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ESSENTIALLY DERIVED VARIETIES

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I. Introduction

1. The 1991 Act of the International Convention for the Protection of New Varieties of Plants ("the 1991 Act") contains in Article 14(5) provisions which extend the scope of protection afforded to the breeder of a protected variety under the provisions of Article 14(1) to (4) to "varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety."

2. The Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants held in Geneva from March 4 to 19, 1991, which unanimously adopted the text of the 1991 Act, resolved (see document DC/91/140) "to request the Secretary-General of UPOV to start work immediately after the Conference on the establishment of draft standard guidelines, for adoption by the Council of UPOV, on essentially derived varieties."

3. Discussion in the Diplomatic Conference prior to the adoption of the above-mentioned resolution suggested:

(a) that any guidelines adopted should have no legally binding force;

(b) that any guidelines adopted could not or should not change the essence of the provisions of the Convention or its interpretation;

(c) that the provisions concerning essential derivation were an integral part of provisions establishing the scope of the breeder's protection; that it was the responsibility of the breeder to establish and defend the scope of protection of his variety in relation to that of other varieties; that guidelines addressed to the Governments of member States might therefore be inappropriate.

II. Nature of Guidelines

4. With the endorsement of its Council, UPOV publishes:

(i) Guidelines for the conduct of tests for distinctness, homogeneity and stability of new varieties of plants for individual species;

(ii) a General Introduction to such guidelines which gives guidance to member States upon the general principles involved in the conduct of tests for distinctness, homogeneity and stability;

(iii) UPOV Recommendations on Variety Denominations.

Such guidelines and recommendations relate in each case to conditions or requirements which must be satisfied prior to a grant of protection for a variety. Since the granting of protection is a matter for the competent authorities of member States, such guidelines and recommendations are, in effect, guidelines and recommendations in relation to the practice of the Offices of member States and addressed to the Governments of member States.

5. Article 5 of the 1991 Act specifies the conditions for the grant of a breeder's right and provides that the grant of a breeder's right shall not be subject to "any further or different conditions." Matters relating to essential derivation are not included in the criteria to be satisfied prior to the grant of a breeder's right. A purported finding of "essential derivation" by a national office at the time of grant might constitute the imposition of a "further condition" or a qualification attaching to the grant and as such be contrary to the provisions of the 1991 Act. This conclusion is consistent with the view repeatedly expressed by delegates in the Diplomatic Conference and in preparatory meetings for the Diplomatic Conference that the existence of a relationship of essential derivation between two protected varieties is a matter for the holders of rights in the varieties. This being so, any guidelines concerning the nature of essential derivation will necessarily be of a fundamentally different nature to existing UPOV guidelines and recommendations which are addressed to member States and concern the practice of their Offices.

III. The Provisions of the 1991 Act Concerning Essential Derivation

6. The full text of Article 14(5) of the 1991 Act reads as follows:

> "(5) [Essentially derived and certain other varieties] (a) The provisions of paragraphs (1) to (4) shall also apply in relation to
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> (i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,
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> (ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and
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> (iii) varieties whose production requires the repeated use of the protected variety.
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> (b) For the purposes of sub-paragraph (a)(i), a variety shall be deemed to be essentially derived from another variety ("the initial variety") when
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> (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.

(c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering."

The specific wording used in the above provisions is examined in the paragraphs which follow.

7. "where the protected variety is not itself an essentially derived variety" (Article 14(5)(a)(i)): The underlined words relate to a situation where, for example, Variety C is essentially derived from Variety B which is in turn essentially derived from Variety A. The words make clear that Variety C does not fall within the scope of the protection of Variety B; the words are not intended and should not be interpreted to require the rights' holder to positively prove that the protected variety is not itself an essentially derived variety before he is able to exercise the rights conferred by Article 14(5)(a)(i). The words provide an opportunity for the breeder of an alleged "essentially derived variety" to show that the initial variety is itself an essentially derived variety.

