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GAZETTE**EXTENSION OF PROTECTION TO FURTHER GENERA AND SPECIES****REPUBLIC OF MOLDOVA**

By virtue of Decision No. 1174 of November 20, 2000, the Government of the Republic of Moldova extended the list of botanic plant genera and species protected under the Law No. 915/1996 on Plant Varieties Protection by 9 new species. The consolidated list of genera and species is reproduced

below (the Latin names and English common names appear in the Decision, whereas the French, German and Spanish common names have been added, without guarantee of concordance, by the Office of the Union).

(Consolidated list of genera and species)

MODIFICATION OF FEES

NETHERLANDS

As a result of the Administrative Agreement concerning the cooperation in examination of plant varieties, the Dutch Board for Plant Breeders' Rights (the Board for PBR) will carry out, at the request of another party, the technical examination of varieties belonging to certain species. It has been agreed that the requesting authority shall pay to the

Board for PBR an amount corresponding to the examination fee prescribed in the Netherlands.

The National examination fees for the Netherlands have been increased as from November 2001 as follows:

(Examination fees table)

NEWSLETTER

**STATES PARTY TO THE INTERNATIONAL CONVENTION FOR
THE PROTECTION OF NEW VARIETIES OF PLANTS**

(Document 422(e))

**WIPO-UPOV SYMPOSIUM
ON THE CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS
IN THE PROMOTION OF BIOTECHNOLOGICAL DEVELOPMENT**

Geneva, October 25, 2002

The Symposium will provide a high-level forum for discussion and analysis. It is expected that it will identify areas for further action to enhance the co-existence of patents and plant breeders' rights in the promotion of biotechnological developments. The program is included overleaf.

The Symposium will be held in Geneva, at the headquarters of WIPO and UPOV, on October 25, 2002. The working languages of the Symposium will be English, French and Spanish with simultaneous interpretation.

All interested persons and organizations are invited to attend the Symposium, free of charge. Participants are requested to register before September 20, 2002.

The Symposium will commence at 9.30 a.m. in Room A, and a luncheon reception will be offered to all participants on October 25, 2002.

Further information on the Symposium, including the registration form, information on the speakers and organizational arrangements will be posted regularly on the UPOV Web site (www.upov.int).

(Program)

LEGISLATION

CZECH REPUBLIC

PROTECTION OF PLANT VARIETY RIGHTS ACT No. 408/2000*

The Parliament has adopted the following Act of the Czech Republic:

PART ONE

CHAPTER I GENERAL PROVISIONS

Article 1

This Act regulates

- a) the rights and obligations with respect to new plant varieties,¹
- b) the powers and role of state administration authorities in the field of plant variety rights to varieties,
- c) the proceedings for the grant of plant variety rights,
- d) the control of variety maintenance, and
- e) the imposition of sanctions for infringement of obligations stipulated by this Act.

Article 2

Definitions

For the purposes of this Act

- a) “plant variety rights” means rights and obligations to plant varieties resulting from an effective decision of the Central Institute for Supervising and Testing in Agriculture (hereinafter “the Institute”),
- b) “holder” means the breeder who has been granted plant variety rights to the variety, or his successor in title,
- c) “breeder” means the natural or legal person, who bred, or discovered and improved (hereinafter “created”) a variety or the person for whom someone else created a variety as part

of fulfilment of tasks in relation to an employment contract or another similar relationship, unless a written agreement stipulates otherwise; legal successor of the breeder shall also be considered as breeder,

- d) “protected variety” means the variety protected by plant variety rights granted pursuant this Act,
- e) “member country” means a Member State of the International Union for the Protection of New Varieties of Plants,²
- f) “list” means the list of applications for the grant of plant variety rights to a variety in which the specifications pursuant to Article 9 (a) to (c) shall be entered,
- g) “small grower” means grower operating in agricultural production on arable land at a maximum area set down in Annex 2 of this Act.

CHAPTER II

Conditions for the Grant of the Plant Variety Rights

Article 3

- (1) The plant variety right may be granted to varieties of all plant genera and species, including hybrids between genera and species (hereinafter “varieties”).
- (2) The plant variety rights may be granted to the variety which satisfies conditions of
 - a) novelty,
 - b) distinctness,
 - c) uniformity, and
 - d) stability.
- (3) The variety denomination must comply with the conditions laid down by this Act (Article 7).

* Coll., on the Protection of Plant Variety Rights and on Amendment to Act No. 92/1996 Coll., on Plant Varieties, Seed and Planting Material of Cultivated Plant. Entered into force on February 1, 2001.
Translation: by the national authorities.

1. Article 2(a) of Act No. 92/1996 Coll., on plant varieties, seed and planting material of cultivated plants, as last amended.
2. Article 1(2) of the Communication of the Ministry of Foreign Affairs on accession of the Czech and Slovak Federal Republic to the International Convention for protection of new varieties of 2 December 1961, in the wording revised in Geneva 10 November 1972 and 23 October 1978.

(4) Plant variety rights shall be granted and obligations relating to their grant shall be stipulated by the Institute, if the criteria specified by this Act are satisfied.

Article 4

Novelty

(1) The variety shall be deemed to satisfy the condition of novelty if, at the day of filing of the application for grant of plant variety rights the propagating material³ or material from the variety harvest (hereinafter the “harvested material”) has not been sold or otherwise disposed of to others by or with the consent of the breeder, for purposes of exploitation of the variety

- a) in the territory of the Czech Republic earlier than one year before the application has been filed, or
- b) outside the Czech territory earlier than four years before the application has been filed or, in the case of trees or of vines, earlier than six years before the application has been filed.

(2) The following shall not be deemed to be a disposal of the variety to others within the meaning of paragraph 1:

- a) if the breeder supplies propagating or the harvested material of the variety
 1. in order to fulfil statutory duties,⁴ or
 2. to others based on a contractual relation solely for the purpose of production, propagation, conditioning or storage, provided the breeder preserves the exclusive right of disposal of the variety material; should, however, the propagating material of the variety be repeatedly used for the production of a hybrid variety, the material of which is sold or otherwise disposed, such use of the propagating material of the variety shall be deemed to be a disposal of the variety to others for purposes of exploitation of the variety, or
- b) if the breeder sells or otherwise provides, without reference to the variety, to a third person propagating or harvested material which has been produced from plants grown for experimental purposes or for the creation of other varieties and which is not used for further propagation, or
- c) if the breeder had displayed the variety at an international exhibition in compliance with an international treaty.⁵

3. Article 2(g) of ACt 92/1996 Coll.

4. E.g. Act No. 92/1996 Coll. as amended.

5. Convention on International Exhibitions concluded in Paris on 22 November 1928 and published in the Collection of Laws and Orders of Czechoslovak Republic under No. 46/1932.

6. Article 11(1) of Act 92/1996 Coll.

7. Article 2(f) of Act 92/1996 Coll.

Article 5

Distinctness

(1) The variety shall be deemed to satisfy the condition of distinctness if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge as of the date of the filing of the application for grant of plant variety rights by reference to the expression of at least one characteristic resulting from its genotype or combination of genotypes.

(2) The following varieties shall be deemed to be of matter of common knowledge

- a) protected in the Czech Republic or abroad,
- b) entered in the official plant variety register⁶ in the Czech Republic or a similar register abroad,
- c) in respect of which an application for grant of plant variety rights or for entry in the plant variety register has been filed in the Czech Republic provided the application will led to the granting or entering,
- d) in respect of which an application for grant of plant variety rights or for entry in the plant variety register has been filed abroad, provided the application will led to the grant or entry, or
- e) offered for sale or sold in the Czech Republic or abroad

Article 6

Uniformity and Stability

The variety shall be deemed to satisfy the conditions of uniformity and stability⁴ if it meets the features stipulated in a special legal regulation⁴.

Article 7

Variety Denomination

(1) The same variety denomination shall be used for an identical variety in the Czech Republic and any other contractual⁷ or member country. It shall not be applicable if the denomination contradicts the provisions of paragraph 2.

(2) A designation may not be used as a variety denomination if

- a) it consists solely of figures, except where this is an established practice for designating varieties,
- b) it is identical or may be confused with the denomination of another variety of the same or of a closely related species in the Czech Republic, a contractual or a member country,
- c) it is liable to mislead evoking false impressions concerning the value, characteristics or origin of the variety or the identity of the breeder,
- d) it is identical to or may be confused with a trademark, appellation of origin or geographical indication for the same or similar products or otherwise infringing the rights or safeguarded interests of other persons,
- e) it is unsuitable for linguistic reasons.
- d) information on all previous applications for protection for the variety in question,
- e) information on previous exploitation of the variety,
- f) a description of the variety.

Article 10

Plant variety rights to a variety may be granted to a breeder who filed an application for grant of such rights with the Institute. Should more than one breeder have jointly participated in the variety creation, the granted plant variety rights to such protected variety shall be shared equally, unless stipulated otherwise in a written agreement between them.

Article 11

(1) The Institute shall enter the application in the list of applications in succession by delivery date and will examine whether the variety may be subject to plant variety rights, whether there are no obstacles hindering further proceedings for the grant of plant variety rights and whether an administrative fee has been paid.

(2) Should the application not comply with the details and requirements stipulated by this Act or should obstacles exist hindering further proceedings, the Institute will call the applicant to make corrections. If the applicant fails, within the time limit, to correct defects, the Institute shall stay the proceedings, provided the applicant has been notified of such consequence in the above call.

Article 12

(1) If more applications for the grant of the plant variety rights to the same variety have been filed with the Institute, such right may only be granted to one applicant, i.e. the one, whose application was submitted first; the right of priority resulting from an earlier filing of the application in any member country must be honoured, provided further conditions specified by this Act have been met.

