not all UPOV member States recommended their routine use.

"(c) Routine Characteristics

– All UPOV asterisked characteristics;
– Some UPOV non-asterisked characteristics if selected by a given State for routine testing;
– Some additional non-UPOV characteristics if selected by a given State for routine testing.

"(d) Additional/Supplementary Characteristics

Any characteristic used in addition to the characteristics recommended by UPOV or in addition to those used routinely at national level.

"(e) Complementary Characteristics

Characteristics which cannot be used at all to establish distinctness, but provide useful information of the variety. Example: DNA marker.

"(f) Last Resort Characteristics

Special case of additional characteristics used only under the following conditions:

(i) with agreement of the applicant
(ii) if all other characteristics fail to establish distinctness
(iii) a test procedure has been agreed between competent authority and the applicant
(iv) if used, can establish distinctness in combination with other characteristics but in the extreme case, alone."

8. This list gave rise to certain observations which are recorded as follows in the Report (document TC/32/7):

"65. When studying the above draft, some experts already proposed to simplify the terms, others proposed different groups (obligatory, optional, additional and special characteristics), others wanted to restrict their definition to the testing of DUS, others felt that their conditions of use should be added, others considered only their use for description purposes and not for DUS. The Committee felt that more time was needed for reflection on the proposed wording and that it would need to come back to the definitions during its next session. In the meantime all experts should study the proposals. Furthermore it was stated that the definitions were less of a technical nature but more of a legal one and should therefore also be presented to the next session of the Administrative and Legal Committee for discussion."

9. Discussions are still ongoing in technical circles on this question, and revised definitions might be available at the time of the session of the Committee.

10. The Office of the Union is of the view that characteristics should all be evaluated from the standpoint of establishing a clear distinction between varieties for the practical purposes of a plant variety protection system which, to be effective, must strike a proper balance between the interests of the applicant and the interests of the owners of existing varieties. Characteristics are either acceptable for this purpose or not. The Office doubts whether the "last resort characteristics," as currently defined, meet the requirements. It questions in

particular the references to the agreement of the applicant (or, for that matter, any other interested party).

Variety Denominations and Trademarks

Indication of the Commercial Designation in the Technical Questionnaire

11. The discussion of the Technical Committee on the above subject was recorded as follows in the Report of the session (document TC/32/7):

> "43. The Committee noted several comments regarding the inclusion of the request for the applicant to give the trade name as a help in identifying the variety. Some of the experts from Spain doubted the value of including a request at the time of application because of the uncertainty of the commercial denomination. Other experts supported the proposal from the TWO to include the trade name in the Technical Questionnaire from a practical viewpoint. The expert from ASSINSEL stated that it was important to keep the notions of variety denomination and trade name clearly separate. It was already difficult at present to find suitable names for a variety denomination.
>
> "44. The Committee agreed that the TWO should discuss this item again at its next session based on the comments from some of the countries. The question should also be submitted to the CAJ for discussion at its next session."

12. The Technical Working Party for Ornamental Plants revisited this question at its twenty-ninth session held from April 15 to 19, 1996, and repeated the request that it had made to the Technical Committee, considering however that the indication of the designation should be facultative (at the discretion of the applicant).

13. The following considerations would seem to be relevant to an examination of the question:

(a) According to the Convention (Article 13(7) and (8) of the 1978 Act and Article 20(7) and (8) of the Act of 1991), whoever commercializes propagating material of a variety which is currently or was formerly protected, is bound to use the denomination of the variety, it being understood that, when a variety is offered for sale or commercialized, he is permitted to associate with it a trademark, trade name or some other similar indication.

(b) It is the practice, particularly in the ornamental plant sector, to use trademarks in the commercialization of plant material, particularly for the harvested material. The variety finishes up by being known primarily under its trademark. There is a resulting need for those managing the protection system to establish some link between denominations and trademarks.