8. "predominantly derived from the initial variety" (Article 14(5)(b)(i): The requirement of predominant derivation from an initial variety means that a variety can only be essentially derived from one variety. Discussions of the revision proposals in the sessions of the Administrative and Legal Committee which preceded the adoption by the Council in October 1990 of a draft Convention consistently showed that the intention was that a variety should only be essentially derived from another variety when it retained virtually the whole genotype of the other variety. This is confined by the words commented upon in paragraph 9 below. A derived variety could not in practice retain the expression of the essential characteristics of the variety from which it is derived unless it is almost entirely derived from that variety.

9. "while retaining the expression of the essential characteristics": The essential characteristics are those which are indispensable or fundamental to the variety. "Characteristics" would seem to embrace all features of a variety including, for example, morphological, physiological, agronomic, industrial and biochemical characteristics. It is suggested that the result of a biochemical test conducted on a variety, for instance, a screening test using a genetic probe, is a characteristic of the variety. "while retaining" requires that the expression of the essential characteristics be derived from the initial variety.

10. "that result from the genotype": These words make clear that only characteristics of a variety which are heritable genetically should be taken into account. Any descriptive features of plant material that represent environmental effects should be disregarded. It has been questioned whether the test result arising from the use of a genetic probe, e.g. an RFLP, is a characteristic that "results from the genotype." It has been suggested that the test result of using such a probe "results from the genotype."

11. "(ii) it is clearly distinguishable from the initial variety": These words establish that essential derivation is concerned only with varieties that are clearly distinguishable from an initial variety and which are accordingly protectable independently from the initial variety.

12. "(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 original variety": The words "except for the differences which result from the act of derivation" do not set a limit to the amount of difference which may exist where a variety is considered to be essentially derived. A limit is, however, set by the words of subparagraph (i). The differences must not be such that the variety fails "to retain the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety." A comparison between subparagraphs (i) and (iii) of Article 14(5)(b) is somewhat problematic in that (i) would seem to require the whole of the expression of the essential characteristics that result from the genotype of the initial variety while (iii) requires only that the derived variety conform to the initial variety except for differences resulting from the act of derivation (however, see the discussions in paragraph 13 below). The examples of essential derivation given in Article 14(5)(c) make clear that the differences which result from the act of derivation should be one or very few.

IV. Establishing the "essential derivation" of a variety.

13. Article 14(5)(b) lays down those conditions that must be satisfied in order that a later variety shall be deemed to be essentially derived from another variety ("the initial variety"). The second of those conditions (established in Article 14(5)(b)(ii)) requires only that the later variety be clearly distinguishable from the initial variety and requires no further comment. The first such condition (established in Article 14(5)(b)(i)) requires that the later variety be derived from the initial variety which in turn requires that genetic materials of the initial variety have been used in the creation of the later variety. The first condition is accordingly concerned with the genetic origin of the later variety. The third such condition (established in Article 14(5)(b)(iii)) requires that the later variety conforms to ("is made similar to") the initial variety in the expression of the inherited essential characteristics of the initial variety apart from the differences which result from the act of derivation. The third condition is accordingly concerned with the degree of similarity of the later variety to the initial variety. Whilst the first condition also makes reference to the degree of similarity, the primary function of the first condition is to establish a requirement relating to the genetic origin of the variety.

14. The question of the genetic origin of the later variety posed by Article 14(5)(b)(i) is primarily a question of fact to be established using all available evidence including the personal testimony of individual witnesses, laboratory and field record books, knowledge concerning the inheritance of particular characteristics, the results of bio-chemical tests and so on. The question of the degree of similarity of the later variety to the initial variety primarily calls for a value judgement whether the later variety does or does not conform to the initial variety in the expression of its essential, heritable characteristics.

V. The question of the genetic origin

15. A major difficulty in practice in the implementation of legal provisions relating to essential derivation for litigants alleging infringement will be establishing as a matter of fact that Variety A is derived from Variety B, where this fact is not admitted by the defendant in the action or has not been otherwise admitted in a public document. Derivation will be inferred in many cases from the weight of evidence concerning the variety's genetic origins (how could such a degree of similarity have resulted unless A were derived from B?) but difficulty will remain in some cases.