(2) Should the applicant file an application in another member country prior to filing an application in the Czech Republic, he will enjoy the priority right in respect of filing for the same plant variety in the Czech republic over a period of 12 months of filing his previous application in another member country, provided such right has been exercised in the application filed with the Institute. The right of priority will not be taken into account unless within three months of filing the application with the Institute, the applicant submits a certified copy of his previous application filed in another member country.

Article 13

(1) The Institute will publish the following information in the Bulletin of the Ministry of Agriculture (hereinafter "the Bulletin"):

CHAPTER III

PROCEEDINGS IN MATTERS OF PLANT VARIETY RIGHTS TO PLANT VARIETIES

Article 8

(1) Breeder who is a citizen of the Czech Republic or is a legal person having its registered office in the Czech Republic or who is a national or a legal person having its registered office in a member or contractual country (hereinafter "the applicant") shall be entitled to file an application for a grant of plant variety rights to a variety (hereinafter "the application"). An application may be filed jointly by several applicants.

(2) The Institute may grant the eligibility for filing the application to persons who do not qualify under the provisions of paragraph 1, provided:

- a) they are citizens of a country which provides similar protection of varieties of the same botanical taxon to persons from member or contractual countries, or
- b) they are legal persons having a registered office in a country which provides similar protection of varieties at the same level of botanical classification to persons from member or contractual countries.

Article 9

The application must contain the following

- a) the applicant's name, surname and permanent residence address provided he is a natural person or in case of a legal person, its business name, registered office and legal form.
- b) Latin and Czech name of the species, or another botanical taxon, if appropriate,
- c) a proposed denomination or provisional designation of the variety,

- a) information on applications filed in succession by filing date including information regarding the applicants [Article 9 (a)],
 - b) change to the proposed variety denomination or the proposed variety denomination, if the application included only a provisional designation [Article 9 (c)].
- (2) Anyone may object with the Institute against:
- a) a filed application, by the latest until the decision under Article 11 (2) or Article 16 has been issued,
 - b) the proposed variety denomination, by the latest within three months of its publication in the Bulletin.
- (3) Objections under paragraph 2 will be resolved by the Institute by the latest until the decision under Article 11 (2) or Article 16 has been issued. The Institute makes the decisions on objections; no appeal lies against such decision.

Article 14

(1) After all details and requirements under Article 11 (1), have been complied with, the Institute will examine whether the variety meets the conditions of being novelty, distinctness, uniformity and stability and whether the proposed variety denomination complies with the conditions stipulated under Article 7. Compliance with the requirements of distinctness, uniformity and stability is ascertained using field and laboratory tests. When examining varieties to ascertain compliance with the conditions, the Institute may use the results of examinations of distinctness, uniformity and stability performed by professional institutions abroad.

- (2) The applicant shall be obliged
- a) to provide to the Institute the plant material necessary for the examination of the variety according to paragraph 1, within a reasonable period prescribed by the Institute,
 - b) to reimburse the Institute for expenses incurred in connection with the performance of special acts during the proceedings for the grant of plant variety rights.

Article 15

Transfer of Application

In the course of the proceeding for the grant of plant variety rights the application can be transferred to another person only with consent of the applicant.

Article 16

Breeder's Certificate

(1) The Institute shall grant the applicant the plant variety rights to the variety and shall approve the proposed variety denomi-

nation by the issuance of a breeder's certificate, provided all conditions stipulated by this Act have been met; otherwise the proceeding shall be terminated.

(2) The breeder's certificate shall include the denomination of the species to which the variety belongs, variety denomination, name, surname, permanent residence address or business name, registered office and legal form of the holder. The certificate will also include the variety description prepared on the basis of the results of tests of distinctness, uniformity and stability.

Article 17

Using the Variety Denomination

- (1) Everyone offering or providing for use material of the protected variety or variety under Article 19 (4), is obliged to use the approved variety denomination. Should this variety denomination be used in a written form together with a trademark, brand or other specification, it must be clearly distinguishable from such specification.
- (2) Denomination of a protected variety or a variety protected in another member country or denomination, which may be confused with such denomination, may not be used for another variety of the same or related species.
- (3) The provisions of paragraph 1 and 2 shall apply also for the period after the termination of the plant variety rights.

Article 18

Variety Maintenance Control

- (1) The holder shall be obliged to ensure the maintenance of the protected variety over the entire period of the plant variety rights duration to make sure that the characteristics specifying the variety remain unchanged.
- (2) The Institute performs verification testing to control the maintenance of the protected variety. The execution of this control is regulated by a special Act³, unless this Act stipulates otherwise.
- (3) The employees of the Institute entrusted with the execution of control are entitled to enter grounds, companies and their branch offices, premises, establishments and facilities in which the holder or a person entrusted by him handles the protected variety, and request from such persons necessary documentation, information and co-operation for a smooth and fast performance of control including allowing them to take necessary quantity of control samples of material of the protected variety. Samples are provided free of charge.
- (4) Upon request by the Institute, the holder is also obliged to deliver free of charge and within reasonable time limit specified by the Institute, material of the protected variety required for the performance of control tests.

3. Act No. 552/1991 Coll., on state control, as amended.

CHAPTER IV

SCOPE OF PLANT VARIETY RIGHTS

Article 19

(1) The holder has the sole authority to use the protected variety consisting of the right to exploit the propagating material of such variety as follows:

- a) production or propagation,
- b) conditioning for the purpose of propagation,
- c) offering for sale,
- d) sale or other marketing,⁹
- e) export,
- f) import,
- g) stocking for the purposes specified under letters a) to f).

(2) The holder may provide his consent with the use of the protected variety (hereinafter “the license”) to a third person; the license is provided in writing and must include an agreement on the license charge.

(3) The provisions of paragraph 1 and 2 also relate to the harvested material of the protected variety, including whole plants and their parts, if obtained from the propagating material of the protected variety without a license provided by the holder who could not exercise these rights in respect of the above propagating material.

(4) The provisions of paragraph 1 to 3 also relate to:

- a) varieties essentially derived from the protected variety,
- b) varieties which are not distinct from the protected variety,
- c) varieties whose production requires the repeated use of the protected variety.

(5) If the protected variety itself is an essentially derived variety, the exclusive right to such variety held by the holder does not include varieties derived from such variety.

(6) Varieties shall be considered as essentially derived from another variety (hereinafter “the initial variety”), if:

- a) they are predominantly derived from the initial variety or from a variety which itself is essentially derived from the initial variety,
- b) are distinct from the initial variety, and
- c) except for the differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of characteristics resulting from the genotype or the combination of genotypes of the initial variety.

(7) Essentially derived varieties may be obtained, in particular, by the selection of a natural or induced mutation or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering methods.

(8) If an essentially derived variety is a protected variety, then the right of the holder to the initial variety is limited with respect to this essentially derived variety to the extent of providing the license for the variety use to the holder to this variety. The holder to an essentially derived variety may use this variety only provided he has a license issued by the holder to the initial plant variety.

(9) The following exploitation of the propagation material shall not constitute a breach of the plant variety rights (paragraph 1)

- a) performed for research,
- b) performed with the aim to create additional varieties including exploiting such varieties except for varieties under paragraph 4,
- c) performed for own use of a natural person.

(10) In respect of plants specified in Annex 1 of this Act, persons¹⁰ operating in agricultural production (hereinafter “the growers”) shall be entitled to exploit, for the purpose of propagation, without holding a license issued by the holder, to ensure production in their own business¹¹ on arable land owned, leased or subleased by them, harvested material acquired on such land through the cultivation of propagating material³ of a protected variety, except for a hybrid or synthetic variety (hereinafter “farm saved seed”).

(11) When exploiting farm saved seed under paragraph 10

- a) growers are not limited as to the quantity of their plant production produced on land used by them for the needs of their business,¹¹
- b) growers may process farm saved seed for further sowing and planting either themselves or by suppliers of processing services,¹⁰ (hereinafter “seed processors”); the alteration must be performed in a manner ensuring that the product submitted for processing is identical with the resulting product,
- c) growers are obliged to pay to the holder only reasonable remuneration for the use of farm saved seed which is significantly lower than an arms length price of a licence; the obligation to pay reasonable consideration for the use of farm seed does not apply for small growers.

(12) The holder is entitled to request necessary information in writing from growers and seed processors in relation to the farm saved seed of the variety exploited or altered by them for which plant variety rights have been granted to the holder.

9. E.g. Article 151(b), 628 of the Civil Code, as amended.

10. Article 2 of the Commercial Code, as amended.

11. Article 5 of the Commercial Code, as amended.

(13) Growers and seed processors are obliged, upon request, to provide to the holder, information in writing about their name, surname, permanent residence address and identification number in case of natural persons, and business name, registered office, identification number and legal form in case of legal persons.

(14) Seed processors are obliged, upon request, to provide to the holder information in writing about the quantity of farm saved seed delivered to them for processing, as well as the resulting quantity of processed seed, the date and location of processing and identification of the person for whom the processing was performed.

(15) Growers are obliged, upon request, to provide to the holder, information in writing about the scope of use of farm saved seed.

(16) The holders are obliged, upon request, to provide to the breeders information in writing regarding the amount of reimbursement to be requested under paragraph 11 (c) .

Article 20

(1) Plant variety rights do not extend to acts concerning any material of the protected variety or of a variety under Article 19 (4), which was sold or otherwise marketed in the territory of the Czech Republic by the holder or with his consent or the exploitation of any material derived therefrom, unless this represents

- a) further propagation of such varieties, or
- b) export of material of such varieties which enables their further propagation into a country that does not protect plant varieties of the same plant genus or species to which this variety belongs; this does not apply provided such material is designed for final consumption.