(c) If one sticks strictly to the obligations resulting from the Convention, it is not obligatory to use the variety denomination when commercializing harvested material. The need to establish some link is all the more necessary as a result of this.

(d) On the other hand, to request on a facultative basis an indication of the commercial designation which will possibly be used at a later stage can only provide a partial

answer to the problem, since the designation is not necessarily fixed at the moment of filing an application. It can subsequently vary over time, in space and even according to channels of trade. A designation might equally be re-used for another variety. As a consequence, if one wishes to obtain information on commercial designations, the most effect procedure would be to periodically ask breeders, if they are willing, to provide this information for all varieties which they are currently marketing. Such an approach would avoid the difficulty of the legality of including an item in an official form which has no legal basis, but would create an additional unrewarded administrative task which national offices might be reluctant to undertake particularly in view of the questionable value and usefulness of the resulting information.

(e) The rules concerning novelty permit the commercialization of the variety in the State where the application is filed and in other States. The Model Form for the Application for Plant Breeders' Rights (Section 10 in the Collection of Important Texts and Documents) includes a heading under which the applicant is requested to describe the commercialization situation. In an appropriate case, he must provide the "denomination" under which the variety has been offered for sale or commercialized in the State where the application is filed or under which it has been offered for sale or commercialized for the first time in another State. The instructions for converting the model form into a national form note that certain States request more detailed information, in particular the date of the first commercial use in each country and "the names under which the variety was marketed there," and that "It is recommended that this information be requested on a special form." It would perhaps be useful to revise the heading in question in such a way that the applicant should be requested to indicate not only the denomination but also any other designation which has already been used in the commercial exploitation of the variety.

(f) The central database (on CD-ROM) on plant variety protection and related matters contains an item providing for an indication of commercial designations.

14. There may be no wholly satisfactory solution to the confusion caused by trademarks and trade names, other than to reassert the obligation under the Convention to use the denomination in relation to selling and marketing, and to persuade all other persons associated with varietal evaluation and commentaries to use the denomination as well as any trade mark in their literature.

Question in the Technical Questionnaire Concerning the Status of the Variety as Regards Legislation on the Protection of the Environment and on Human and Animal Health

15. At its thirty-second session, the Technical Committee took note of and approved the following (paragraph 17 of document TC/32/7):

> "(c) The necessity that the applicant state in the Technical Questionnaire, whether the candidate variety is a transgenic/GM variety or not. As the definition of GM variety may differ from State to State it proposed instead to include the following version in the Technical Questionnaires:
> Does the variety require prior authorization for release under legislation concerning the protection of the environment, human and animal health, in the country in which the application is made?

Yes/oui/ja [ ]
no/non/nein [ ]

Has such authorization been obtained?

Yes/oui/ja [ ]
no/non/nein [ ]"

16. However, after the session, the Delegation of Germany asked that the "release" question should first be examined as a whole by the Administrative and Legal Committee before being included in test guidelines. Accordingly, the Office of the Union has, after consultation with the Chairman of the Technical Committee, decided to await the conclusions of the Administrative and Legal Committee but, meanwhile, to publish the guidelines which had been adopted at the session, without this addition.

17. It would seem that the object of the question is to make sure that the plant material required for the examination can be transmitted to the authority responsible for the examination and that the authority can grow the variety (and that a question relating to the authorization for release would be devoid of any legal basis). There will accordingly be a necessity to reformulate the first question, on the one hand, in order to ask if any special authorization is required (under legislation concerning the protection of the environment and of human and animal health, of legislation on genetic engineering or any other law) and, on the other hand, to take into account the fact that the examination may be carried out in a State other than that in which the application is filed. Two options exist:

(a) to replace "country where the application is filed" by "country where the examination will be carried out";

(b) the latter not always being known in advance, to pose the question in a general way, which will call for some modification to the second question.

18. *The Committee is requested to advise the Technical Committee in relation to the questions raised in this document.*

[End of document]