16. Some help could be provided by national offices if they were to demand more precise and meaningful information on genealogy in technical questionnaires addressed to applicants for protection and if the completed questionnaires could be made available for search in all member States by parties able to demonstrate a bona fide interest. It should not be acceptable, for example, that all information relating to genealogy is presented in the form of meaningless codes.

17. Another possibility raised by an international non-governmental organization, but not taken up by UPOV in the revision process, would be to provide in national laws for some modification of the burden of proof The suggestion, modified so as to relate to the text of Article 14(5), was that once the plaintiff in an infringement action establishes that an alleged essentially derived variety expresses the essential characteristics that result from the genotype or combination of genotypes of the initial variety, the burden of proof should fall upon the defendant to establish that his variety was not derived from the initial variety. In view of the precise records kept by serious plant breeders, the defendant would be in a uniquely strong position to provide evidence on this point.

18. Whilst it is normally the responsibility of the plaintiff in an infringement action to establish the fact of infringement, the UPOV Convention is silent upon the question of the burden of proof and it is open to member States to modify the normal burden of proof should they wish to do so. It should be noted that a similar proposal to reverse the burden of proof is contained in Article 24 of the "Basic Proposal for the Treaty and Regulation" submitted to the Diplomatic Conference for the Conclusion of a Treaty supplementing the Paris Convention as far as Patents are concerned, the first part of which was held in The Hague, Netherlands, in June 1991. The proposal of the said Article 24 concerns the reversal of the burden of proof in infringement proceedings concerning processes for obtaining products where the plaintiff has in many cases a difficult or impossible task to prove use of the process while the defendant can with ease demonstrate that he did not use the process.

VI. The Question of the Degree of Similarity

19. A judgement on the question of the degree of similarity must be reached on the basis of the essential characteristics which result from the genotype. "Essential" has the meanings "fundamental" or "indispensable." The language finally adopted in Article 14(5)(iii) replaced Article 14(2)(b)(iii) in the Basic Proposal considered by the Diplomatic Conference. Article 14(2)(b)(iii) of the Basic Proposal provided that the essentially derived variety must "conform to the genotype or combination of genotypes of the initial variety ..." This language was initially replaced by the adoption by the Conference of the proposal of Japan contained in document DC/91/66 which proposed that Article 14(2)(b)(iii) of the Basic Proposal be reworded to read:

"(iii) the characteristics that are the expression of its genotype or its combination of genotypes conform to those of the initial variety apart from the differences which result from the method of derivation."

It is suggested that Article 14(2)(b)(iii) of the Basic Proposal and the Japanese proposal which replaced it called for the degree of similarity between varieties to be assessed on the basis of the characteristics of the variety taken as a whole and not on the basis of individual characteristics taken in isolation. The language of the Japanese proposal was subsequently amended by the Drafting Committee but it is suggested that no change in substance was intended. It is suggested that it should not be possible to conclude that a derived variety does not attain the necessary degree of similarity simply because it does not express one single characteristic (perhaps very simply inherited) taken in isolation.

20. Taken individually the characteristics that are "essential" would vary from species to species, from variety to variety, and even from member State to member State. It is clearly not desirable that decisions on whether a variety is or is not essentially derived should be taken differently in UPOV member States.

21. To fulfill the conditions imposed by Article 14(5)(b)(iii) a later variety must conform to the initial variety in the expression of the essential heritable characteristics of the initial variety "except for the differences which result from the act of derivation". Theoretically, if variety A is crossed with variety B and variety X is selected from the resulting progeny, if variety X derives less than half of its essential heritable characteristics (i.e. of its genotype) from A and more than half from B, it will be essentially derived from B since apart from the characteristics derived from A, it conforms to the expression of the essential characteristics of B. This is clearly not the intended interpretation. A later variety cannot fulfill the conditions of Article 14(5)(b)(i) unless it is predominantly derived from the initial variety while retaining, without qualification in Article 14(5)(b)(i), the expression of the essential heritable characteristics of the initial variety.