(2) Material of plant variety under paragraph 1 shall be understood as

- a) any propagating material of the protected variety,
- b) harvested material of the protected variety.

Article 21

Compulsory License

(1) Upon request, the Ministry of Agriculture (hereinafter “the Ministry”) may grant a compulsory license for the exploitation of a protected variety in a manner specified under Article 19 (1) to one or more persons, if the holder refuses to issue a license for such exploitation in the required scope and if such exploitation is in public interest. The Ministry shall inform the Institute about the grant of a compulsory license.

(2) When granting a compulsory license, the Ministry shall stipulate the conditions, time limitation and scope of the exploitation including the payment of an appropriate royalty to the holder in respect of such license.

(3) On the expiry of one year after the grant of the compulsory license, each participant of the proceeding for the grant of the compulsory license may request the Ministry in writing to cancel or amend the decision on the grant of the compulsory license. Only a change of circumstances on the basis of which the decision was made may constitute a reason for such request.

(4) The Ministry may grant a compulsory license in respect of an essentially derived variety based on a proposal of the holder to this variety if the holder of the initial variety refuses to provide a license for the exploitation of the essentially derived variety and if such exploitation is in public interest.

CHAPTER V

SANCTIONS

Article 22

(1) Any person who violates an obligation stipulated by this Act or who obstructs the execution of control performed under this Act shall be liable to a fine imposed by the Institute, not exceeding CZK 500,000.

(2) When determining the amount of the fine the Institute shall take into account the importance, manner, duration, consequences of the wrongful act and circumstances under which such act occurred.

(3) Proceeding on imposing penalty may be opened by the latest within one year of the day when the Institute established the violation.

(4) Fines are imposed and collected by the Institute. The revenue from the fines represents the Czech Republic’s state budget revenue. Fines are levied by the financial office with territorial jurisdiction.¹² Enforcement is performed in accordance with a special legal regulation.¹³

CHAPTER VI

COMMON, TRANSITORY AND FINAL PROVISIONS

Article 23

Duration of the Plant Variety Rights

(1) The plant variety rights may be maintained until the end of the twenty-fifth year after the year in which the grant of such rights came into effect; for protected varieties of trees, hops, vines and potatoes, the plant variety rights may be main-

12. Act No. 531/1990 Coll., on financial offices with territorial jurisdiction, as amended.

13. Act No. 337/1992 Coll., on the administration of taxes and fees, as amended.

tained until the end of the thirtieth year following the year in which the grant of such rights came into effect.

(2) For the period from filing the application until the grant of plant variety rights to the variety becomes legally effective, the holder is entitled to a reasonable compensation from each person who during such period exploited the variety in a manner which would require granting a license by the holder after such rights have been granted.

Article 24

Transfer of the Plant Variety Rights

(1) The holder may transfer the plant variety rights to the protected variety to a third person based on a written contract. If plant variety rights to the same protected variety belong to more persons, the share in such rights may be transferred to any of the co-holders without consent of the rest of them; a co-holder may transfer his share to a third person only provided none of the other co-holders accepts his written offer for transfer within one month upon its delivery.

(2) Unless this Act stipulates otherwise, the relations between the co-holders shall be governed by the Civil Code.

(3) A contract on the transfer of the plant variety rights to the protected variety or on the transfer of a share of the plant variety rights to the protected variety becomes effective on the day of its entry to the Register of Protected Varieties kept by the Institute. The Institute will make the entry after the administrative fee under special legal regulation¹⁴ has been paid.

Article 25

Termination and Cancellation of the Plant Variety Rights

(1) The plant variety rights shall terminate upon the expiry of the period stipulated by this Act or if the holder fails to pay the administrative fee as per the special legal regulation¹⁴ even after a written notification by the Institute within a period specified by the Institute, or if the holder renounces his plant variety rights in writing to the Institute.

(2) Before the expiration of the plant variety rights the Institute shall terminate such rights if the protected variety no longer meets the condition of uniformity and stability or if the holder fails to comply with his obligation under Article 18 (1) or (2).

(3) If it is revealed that at the time of the issue of the breeder's certificate effectively granting the plant variety rights, not all the conditions for their granting have been met, the Institute shall cancel such breeder's certificate; in such case the plant variety rights granted shall be regarded as null and void.

Article 26

(1) The grants issued, termination, cancellation of plant variety rights, transfer of or any change to plant variety rights to the protected plant variety, compulsory license, change of name, surname, business name, permanent residence address or registered office of the holder, shall be entered in the Register of Protected Varieties kept by the Institute; information about the above facts shall publish the Ministry in the Bulletin.

(2) Upon request of a contracting party, licenses concluded under Article 19 (2) may also be entered in the Register of Protected Varieties.

Article 27

Resolution of Disputes

(1) Disputes resulting from legal relations established on the basis of this Act shall be discussed and decided by courts.

(2) In case of an infringement of a right protected under this Act, the person whose right has been threatened or infringed may claim from the infringer to refrain from such acting and correct the defect. If the infringement caused a damage, the damaged is entitled to compensation. In case of non-property damages the damaged is entitled to reasonable satisfaction which may consist of pecuniary compensation.

(3) Upon request by the damaged person, the respective court may decide that the plant propagating material or harvested material to which the infringement of the exclusive rights of the holder relates and which is held by the person infringing the exclusive rights of the holder shall be destroyed unless the infringement of the right may be corrected in another manner and destruction of plant material would be inadequate to such infringement.

Article 28

(1) Unless this Act stipulates otherwise, the decision-making under this Act shall be governed by the Rules of Administration¹⁵.

(2) The Institute is entitled to stay the proceedings indefinitely if requested by the applicant for serious reasons.

(3) The decision on the grant of the plant variety rights will be made by the Institute within three months

a) after the completion of tests required for the decision or after the receipt of the test results performed by other professional institutions, and

b) after the expiration of the deadline for filing of objections under Article 13 (2) (b).

14. Act No. 368/1992 Coll., on administrative fees, as amended.

15. Act No. 71/1967 Coll., on administrative procedures (Administrative Procedure Code, as amended).

(4) Appeals against the Institute's decisions shall be decided by the Ministry.

Transitional Provisions

Article 29

(1) Proceedings in the matters of plant variety protection not completed before the effective day of this Act shall be completed in accordance with this Act.

(2) Unless this Act stipulates otherwise, legal relations that arose before its effective date shall be governed by this Act; however, the inception of such legal relations and claims arising from them before the effective day of this Act shall be resolved in accordance with the existing regulations.

(3) On the effective day of this Act rights and obligations under this Act shall become effective for the owner of breeder's certificate granted under the existing regulations; the duration of such breeder's certificate, however, shall be counted as per Act No. 132/1989 Coll. in the wording of Act No. 93/1996 Coll. The exclusive right of the holder to a variety, which under this Act is considered as an initial variety, shall not relate to varieties for which the breeder's certificate has been granted under the existing regulations and which can be considered as essentially derived varieties under this Act.

Article 30

Plant variety rights may also be granted to varieties the propagating material or harvested material of which was not sold or provided for use to third persons by the breeder or with his consent for more than four years and in case of trees for more than six years before the effective date of this Act, if the varieties are varieties of genera or plant species or their hybrids not covered by the existing regulations. In such case the application for the grant of plant variety rights must be filed by the latest within one year of the effective day of this Act and at the time of the application filing the variety must be registered in the State Variety Book (National List) under a special legal regulation⁶ or must enjoy a variety protection in a member country. The duration of plant variety rights specified in Article 23 (1) shall be shortened in such case by the time calculated from the day of the entry of the variety in the State Variety Book until the effective date of the grant of the plant variety rights to variety or by the time calculated from the day of grant the plant variety rights to variety in the member country until the effective date of the grant the plant variety rights to variety under this Act.

Article 31

If before the effective date of this Act a third person, to which the existing regulations on the protection of rights to varieties do not apply, exploits the variety of plant genera and species or the hybrids thereof, the holder under this Act is obliged to allow such third person free of charge further exploitation of this variety until the end of the year, or, in case of trees, until the end of the second year following after the year in which

this Act became effective; after the expiration of the above period, the holder is obliged to allow such third person to further exploit the variety for an usual license charge.

PART TWO

Amendment of Act No. 92/1996 Coll., on plant varieties, seed and planting material of cultivated plants, as amended
Article 32

Act No. 92/1996 Coll. on plant varieties, seed and planting material of cultivated plants, in the wording of Act No. 357/1999 Coll. and Act No. 153/2000 Coll., shall be amended as follows:

1. In Article 2 (a) shall be as follows:

“a) “variety” means a plant grouping within the lowest rank of botanical classification, which can be defined by expression of characteristics resulting from a certain genotype or combination of genotypes, distinguishable from any other plant grouping by the expression of at least one of these characteristics and considered as a unit with regard to its suitability being propagated unchanged.”.

2. In Article 8 (2) and (3) shall be as follows:

“(2) The variety shall be deemed to be uniform if it is sufficiently uniform in characteristics which are included in the examination for distinctness, as well as characteristics used for the variety description, subject to the variation that may reasonably be expected from the particular features of its propagation.

(3) The variety shall be deemed to be stable if the expression of the characteristics included in the examination of distinctness as well as characteristics used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle”.

3. In Article 21, a new paragraph 3 shall be inserted after paragraph 2 as follows:

“(3) For the purpose of import and marketing, ornamental varieties of species listed in the list of species shall be considered as varieties of species not listed in the list of species.”

The existing paragraph 3 shall become paragraph 4.

4. In Article 22 (2), the following sentence shall be added at the end of subparagraph g): “For fruit trees, hops and vines the maintainer of variety not protected under special legal regulation³ must express his consent only in respect of the certification of the mother stocks, buds and rootstocks.”

5. In Article 31, a new paragraph 3 shall be inserted after paragraph 2 as follows:

“(3) For species not listed in the list of species, the registration obligation under paragraph (1) shall not relate to

a person producing or putting into market commercial propagating material of ornamental species.”

The existing paragraph 3 and 4 shall become paragraph (4) and (5).

PART THREE

REPEALING PROVISIONS

Article 33

The following is hereby repealed:

1. Act No. 132/1989 Coll., on the legal protection of new varieties of plants and breeds of animals, as amended by Act No. 93/1999 Coll. and Act No. 206/2000 Coll.
2. Decree No. 133/1989 Coll. implementing some of the provisions of Act No. 132/1989 on the legal protection of new varieties of plants and breeds of animals, as amended by Decree No. 514/1999 Coll.

3. Decree No. 134/1989 Coll. setting out the list of economically significant genera and species of plants and animals, as amended by Decree No. 515/1999 Coll. and Decree No. 118/2000 Coll.

PART FOUR

FORCE

Article 34

This Act shall enter into force on 1 February 2001.

Annex No. 1 to Act No. 408/2000 Coll.

Plant Species List [Article 19 (10)]

a) Cereals:

Avena sativa L.	Oats
Hordeum vulgare L.	Barley
Secale cereale L.	Rye
Triticosecale Wittm.	Triticale
Triticum aestivum L. emend. Fiori et Paol.	Common wheat
Triticum durum Desf.	Durum wheat
Triticum spelta L.	Spelt wheat

b) Fodder plants:

Lupinus luteus L.	Yellow lupin
Medicago sativa L.	Lucerne
Pisum sativum L. (partim)	Field pea
Trifolium alexandrinum L.	Berseem/Egyptian clover
Trifolium resupinatum L.	Persian clover
Vicia faba L.	Field bean
Vicia sativa L.	Common vetch

c) Potatoes:

Solanum tuberosum L.	Potatoes
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d) Oil and fibre plants:

Brassica napus L. (partim)	Swede rape
Brassica rapa L. (partim)	Turnip rape
Linum usitatissimum L.	Linseed (except flax)

Annex No. 2 to Act No. 408/2000 Coll.

Maximum area of arable land [Article 19 (11) (c)]

1.		2.	3.	4.	
Average price category of agricultural land (including arable land) in cadastral areas*		Average yield of cereals in t/ha**	Maximum area (ha) of arable land on which a small grower operates ***	Conversion coefficient (ph)****	
Category denomination	CZK/m ²			Conversion coefficient symbol	Conversion coefficient value
va	less than 3.5	3.40	va 27	ka	1
vb	3.51-4	3.91	vb 23	kb	1.17
vc	4.01-6	4.17	vc 22	kc	1.23
vd	6.01-8	4.73	vd 19	kd	1.42
ve	more than 8	5.51	ve 17	ke	1.59

Maximum acreage calculation formula:

$$va \times ka + vb \times kb + vc \times kc + vd \times kd + ve \times ke = ph$$

Explanation of symbols used in the maximum acreage calculation formula:

- va, vb, vc, vd, ve - maximum land acreage in individual categories according to column 3
ka, kb, kc, kd, ke - conversion coefficients according to column 4,
ph - converted value (maximum acreage).

* Decree No. 215/1995 Coll. stipulating the list of cadastral areas and their adjoined average prices of agricultural land in the wording of Decree No. 282/1996 Coll., Decree No. 285/1997 Coll., Decree No. 262/1998 Coll. and Decree No. 298/1999 Coll.

** Average yield is determined based on supporting documentation on actual cereal yield for the period 1995 through 1999.

*** Acreage is determined based on the criterion of maximum harvest production of 92 tons of cereals which is based on Article 14(3) of the Council Regulation No. 2100/94 of 27 July 1994 and the Commission Regulation No. 1768/95 of 24 July 1995.

**** If the price of the arable land on which the small grower is operating falls into more categories, then the acreage of land pertaining to each individual category according to column 1 shall be multiplied by the conversion coefficient. Individual

NICARAGUA

LAW FOR THE PROTECTION OF
NEW VARIETIES OF PLANTS No. 318

THE PRESIDENT OF THE REPUBLIC OF NICARAGUA

Informs the people of Nicaragua that:

**THE NATIONAL ASSEMBLY OF THE REPUBLIC OF
NICARAGUA**

Pursuant to its authority:

HAS ENACTED

The following:

LAW FOR THE PROTECTION OF
NEW VARIETIES OF PLANTS

CHAPTER I

GENERAL PROVISIONS

Article 1

Purpose

The purpose of this Law is to establish the legal provisions for the protection of the rights of natural or legal persons who, by natural means or genetic engineering, have created or discovered and used a new plant variety, and to whom shall be granted the title of breeder.

Article 2

Competent Authority

The Ministry of Public Works, Industry and Trade, acting through the Intellectual Property Register (RPI), shall be the department of the executive responsible for the administration and application of this Law.

Article 3

Definitions

For the purposes of this Law, the following meanings shall apply:

Relevant characteristics means phenotypical and genotypical expressions peculiar to the plant variety that enable it to be identified as such.

Plant variety means the plant grouping within a single botanical taxon of the lowest known rank which, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be:

- (a) defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- (b) distinguished from any other plant grouping by the expression of at least one of said characteristics, and
- (c) considered as a unit with regard to its suitability for being propagated without change.

Propagating material means any material for the reproduction of plants, whether by sexual or asexual reproduction, that may be used for the production or multiplication of a plant variety, including seeds for sowing and any whole plant or parts thereof, from which it is possible to bring about the reproduction of whole plants or seeds.

Reference specimen means the smallest entity used by the breeder to maintain his variety, from which the representative sample is taken for registration of the variety.

Reproductive or vegetative propagating material means seeds, fruits, plants or parts thereof that are used for the reproduction of plants, including also whole plants.

Breeder means a natural or legal person who has created or discovered and used a new plant variety either by natural means or genetic engineering.

Recognized priority means precedence for the grant of a breeder's rights based on the filing abroad of an application that relates entirely or partly to the same subject matter in respect of which a subsequent application is filed in the Republic of Nicaragua.

Protected variety means a variety which is the subject of a breeder's right and is entered in the Intellectual Property Register (RPI) of the Ministry of Public Works, Industry and Trade, and for which the corresponding breeder's certificate has been issued.

Register means the Intellectual Property Register (RPI) of the Ministry of Public Works, Industry and Trade, in which applications and the rights granted to breeders of plant varieties will be entered.

Examination Committee means the Examination Committee for the Protection of Plant Varieties (CCPVV), a national body created under Article 69 of this Law.

Breeder's certificate means the document issued by the Ministry of Public Works, Industry and Trade (MIFIC) that recognizes and protects the breeder's rights in a plant variety.

* Translation prepared by the Office of the Union and confirmed by the Nicaraguan authorities.

International Convention for the Protection of New Varieties of Plants of December 2, 1961, as revised at Geneva on November 10, 1972, October 23, 1978, and March 19, 1991 means the International Convention open to accession by States, the objective of which is the protection of plant varieties by means of industrial property rights, and which is the legal basis of the International Union for the Protection of New Varieties of Plants (UPOV).

International Union for the Protection of New Varieties of Plants (UPOV) means the intergovernmental organization with headquarters in Geneva, Switzerland, based on the International Convention for the Protection of New Varieties of Plants, the signatory countries to which constitute its membership.

Article 4

Legal Protection

This Law shall grant legal protection to the breeders of plant varieties, be they nationals of the Republic of Nicaragua or foreigners resident in the country.

Article 5

Reciprocity

The nationals of any State, irrespective of whether they are members of the International Union for the Protection of New Varieties of Plants (UPOV), granting effective protection to the breeders of plant varieties from Nicaragua, shall be beneficiaries of this Law by virtue of reciprocity.

CHAPTER II

BREEDER'S RIGHTS

Article 6

Nature of a Breeder's Right

A breeder's right shall be considered to be industrial property rights and the provisions in force of the Law on Inventions shall apply to them subsidiarily.

Article 7

Characteristics of the Rights

A breeder's right shall be marketable, transferable and inheritable. The heir or successor in title may make use of the rights, derive benefit from them and dispose of them throughout the term of their validity. The owner of the right may grant third parties operating licenses for the use of protected varieties.

Article 8

Scope of a Breeder's Right

The authorization of the breeder or of the person to whom a breeder's right has been granted shall be required for the following acts performed on reproductive or propagating material of the protected variety, in the following cases:

- (a) production or reproduction;
- (b) preparation for the purposes of reproduction or propagation;
- (c) marketing;
- (d) export;
- (e) import;
- (f) donation.

The breeder's authorization shall likewise be required for the use of ornamental varieties, or part thereof, that are usually marketed for purposes other than propagation, intended in this case for the production or reproduction of said variety.

The breeder may make the authorization that he has given under the foregoing paragraphs subject to certain conditions and limitations, and shall do so in writing.

Article 9

The above provisions shall likewise apply to:

- (a) varieties essentially derived from the protected variety where the latter is not itself an essentially derived variety, pursuant to Article 11 of this Law;
- (b) varieties that are not clearly distinguishable from the protected variety, in accordance with Article 18 of this Law;
- (c) varieties whose production requires the repeated use of the protected variety

Article 10

Application of a Breeder's Right

A breeder's right shall apply to the varieties of all plant genera and species.