22. Examples of possible essential derivation are set out, as a basis for discussion, in the annex to this document.

[Annex follows]

ANNEX

Example 1: A pyramid

[Each $^+$ is a characteristic added by genetic engineering or complete backcrossing and controlled by a single gene or by a few closely linked genes]

Variety A - the initial protected variety

Variety A^+ - is distinct from and predominantly derived from A

Variety A^{++} - is distinct from A^+ and is predominantly derived from A^+

Variety A^{+++} - is distinct from A^{++} and is predominantly derived from A^{++}.

1.1 Question: Is variety A^+ essentially derived from A?

1.1 Answer:

Yes, if it is predominantly derived in such a way that it retains the expression of the essential inherited characteristics (that is the characteristics that "result from the genotype") of the initial variety AND if in the final result, except for the differences which result from the act of derivation (added characteristic$^+$ in this case) it conforms as required by Article 14(5)(b)(iii).

1.2 Question: Is variety A^{++} essentially derived from A^+?

1.2 Answer:

(i) Same answer as for 1.1. but with different consequences. Since variety A^+ is itself essentially derived from A, it fails to satisfy the requirement of Article 14(5)(a)(i). Accordingly the scope of protection of variety A^+ does not cover variety A^{++}.

(ii) Variety A^{++} may, however, be essentially derived from variety A if it retains the expression of the essential inherited characteristics of variety A and if it conforms as required by Article 14(5)(b)(iii).

1.3 Question: Is variety A^{+++} essentially derived from variety A and if so how many further characteristics can be added to it before it ceases to be essentially derived from A?

1.3 Answer:

Variety A^{+++} will be essentially derived from A if it satisfies the provision of Article 14(5)(b)(i) and (iii). Varieties with further added characteristics similarly derived would continue to be essentially derived until such time as a variety is developed which ceases to conform to the initial variety in the expressions of its essential characteristics inherited

from A. A decision on this question in an infringement suit would be a value judgement based upon the available evidence.

Example 2: Reselection

2.1 A protected variety of a self-pollinating species has two elements A and B which were not separately identified and described at the date of the grant of protection. A breeder selects component B from the variety and seeks to protect it as a new variety.

2.1 Question: Will the new variety be essentially derived from the protected variety? Does the position vary if:

(a) the protected variety comprised 50% element A and 50% B
(b) the protected variety comprised 80% element A and 20% B
(c) the protected variety comprised 95% element A and 5% B
(d) the protected variety comprised 99.9% element A and 0.1% B

Is the position different if B is very different genetically from A?

2.1 Answer:

(i) A supplementary question to ask prior to giving an answer would seem to be: "Is element B part of the variety?" The answer to this question may vary depending upon the law and practice of individual member States. In all countries where the identity of the variety is established by the definitive sample of propagating material of the variety rather than a written description, element B will be part of the variety if it is present in the definitive sample and if it is appropriately related genetically to element A.

(ii) Where element B is not appropriately related genetically to element A (for example, it is an outcrossing or a physical admixture and does not result from residual genetic variation) and it is present at less than the 5% level, it could be argued that element B is not part of the variety particularly where it has not been identified and described at the date of grant of protection.

(iii) Where element B is part of the variety (that is it represents residual genetic variation) and present in excess of 0.1% of the variety, a selection of element B might not be considered to be a distinct variety. The selection of element B, present at the 0.1% level or less, if considered to be part of the variety (that is it represents residual genetic variation and is not an admixture or an outcrossing) would be derived from the protected variety.

(iv) Whether element B would or would not be an essentially derived variety would depend upon whether it satisfied the requirements of Article 14(5)(b)(iii).

2.2 A breeder selects on the basis of earliness one hundred clones from a population of plants of a protected cross-pollinating forage variety A. A new variety B results from the cross-pollination of the selected clones and is distinct from the protected variety A on the basis of earliness.

2.2 Question: Is the new variety B essentially derived from the protected variety A? Would the position change if only 5 clones were selected?