Article 11

Essentially Derived Variety

A variety shall be considered essentially derived from an initial variety, if:

- (a) it is mainly derived from the initial variety, or from a variety itself derived mainly from the initial variety, and at the same time retains the expressions of the essential characteristics resulting from the genotype or combination of genotypes of the initial variety;
- (b) it is clearly distinguishable from the initial variety; and,
- (c) it conforms, subject to the differences resulting from the derivation, to the initial variety in the expression of the essential characteristics resulting from the genotype or combination of genotypes of the initial variety.

Article 12

Exceptions to a Breeder's Right

The authorization of the breeder shall not be necessary for use of the protected variety, where:

- (a) it is a source or ingredient for research into the genetic improvement of other plant varieties;
- (b) the farmer uses the harvest produce obtained through cultivation for reproduction or multiplication purposes on his own land;
- (c) the produce harvested is used or sold for human or animal consumption, or as a raw material.

Article 13

Renunciation of a Breeder's Right

The breeder may renounce the rights conferred on him by this Law; renunciation shall be evidenced in writing and shall be entered in the appropriate register. It shall be irrevocable, and the use and exploitation of the plant variety shall pass into the public domain.

Article 14

Judicial Award of a Breeder's Right

Where a person not entitled to protection files an application for a breeder's right, the holder of the right or his successor in title may file a request for award to him of the application or, where already granted, of the breeder's right.

The request for the award shall be statute-barred after five years have elapsed following the date of the publication of the grant of the breeder's rights. Such an action against a defendant who has acted in bad faith shall not be subject to any statute-barring.

If the request is successful, any third party rights granted under the breeder's right during the time that has passed shall lapse.

Nevertheless, the holders of exploitation rights acquired in good faith who have taken genuine and effective measures to benefit from those rights prior to the date of notification of the

request or, failing that, of the decision, may carry out or continue to carry out the acts of exploitation resulting from the steps that they have taken, provided that equitable remuneration is paid to the rights owner.

Article 15

Rights' Owner

The entitlement to apply for a breeder's right shall belong to the natural or legal person considered to be the breeder or his successor in title.

Where two or more persons have created or discovered a variety jointly, the right to protection shall belong to them jointly. Unless otherwise provided between the joint breeders, the shares of the joint breeders shall be equal.

Where the breeder is considered to be an employee or worker, the right to apply for the breeder's right shall be governed by the employment contract under which the variety was created or discovered, in accordance with the law applicable to said contract.

CHAPTER III

CONDITIONS FOR THE PROTECTION OF A BREEDER'S RIGHT

Article 16

Conditions of Protection

A breeder's right shall be granted for a plant variety where the variety combines the following features:

- (a) novelty;
- (b) distinctness;
- (c) homogeneity;
- (d) stability;
- (e) it is a denomination that complies with the provisions of Chapter VI of this Law.

The grant of the breeder's right may be dependent only on the above conditions, and shall be granted subject to the breeder having complied with the formalities provided for in this Chapter and having paid the prescribed fees.

Article 17

Novelty

A variety shall be considered novel if, on the filing date of the breeder's right application, the reproductive or propagating material, or produce harvested from the variety, has not been offered for sale or marketed by the breeder or his successor in title or representative:

- (a) on national territory for up to one year prior to the filing date of the application;

- (b) on the territory of any other State for more than four years or, in the case of trees and vines, for more than six years prior to that date.

Article 18

Distinctness

A plant variety shall be considered distinct if it is technically and clearly distinguishable by one or more relevant characteristics from any other variety whose existence is a matter of common knowledge on the filing date of the application; said characteristics shall be readily recognized by a person skilled in the art, and shall be described accurately in the corresponding application.

The filing in any country of an application for a breeder's right or entry in a catalogue of varieties given marketing approval shall be regarded as making the variety applied for well-known as from the application date, if the application leads to the grant of the breeder's right or to entry in the catalogue, according to the individual case.

Common knowledge of the existence of another variety may be established by reference to various factors, including:

- (a) exploitation of the variety already in progress;
- (b) entry of the variety in a register of varieties kept by a recognized professional association;
- (c) the presence of the variety in a reference collection.

Article 19

Homogeneity

A plant variety shall be considered homogenous if it is sufficiently uniform in terms of its relevant characteristics, subject to the variation that may be expected from the particular features of its sexual reproduction or vegetative propagation.

Article 20

Stability

A plant variety shall be considered stable if its relevant characteristics remain unchanged after repeated reproduction or propagation or, in the case of a particular cycle of reproduction or propagation, at the end of each cycle.

CHAPTER IV

ESTABLISHMENT, TERM, LIMITATION

Article 21

Establishment of Registration Rights and Authority

A breeder's right shall be established through entry in the Intellectual Property Register (RPI) of the Ministry of Public

Works, Industry and Trade, and the granting thereby of a breeder's certificate, within the time limits and on the conditions laid down in this Law.

Article 22

Term

The rights granted to the breeder shall have a term of twenty years for all species, calculated from the date of the grant of the title of protection.

The breeder's right shall remain in force only for as long as the fees payable for the registration and maintenance of the rights are paid by the time limits specified in this Law.

Once the terms of protection for a plant variety have expired, its use and exploitation shall pass into the public domain.

Article 23

Limitation of the Exercise of Protected Rights

The free exercise of the exclusive right granted to a breeder of plant varieties may only be limited in the public interest. In such cases, use may be made of the grant of compulsory licenses for the exploitation of registered varieties.

When a compulsory license is granted, the competent authority shall set equitable remuneration which the licensee holding the compulsory license has to pay to the breeder of the plant variety.

CHAPTER V

REGISTRATION AND APPLICATION

Article 24

Registration of Rights

Rights shall be entered in the Intellectual Property Register (RPI) of the Ministry of Public Works, Industry and Trade (MIFIC).

The RPI shall register the applications and rights granted, and shall distinguish between registration of applications and registration of rights granted. Said registers shall be public.

The RPI shall retain the contents of their files, in the form of originals or reproductions, for a period of five years from the date of withdrawal or rejection of the application, or the date of lapse of the breeder's right, according to the individual case.

Article 25

Access to Information

The RPI shall guarantee access to any information contained in register entries, and any person having a legitimate interest

may consult the documents relating to the application and the grant of breeders' rights.

In the case of varieties whose production calls for the repeated use of parent varieties, the applicant may, on filing his application, request the documents and trials relating to the components to be exempted from publicity measures.

Article 26

RPI Entries

The following shall be entered in the Intellectual Property Register:

- I. Applications for breeders' rights;
- II. Filing records;
- III. The grant of rights and the breeder's certificate, which shall specify:
 - (a) denomination of the protected plant variety;
 - (b) characteristics of the protected variety;
 - (c) species to which it belongs, and scientific and common name;
 - (d) name and address of the owner or owners of the plant variety, or their successors in title or legal representative, as well as their legal status; and
 - (e) date of grant and term of validity.
- IV. Renunciation of the rights conferred by this Law.
- V. Transfers and obligations stemming from the rights conferred by this Law;
- VI. Issue of compulsory licenses as provided for by this Law;
- VII. End of the validity of the rights and breeder's certificate, whether due to lapse or expiry of the period concerned, and also the precautionary institution of proceedings for invalidation and revocation of a breeder's certificate, including the final decision.
- VIII. Declaration that the plant varieties have passed into the public domain.

Article 27

Recording in the Register

In order to be binding on third parties, both breeders' titles and transfers of rights shall be recorded in the Register.

Article 28

Publication

The RPI shall order the publication, in the Official Journal *La Gaceta* and/or such media as it considers suitable, of entries made in the Register, applications for breeders' titles and any information on the subject matter of this Law considered to be of interest; the cost of such publication shall be borne by the breeder.

The RPI shall regularly publish plant variety registrations and applications under the following headings:

- (a) applications for the grant of breeders' rights;
- (b) requests for approval of variety denominations;
- (c) registration of new denominations for protected varieties;
- (d) withdrawal of applications for the grant of breeders' rights;
- (e) rejection of applications for the grant of breeders' rights;
- (f) grant of breeders' rights;
- (g) changes concerning persons (applicants, owners and agents);
- (h) lapse of breeders' rights;
- (i) licenses;
- (j) official announcements.

The cost of the above publications shall be borne fully by the persons concerned.

Article 29

Fees

The administrative acts performed by the RPI shall be subject to the payment of service fees. For the purposes of this Chapter, the amounts and the fees provided for in Article 85 of this Law shall be applicable.

Article 30

Registration of Varieties

Registrations made with the Ministry of Agriculture, Fisheries and Forestry (MAG-FOR) Directorate General of Seeds shall be valid for the purposes laid down in Law No. 280 (Law on Seed Production and Trade) published in the Official Journal *La Gaceta* No. 26 of February 9, 1998 as regards their authorization for dissemination, marketing and other effects, but shall not grant breeder's rights.

Article 31

Status of the Applicant

Any natural or legal person may apply personally, or through a duly accredited representative, for breeder status. Where a plant variety is obtained and developed by two or more natural or legal persons jointly, those persons shall specify in the application the corresponding share of each party and shall appoint a joint representative, failing which the first person named shall be considered such.

Article 32

Form and Content of the Application

The application shall be filed with the RPI, and shall include at least the following information, on pain of rejection:

- (a) name and address of the applicant, or his legal representative;
- (b) name and address of the breeder where he is not the applicant;
- (c) identification of the species (scientific and common name);
- (d) denomination proposed for the variety, or a provisional designation;
- (e) where the priority of an earlier application is claimed, the UPOV Member State that received the application in question and also the filing date shall be mentioned;
- (f) technical description of the variety, which contains the morphological, physiological, physical and chemical, and industrial or technological characteristics allowing it to be identified. The description shall be accompanied by drawings, photographs or any other technical feature necessary to illustrate the description. Specification of the genealogy and origin of the variety.

Similarly, the applicant shall state the grounds for the distinctiveness of the variety and shall indicate the reasons for which he considers that the variety can be distinguished from or is novel in relation to those already existing, well known or those which, in his opinion, are more alike.

The registration authority may modify the grounds for distinctiveness or assist the applicant in so doing where, on the basis of comparative studies, this is considered necessary.

The application authority may, where considered necessary, request from the applicant field trials and/or laboratory tests in order to verify the characteristics attributed to the novel variety;

- (g) place for the receipt of notifications;
- (h) reproduction or propagation mechanisms and description of the method used by the breeder to maintain the variety;

- (i) proof of payment of the application fee;

- (j) applicant's signature.

The other data established by the Regulations or any additional technical information for the case or species which so require, according to the stipulations of the application authority.

Article 33

Proposed Denomination

The application for a breeder's title shall propose a denomination for the variety in accordance with Article 50 of this Law, which, if it is to be approved, shall differ from any other denomination existing in the country or abroad, meet the other requirements laid down in the Regulations under this Law, and not be identical or similar, to the point of confusion, to a previously protected denomination.

Where the denomination does not meet the foregoing requirements, the Application Authority shall notify the applicant of its rejection and shall request him to propose another denomination within a fixed period of thirty (30) days.

Article 34

Reception and Processing of the Application

The Application Authority shall receive and process applications for breeder's certificates, and shall, on its own initiative or at the request of the Plant Variety Protection Examination Committee (CCPVV), require the delivery of the plant variety or its propagating material in quantities that it considers appropriate and, where applicable, such additional documents and information as it considers necessary to determine whether the legal and regulatory provisions have been met.

Article 35

Revocation of the Application

Applications shall become void where the applicant fails to comply with instructions given to him, by a time limit of three months calculated from the date of notification of said instructions.

Article 36

Filing Date

A filing date shall be assigned to every application filed with the Application Authority that is complete and in order. The date on which the Application Authority receives the information specified in this Title shall be regarded as the filing date.

Article 37

Priority

The applicant may avail himself, with the authority of a UPOV Member State, of the right of priority of an earlier application which either he or his predecessor in title has lawfully filed in respect of the same variety. Where the application filed with the Application Authority has been preceded by two or more applications, priority may be based only on the earliest application.

Article 38

Priority Claim

Priority shall be expressly claimed within a period of twelve (12) months, starting from the day following the filing date of the first application.

In order to claim the priority of an application originally filed outside the country, the application filed with the Application Authority should not claim the grant of rights additional to those deriving from the application filed abroad.

Article 39

Obligation to File Documents

In order to benefit from the right of priority, the applicant shall submit to the Application Authority, within a period of three months starting from the filing date, copies of the documents containing the procedures and formalities established in the Regulations under this Law.

The Application Authority may request the filing, within a period of three months starting from the date of receipt of the communication, of a translation of the first application or of any documents constituting key parts of the first application.

Article 40

Effects of Priority

The effect of the priority shall be that the application shall be considered to have been filed on the filing date of the first application with respect to the conditions of protection relating to the variety.

Article 41

Postponement of the Examination

The applicant may request postponement of the examination of the variety for a maximum period of two years, starting from the expiry date of the priority period. Notwithstanding, if the first application is rejected or withdrawn, the examination of the plant variety may commence prior to the date indicated by

the applicant. In this case, he shall be granted an appropriate period to submit any information and material relevant to the examination of the variety.

Article 42

Examination of the Application as to Form

The application shall comply with the requirements established with respect to substance and form; where those requirements are not fully met, the RPI shall notify the applicant that he has a period of thirty (30) calendar days to correct the omissions. If the specified period expires without the amendments being made, the application shall be deemed not to have been filed.

Article 43

Technical Examination of the Variety

The variety shall be subject to technical examination, the purpose of which shall be to determine whether the variety is distinct, homogenous and stable. Once it has been established that the variety meets the above conditions, the official description of the variety shall be established.

The technical and denomination examination shall be conducted by the MAG-FOR Directorate General of Seeds, under the supervision of the Plant Variety Protection Examination Committee (CCPVV).

The cost of the technical and denomination examination shall be paid directly by the applicant to the institution that conducts the examination, the cost of which shall be determined by the materials used and the rendering of services.

The official description may subsequently be completed or amended according to the development of agricultural and botanical knowledge, without the subject matter of the protection being altered thereby.

Article 44

*Information, Documents and Materials
Necessary for Examination*

The applicant shall supply all the necessary information, documents or material for the purposes of the technical and denomination examination.

Article 45

Examination Cooperation

MAG-FOR may, through the Directorate General of Seeds, enter into administrative agreements with a view to cooperation in the examination of varieties and supervision of plant variety maintenance.

Article 46

Publication of the Application

Applications shall be published by the Application Authority in the Official Journal *La Gaceta* and/or in such media as it considers suitable, and shall include the items mentioned in the Regulations under this Law. The cost of publication shall be borne by the breeder.

Article 47

Substantive Examination of the Application

The application shall be examined with respect to its substance in order to establish, on the basis of the information submitted, that the variety complies with the requirements and that the applicant is qualified according to the provisions laid down in this Law. Where that is not the case, the application shall be rejected.

Article 48

Objections to the Grant of Breeders' Rights

Once the application has been published, any person may file objections to the grant of breeders' rights, in accordance with the Regulations under this Law.

Article 49

Grant of Breeders' Rights or Rejection of the Application

The RPI shall grant breeders' rights where, as a result of the technical examination and that relating to the variety denomination, the variety is found to comply with the requirements of this Law.

The grant of a breeder's right or the rejection of the application shall be entered in the Intellectual Property Register (RPI) and published in the Official Journal *La Gaceta*.

Once the breeder's title has been issued, the denomination shall remain firmly established, even where the plant variety passes into the public domain.

CHAPTER VI

DENOMINATION AND MAINTENANCE
OF PLANT VARIETIES

Article 50

Denomination

The denomination is intended to be the generic designation of the variety. Designations may be any words, combinations of words and figures, and combinations of letters and figures that may or may not have a prior meaning, provided that the signs

in question serve to identify the variety. Denominations may consist solely of figures, only where this is an established practice for designating varieties.

A pre-existing variety of the same botanical species or of a similar species shall differ from any denomination that it designates in any of the UPOV Member States.

Article 51

Prohibition of the Use of the Denomination

A pre-existing denomination of a variety of the same botanical species or of a similar species shall differ from any denomination that it designates in the national territory or in any State. It shall be prohibited to register the denomination of any plant variety as a mark.

Article 52

Conditions for Marketing

Any person who uses a protected variety as reproductive or propagating material shall use the corresponding denomination.

Where a variety is offered for sale or otherwise marketed, it shall be permitted to associate a factory or trade mark, trade name or similar indication with the denomination of the registered variety, provided that the denomination may be easily recognized.

The obligation to use the denomination of the registered variety shall persist, even though the breeder's rights have precluded the variety from passing into the public domain.

Article 53

Grounds for Rejection

Designations shall be denied registration as denominations for varieties where they:

- (a) do not comply with the provisions of Article 51 of this Law;
- (b) are not suitable for the identification of the variety, in particular owing to a lack of distinctiveness or linguistic suitability;
- (c) are contrary to public policy and morality;
- (d) consist solely of signs or information liable to mislead or cause confusion as to the characteristics, designation of species, quality, intended purpose, value, geographical source, time of production or identity of the breeder.
- (e) are a registered mark or in the process of registration.

- (f) are so similar as to cause a risk of confusion with a denomination that designates, on the territory of the Republic of Nicaragua, a pre-existing variety of the same or a similar species, except where the pre-existing variety has ceased to be exploited and its denomination has not acquired any particular significance.

Article 54

Registration Procedures

The proposed denomination of the variety for which protection is sought shall be filed at the same time as the application. On payment of a special fee and the mention of a provisional designation in the application, the applicant may defer the procedure for registration of the denomination for a period of thirty (30) days following the date of receipt of the application. Where no denomination proposal is filed within the period set, the application shall be rejected.

Article 55

Objections by Third Parties

An objection to the registration of the denomination may be filed, alleging any of the grounds for rejection provided for in Article 53 of this Law.

Objections and comments shall be communicated to the applicant, who may respond to them.

Once the response given by the applicant has been studied and facts supporting the objection have been found, the applicant may file a new denomination proposal.

Article 56

Registration and Cancellation of a Denomination

The RPI shall cancel the registered denomination in the following cases:

- (a) if it is found to have been registered despite the provisions of Articles 51 and 53 of this Law;
- (b) where the existence of a legitimate interest is invoked; or
- (c) where a third party submits a court decision prohibiting the use of the denomination in connection with the variety.

The owner shall be informed of the cancellation and shall be invited to submit a proposal for a new denomination. Said proposal shall be subject to the examination and publication procedures provided for in this Law. The new denomination shall be registered and published if it is approved; the former denomination shall be cancelled at the same time.

Article 57

Maintenance of the Variety

The owner shall maintain the protected variety or, where appropriate, its hereditary components, for as long as the breeder's right remain in force.

The owner shall submit, on an annual basis, such information, documents or material as may be considered necessary for the maintenance of the variety to be verified.

CHAPTER VII

TRANSFER OF RIGHTS AND COMPULSORY LICENSES

Article 58

Transfer of Rights

The rights conferred by the breeder's certificate shall provide entitlement to conduct, in relation to those rights, all lawful court business and may be transferred either wholly or in part by virtue of a legal instrument executed before a notary public.