2.2. Answer:

(i) The example tells one that the new variety B is clearly distinguishable from the initial variety on the basis of earliness. It is clearly "predominantly derived" from the initial variety A by selection in the sense that all the initial variation comes from variety A. Additionally a judgment must be made whether the new variety B has been so derived that it retains the expression of the essential characteristics which result from the combination of genotypes of the initial variety A. This will depend in the first instance on the number of clones selected and whether the clones are a representative sample of the original combination of genotypes (apart from earliness). Finally a value judgment must be made on the extent of similarity between variety A and variety B to satisfy Article 14(5)(b)(iii).

(ii) In principle, it would seem more likely that the expression of the essential characteristics of variety A would be retained and that variety B "conforms" with variety A where the new variety B is based upon 100 clones than where it is based on five.

(iii) One may speculate that the greater the number of genes controlling the introduced characteristic (earliness in this example), the more likely it would be that the expression of other essential characteristics would also change so that variety B would no longer retain the expresssion of the essential characteristics of variety A or conform so as to satisfy Article 14(5)(b)(iii).

2.3 A breeder plants in a greenhouse many thousands of seeds of a protected alfalfa variety A, 0.1% of whose plants are resistant to a disease. The breeder inoculates the resulting seedlings with the disease and selects the survivors, which are grown on, flower, cross-pollinate and set seed. The seed produces plants which are screened and selected as before. The cycle is repeated a number of times until the percentage of resistant plants in the population is increased to 40%. The selection scheme is designed to ensure that the gene frequencies of the protected variety are as far as possible maintained with the exception of the gene responsible for resistance whose frequency is increased. 200 resistant plants are cloned and allowed to cross-pollinate to produce breeders seed of a new resistant variety B.

2.3 Question: Is the new variety B essentially derived from the protected variety A?

2.3 Answer:

(i) The new variety B is clearly distinguishable from and is predominantly derived from the initial variety A.

(ii) If variety B retains and conforms to the expression of the essential characteristics that result from the combination of genotypes of variety A (apart from the introduced disease resistance) it will be essentially derived. It is suggested that statistical approaches similar to those used for distinctness testing would be necessary to demonstrate that variety B did so retain and conform to the expression of the essential characteristics of variety A. If the disease resistance is governed by a single resistant gene, it is more likely that the expression of the essential characteristics that result from the combination of genotypes of variety B will be retained and conform so as to satisfy Article 14(5)(b)(iii).

Example 3: Backcrossing

3.1 Simply inherited characteristics

Variety B is used as the recurrent parent which is backcrossed eight times on to variety A. The object of the program is to transfer to variety B a disease resistance characteristic governed by a single gene of variety A; the resulting disease resistant variety B^+ is clearly distinguishable from B.

3.1 Question: Is the new variety B^+ essentially derived from B?

3.1 Answer:

Since variety B^+ seems likely to have retained the essential characteristics that result from the genotype of variety B and to conform so as to satisfy Article 14(5)(b)(iii) (apart from the added disease resistance) it will be essentially derived.

3.2 Characteristics of complex inheritance

The same facts as in example 3.1, except that the disease resistance characteristic, say soybean cyst nematode resistance, is governed by several genes and the screening is technically complex and involves difficult and expensive trials for the screening of each backcross generation.

3.2 Question: Is the resulting soybean cyst nematode resistant variety B^+ essentially derived from B? Does the position vary as the number of backcross generations is reduced and the breeder selects in the segregating progeny? At what point would B^+ cease to be essentially derived from B?

3.2 Answer:

(i) The amount of effort or expenses involved in the development of the soybean cyst nematode resistant variety is irrelevant.

(ii) The fact that the inheritance of the resistance factor is complex will be relevant only insofar as the variety is not derived so as to retain the essential characteristics that result from the genotype of the initial variety and does not conform so as to satisfy Article 14(5)(b)(iii).

(iii) The number of backcross generations is relevant only to the extent that it throws light on whether the variety is likely to be derived while retaining the essential characteristics that result from the genotype of the initial variety.

Example 4: Transformation by genetic engineering

Variety A is transformed by genetic engineering so as to incorporate and express a desirable gene. 100 plants are successfully transformed and screened to select a plant which retains the maximum number of the characteristics of A with the optimal expression of the desirable gene. The selected plant is used as the basis of variety A^+.