Article 59

Processing

In the event of the transfer of the rights referred to in this Law, the beneficiary, transferee or successor in title to those rights shall be obliged to submit to the RPI:

- (a) his name, nationality and address;
- (b) documents evidencing the transfer of the rights and, where appropriate, the obligation to maintain the relevant characteristics of the plant variety or its propagating material, where those rights are marketed and exploited.

Article 60

Obligations

In the event of total transfer, the beneficiary or successor in title shall assume all the obligations and rights deriving from the breeder's title, with the exception of the right referred to in this Law.

Article 61

Registration

The transfer of rights shall take effect when those rights are recorded in the RPI, in accordance with this Law.

Article 62

Protection of Rights

The beneficiary, transferee or successor in title may institute legal actions for protection of the breeder's right as if he were the owner thereof, unless otherwise agreed.

Article 63

Other Responsibilities

A person who receives the material from a protected plant variety shall be responsible for any use or exploitation which differs from that laid down in this Law and its Regulations.

Article 64

Grants

The RPI may grant compulsory licenses in any of the following cases:

- (a) where the protected variety is declared to be of public interest.
- (b) where a protected plant variety is used and is stated to be essential to satisfy the basic needs of a population sector and there are insufficient supplies, or
- (c) where incorrect practices are carried out, affecting free competition.

Article 65

Application for Compulsory Licenses

Any person may request a compulsory license to be granted, corresponding to the breeder's right in the cases laid down in Article 64 of this Law, if it meets the following requirements:

- (a) An applicant shall submit proof that he has sufficient capacity to carry out the use and shall prove that he has previously sought authorization from the rights owner on reasonable terms and market conditions, and also that the efforts have not had effect for a reasonable period.
- (b) Three years have elapsed between the date on which the breeder's rights were granted and the date of application for the grant of the compulsory license.
- (c) The person requesting the grant of the compulsory license has paid the fee prescribed in the Regulations.

Article 66

Conditions Governing Compulsory Licenses

The compulsory license shall be granted in order to supply the domestic market and its owner shall receive appropriate re-

muneration. In the absence of agreement, the competent judicial authority shall fix the amount and the method of payment.

No compulsory license may be granted with exclusive character, nor may it be assigned and, at the end of the period for which it was granted, the owner of the plant variety may have his rights fully restored.

Article 67

Grant of Compulsory Licenses

The decision granting a compulsory license shall specify the scope of the license, its term (minimum two years and maximum four years), the amount and method of payment of the remuneration payable to the owner;

Article 68

Revocation and Amendment of the Compulsory License

A compulsory license may be totally or partially revoked by the competent judicial authority, at the request of any interested party, if the licensee fails to discharge the obligations incumbent on him, and if the circumstances that gave rise to the grant of the license have ceased to exist and are unlikely to recur. In the latter case, said authority may take the necessary steps for the appropriate protection of the legitimate interests of the licensee affected by the revocation.

A compulsory license may be amended by the Application Authority, at the request of the party concerned, where new facts or circumstances so dictate, especially where the owner of the plant variety has granted contractual licenses on conditions more favorable than those accorded to the beneficiary of the compulsory license.

CHAPTER VIII

PLANT VARIETY PROTECTION
EXAMINATION COMMITTEE

Article 69

Establishment

The Plant Variety Protection Examination Committee shall be established and shall operate under the administration of MAGFOR, which shall be mandated to provide technical advice on:

- (a) applications for breeders' rights;
- (b) procedures for carrying out and evaluating technical field trials and laboratory tests;
- (c) drafting relevant standards relating to the characterization and evaluation of plant varieties for descriptive purposes; and

- (d) the other duties stipulated by the Regulations under this Law.

Article 70

Integration and Operation

The Plant Variety Protection Examination Committee (CCPVV) shall comprise members from the Ministries of Public Works, Industry and Trade, Agriculture, Fisheries and Forestry, Environment and Natural Resources, and shall establish the Regulations under this Law so as to determine its structure and operations. Committee members shall also come from the National Agrarian University (UNA), the National University of León and other relevant specialized centers.

CHAPTER IX

PROCEDURES AND NOTIFICATIONS

Article 71

Procedures

The procedures laid down in this Law in relation to the causes of invalidity, lapse and sanctions shall be implemented and settled in accordance with this Law.

Article 72

Notification

In administrative proceedings for invalidation, lapse and the imposition of sanctions, the opposite or potentially injured third party shall be notified so that, within a period of thirty (30) working days following notification, he may make in writing whatever statement may serve his interests.

CHAPTER X

INVALIDITY

Article 73

Causes of Invalidity

The judicial authority shall declare the breeder's right over a plant variety to be invalid only in the following cases:

- (a) the variety is not novel or distinct on the application filing date or the priority date, as the case may be;
- (b) the grant of breeders' rights was essentially based on information and documents supplied by the applicant, and the variety was not uniform or stable on said date;

- (c) breeders' rights were granted to a person not entitled to them, unless they have been transferred to the appropriate person.

Article 74

The Party Requesting Invalidation

Any person providing evidence of interest shall be entitled to file a request for invalidation.

CHAPTER XI

LAPSE

Article 75

Causes

Breeders' rights and the registration thereof shall lapse only in the following cases:

- (a) it is found that the protected variety no longer effectively meets the requirements of uniformity and stability;
- (b) the annual fee has not been paid, for a period of three (3) months following express demand therefor;
- (c) the breeder is unable to provide the competent authority with the reproductive or propagating material of the protected plant variety within a period of six months following the date on which the breeder was called upon to do so;
- (d) the breeder fails to submit the documents or information required for the maintenance of the variety to be verified, within the established period;
- (e) the RPI cancels the registered denomination of a variety and the granted rights owner fails to propose another appropriate denomination within the time allowed, as provided for in Article 56 of this Law.

Article 76

The Party Requesting the Lapse

The RPI or any natural or legal person providing evidence of an interest shall be entitled to file a request for lapse.

Article 77

Passage into the Public Domain

Where a breeder's right have been declared lapsed, in accordance with Article 75(a) and (b) of this Law, the plant variety in question shall pass into the public domain.

CHAPTER XII

ACTIONS FOR INFRINGEMENT OF RIGHTS

Article 78

Fraud in Connection with Variety Denominations

Without prejudice to the resulting damage and such outgoing profit as may be claimed, any natural or legal person using a protected variety denomination without the authorization of the right's owner, and who omits to use a registered denomination in violation of the provisions of this Law, will be fined between C\$200,000.00 (two hundred thousand córdobas) and C\$900,000.00 (nine hundred thousand córdobas), in accordance with the exchange rate as approved by the Central Bank of Nicaragua on that date.

Article 79

Civil Remedies

Any person who, without being authorized to do so, engages in acts that require the authorization of the owner of the rights to the plant variety, makes use of a denomination or fails to use a denomination of a protected variety in violation of the provisions of this Law may be reported by the breeder or by a licensee, and the civil procedure provisions laid down for rights deriving from industrial property, as established in the Patent Law in force, shall be applicable to him.

Article 80

Criminal Sanctions

Any act that involves the improper use of a breeder's right and any knowingly committed infringement shall constitute punishable offences for the purposes of this Law. In that connection, the provisions, procedures and sanctions laid down in the relevant laws shall be applicable.

Article 81

Preventive Actions

Any person initiating an action for infringement of rights protected by this Law may apply to the competent authority for the imposition of immediate measures to prevent the offence being committed.

The following preventive measures may, *inter alia*, be imposed:

- (a) immediate cessation of the acts constituting the infringement;
- (b) withdrawal from circulation, or prohibition of the placing in circulation, of the reproductive or propagating

material of the protected plant variety by which the rights protected by this Law are infringed;

- (c) withdrawal from circulation of objects, cartons, containers, packaging, paperwork, and advertising and similar material by which any of the rights protected by this Law would be infringed;
- (d) seizure or confiscation of the products of the infringement and of the main materials and means having served for the commission thereof;
- (e) suspension of the exploitation of the goods, materials or means referred to in the preceding subparagraphs;
- (f) provision of a bond or other guarantee considered sufficient by the competent judicial authority; and,
- (g) submission of documents or movable goods.

Article 82

Guarantees and Conditions in the Case of Preventive Actions

A preventive action shall be imposed only where the person applying for it proves his entitlement to act and the existence of the right infringed. The competent authority shall require the person applying for it first to provide sufficient guarantees in accordance with the Code of Civil Procedure.

Any person applying for preventive action in relation to specific merchandise shall provide the necessary information and a precise description identifying the merchandise to which the measure is to relate.

Article 83

Actions "Inaudita altera parte"

Where preventive action has been instituted without the intervention of the other party, that party shall be informed within three days. The party concerned may appeal to the competent authority against the action instituted. The authority may revoke, modify or confirm the preventive action.

Article 84

Duration of Preventive Action

Any preventive action shall become void as of right if the action on the main infringement is not initiated within fifteen (15) working days of the date on which the preventive action was instituted; this may be decreed at the request of a party or *ex officio* by the competent authority dealing with the case, which shall order payment of costs and damages by the party requesting the measure.

CHAPTER XIII

FEES AND OTHER PAYMENTS

Article 85

Fees

The breeder shall pay the fees established by the Application Authority for the following items:

- (a) breeder's application;
- (b) request concerning an amendment, change, correction, transfer or license;
- (c) issue of duplicate title;
- (d) information services;
- (e) substantive examination.

The annual fee for maintenance of protection rights shall be C\$5,000.00 (five thousand córdobas).

The amount calculated shall be paid in national legal tender, the applicable exchange rate being that set by the Central Bank of Nicaragua on the date of the transaction.

The amount payable for the technical and substantive examination shall be fixed by the Application Authority, taking into account the costs and technical service provided by the authority itself or by the institution(s) that have provided technical services for the trials, with the necessary advice being provided by the Plant Variety Protection Examination Committee (CCPVV).