4.1 Question: Is variety A^+ essentially derived from variety A? Does the position change if

(a) it is necessary to modify and select within many thousands of plants to identify the desirable plant, or

(b) it was expensive and difficult to develop the transformation process?

4.1 Answer:

(i) Variety A^+ is likely to be clearly distinguishable from variety A on the basis of the expression of the desirable $gene^+$ and is clearly predominantly derived from variety A.

(ii) The effort, experience and difficulty of incorporating $gene^+$ into variety A is irrelevant, as such, but may throw light on the extent to which the derived variety retains the expression of the essential characteristics that result from the genotype of variety A.

(iii) Whether variety A^+ is essentially derived will depend upon whether it has (apart from the difference resulting from $gene^+$) retained the expression of the essential characteristics that result from the genotype of variety A and conforms so as to satisfy Article 14(5)(b)(iii). It can be expected that in many cases variety A^+ will be essentially derived from variety A.

Example 5: Somaclonal variants

Cells derived from variety A are maintained in tissue culture in the form of callus. Plants are regenerated from such callus tissue and include variants from variety A which are distinct and stable.

5.1 Question: Are such variants essentially derived from variety A? Does the position change if the genetic differences between such variants are small or large?

5.1 Answer:

(i) The variants will be predominantly derived from variety A.

(ii) Whether a variety based upon a particular variant will be essentially derived will depend upon whether it retains the essential characteristics resulting from the genotype of variety A and apart from specified differences resulting from selection it conforms so as to satisfy Article 14(5)(b)(iii).

(iii) If the selected difference is very large it will be less likely that the variant will so retain such essential characteristics. A variety based on such a variant will thus be less likely to be essentially derived from variety A.

Example 6: Natural and induced mutations

A mutation is discovered in variety A and used to create a new variety B.

6.1 Question: Is variety B essentially derived from variety A? Does the position differ if the mutation results from a simple genetic change or if the change is more complex, or if the mutation is artificially induced?

Answer:

(i) Variety B is predominantly derived from variety A and is clearly distinguishable from variety A.

(ii) Whether the mutation is naturally or artificially induced is irrelevant.

(iii) The only remaining questions are whether variety B is derived from variety A while retaining the expression of the essential characteristics that result from the genotype of variety A and whether variety B conforms with variety A so as to satisfy Article 14(5)(b)(iii). In most cases this will be so and variety B will be essentially derived from variety A.

(iv) The complexity of the genetic change may, however, result in a mutation that no longer retains the expression of the essential characteristics that result from the genotype of variety A. In this case variety B would not be essentially derived from variety A.

(v) Where variety A is a mutation of an unprotected variety X, variety B may be essentially derived from variety A but will not fall within the scope of protection of variety A since variety A is itself an essentially derived variety. This fact will be of importance for species where mutation breeding is a frequently used technique.

Example 7: Change of chromosome number

The opinions differ on whether varieties resulting from the doubling or halving of the chromosome number should or should not be regarded as retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety. It is suggested that the criteria of essential derivation can be applied where the breeding technique involves a change in chromosome number in exactly the same way as with other breeding techniques.

Example 8: Cell fusion

A breeder transfers the nucleus from a cell of variety A into a cell from variety B with differing and alien cytoplasm, in which the nucleus of variety B has been destroyed, with a view to creating a male sterile version of variety A.

8.1 Question: Will the male sterile line be essentially derived?

8.1 Answer:

(i) The male sterile version of variety A will be clearly distinguishable from variety A on the basis of its male sterility and will be predominantly derived genetically from variety A (it is suggested that the small amount of DNA derived from the cytoplasmic organelles of variety B would be irrelevant)

so as to retain the essential characteristics that result from the genotype of variety A.

(ii) It will be a question of judgment whether the male sterile version of variety A conforms to the expression of the heritable characteristics of variety A apart from the introduced male sterility so as to satisfy Article 14(5)(b)(iii).

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