Article 86

Information Services

The Application Authority shall offer such services and documentation as may be required under this Law, subject to payment of the fee prescribed above.

Article 87

Procedures for Payment of the Annual Fee for Maintenance of Protection Rights

In order for a plant variety protection title to remain in force, the annual fee shall be paid. The first payment shall be made when the application is filed and subsequent fees on January 31 each year.

CHAPTER XIV

TRANSITIONAL AND ADMINISTRATIVE PROVISIONS

Article 88

Transitional Derogation from the Novelty Condition and Transitional Fixing of the Protection Period

(1) Varieties shall not be regarded as having lost their novelty where they have been entered in the Register of Varieties set up under Law No. 280 (Law on Seed Protection and Trade), for a period not exceeding five years prior to the entry into force of this Law.

(2) It shall likewise be considered that the varieties entered in a register of protected varieties of another country have not lost their novelty.

In relation to the protection period and subject to their compliance with the remaining requirements of this Law, the Application Authority may grant a breeder's right for the varieties detailed in paragraphs (1) and (2) for a resulting period of protection:

- (a) For the varieties in paragraph (1), the difference between the national period of protection and the years of entry in the breeds register, and
- (b) For the varieties in paragraph (2), the difference between the national period of protection and the years of protection completed in the country of origin. Where protection exists for the same variety in various countries, the earliest protection period shall be considered for those purposes.

In order to benefit from the condition of novelty according to paragraphs (1) and (2), and the protection period indicated in subparagraphs (a) and (b), a breeder's right shall be requested for the variety in question within a period of one year of the application of the breeder's rights in the country.

CHAPTER XV

ADMINISTRATIVE PROVISIONS

Article 89

This Law shall establish the authority of the breeder's intellectual property rights; the rights to import, distribute and market seeds shall be subject to the regulations established in Law No. 280 (Law on Seed Production and Trade), published in the Official Journal *La Gaceta* No. 26, of February 9, 1998.

Article 90

Regulations

This Law shall be regulated in accordance with Article 150 of the Political Constitution.

Article 91

Entry into Force

This Law shall enter into force ninety (90) days after its publication in the Official Journal *La Gaceta*.

Done in the City of Managua, in the Hall of Sessions of the National Assembly, on October 20, 1999. **IVAN ESCOBAR FORNOS**, President of the National Assembly. **VICTOR MANUEL TALAVERA HUETE**, Secretary of the National Assembly.

Therefore published and enacted as a National Law. Managua, November 12, 1999. **ARNOLD ALEMÁN LACAYO**, President of the Republic of Nicaragua.

(Text revised and agreed in February 2001, under the supervision of Ambrosia Lezama Zelaya, Director of the Intellectual Property Register of Nicaragua and Gloria Zelaya Laguna, Head of the RPI Department of Plant Varieties – Nicaragua).

SOUTH AFRICA

GENETICALLY MODIFIED ORGANISMS ACT NO. 15 OF 1997

To provide for measures to promote the responsible development, production, use and application of genetically modified organisms; to ensure that all activities involving the use of genetically modified organisms (including importation, production, release and distribution) shall be carried out in such a way as to limit possible harmful consequences to the environment; to give attention to the prevention of accidents and the effective management of waste; to establish common measures for the evaluation and reduction of the potential risks arising out of activities involving the use of genetically modified organisms; to lay down the necessary requirements and criteria for risk assessments; to establish a council for genetically modified organisms; to ensure that genetically modified organisms are appropriate and do not present a hazard to the environment; and to establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms; and to provide for matters connected therewith.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:-

Definitions

Section 1

In this Act, unless the context otherwise indicates-

- | | |
|---|--|
| <p>(i) “accident” means any incident involving an unintended general release of genetically modified organisms which could have an immediate or delayed adverse impact on the environment; (xxi)</p> <p>(ii) “appeal board” means an appeal board appointed in terms of section 19; (iv)</p> <p>(iii) “applicant” means any person in control of facilities and activities involving genetic modification of organisms and includes “user”; (i)</p> <p>(iv) “Committee” means the Advisory Committee established by section 10; (iv)</p> <p>(v) “contained use” means any activity in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers together with chemical or biological barriers or both are used to limit contact thereof with the environment; (vii)</p> <p>(vi) “control” means to examine, regulate, manage or direct any activity within a person’s jurisdiction; (vi)</p> | <p>(vii) “Council” means the Executive Council for Genetically Modified Organisms established by section 3; (xxv)</p> <p>(viii) “department” means the Department of Agriculture; (ix)</p> <p>(ix) “Director-General” means the Director-General: Department of Agriculture; (x)</p> <p>(x) “environment” means the aggregate of surrounding objects, conditions and influences that influence the life and habits of man or any other organism or collection of organisms; (xx)</p> <p>(xi) “general release” means the introduction of genetically modified organisms into the environment by whatever means, where the organisms are no longer contained by any system of barriers and are no longer under any person’s control, so that the organism is likely to survive and be disseminated; (iii)</p> <p>(xii) “gene therapy” means a technique for delivering functional genes (to replace aberrant ones) into living cells by means of a genetically modified vector or by physical means in order to genetically alter the living cell; (xii)</p> <p>(xiii) “genetically modified or organism” means an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and “genetic modification” shall have a corresponding meaning; (xiii)</p> <p>(xiv) “hazard” means an intrinsic biological, chemical or physical characteristic of a genetically modified organism which could lead to an adverse impact on the environment; (xiv)</p> <p>(xv) “inspector” means any person appointed as an inspector in terms of section 15; (xvi)</p> <p>(xvi) “Minister” means the Minister for Agriculture: (xviii)</p> <p>(xvii) “monitoring” means the maintaining of regular surveillance over the checking of, the warning about or the recording of a situation or process; (xix)</p> <p>(xviii) “notification” means the presentation to the Council of documents containing the information required by the Council; (viii)</p> <p>(xix) “officer” means an officer as defined in section 1(1) of the Public Service Act, 1994 (Proclamation No. 103 of 1994), read with section 1 of the Public Service Amendment Act, 1996 (Act No. 13 of 1996); (v)</p> |
|---|--|

* Text provided by the South African authorities.

- (xx) “organism” means a biological entity, cellular or non-cellular, capable of metabolism replication, reproduction or of transferring genetic material and includes a micro-organism: (xxii)
- (xxi) “permit” means a permit referred to in section 5(a) and includes a written authority; (xxiii)
- (xxii) “prescribed” means prescribed by regulation; (xxix)
- (xxiii) “registrar” means the person appointed under section 8: (xxvi)
- (xxiv) “regulation” means a regulation made under this Act; (xxvii)
- (xxv) “risk” means the probability of causing or incurring a loss or damage or an adverse impact or a misfortune; (xxviii)
- (xxvi) “this Act” includes the regulations; (xv)
- (xxvii) “trial release” means the deliberate release of genetically modified organisms into the environment in the open under conditions where the degree of dissemination of the genetically modified organisms is limited by chemical or physical barriers or by built-in barriers which prevent the survival of such organisms in the environment; (xxiv)
- (xxviii) “user” means any natural or legal person or institution responsible for the use of genetically modified organisms and includes an end-user or consumer; (xi)
- (xxix) “waste” means any matter, whether gaseous, liquid or solid or any combination thereof, which is, in the opinion of the person in whose possession or under whose control it is, an undesirable or superfluous product, emission, residue or remainder of any process or activity in connection with genetically modified organisms. (ii)
- (i) in *in vitro* fertilisation in humans and animals;
- (ii) in conjugation, transduction, transformation or any other natural process: and
- (iii) in polyploidy induction,
- (c) in which genetically modified organisms as recipient or parental organisms are not employed-
- (i) in mutagenesis;
- (ii) in the construction and use of somatic hybridoma cells; and
- (iii) in cell fusion (including protoplast fusion) of plant cells.

Executive Council of Genetically Modified Organisms

Section 3

- (1) There is hereby established a council to be known as the Executive Council for Genetically Modified Organisms, which shall consist of not more than eight members appointed by the Minister.
- (2) The members referred to in subsection (1) –
- (a) shall be one officer of each of the following national departments of State:
- (i) The Department of Agriculture;
- (ii) the Department of Arts, Culture, Science and Technology;
- (iii) the Department of Environmental Affairs and Tourism;
- (iv) the Department of Health;
- (v) the Department of Labour: and
- (vi) the Department of Trade and Industry,

who shall have knowledge of the implications of genetically modified organisms with regard to the sector represented by his or her department;

- (b) shall include the chairperson of the Committee; and
- (c) may include any other person.

(3) The Minister shall designate a chairperson and a deputy chairperson from among the members of the Council.

(4) The deputy chairperson shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to do so.

Application of Act

Section 2

- (1) This Act shall apply to-
- (a) the genetic modification of organisms:
- (b) the development, production, release, use and application of genetically modified organisms (including viruses and bacteriophages); and
- (c) the use of gene therapy.
- (2) This Act shall not apply to techniques-
- (a) involving human gene therapy;
- (b) in which recombinant DNA molecules or genetically modified organisms are not employed

Objectives of Council

Section 4

The Council shall advise the Minister on all aspects concerning the development, production, use, application and release of genetically modified organisms, and to ensure that all activities with regard to the development, production, use, application and release of genetically modified organisms are performed in accordance with the provisions of this Act.

Powers and duties of Council

Section 5

In order to achieve its objectives, the Council may-

- (a) require any applicant for a permit to use facilities for the development, production, use or application of genetically modified organisms or to release such organisms into the environment, to submit to the Council through the registrar, an assessment of the risk and, where required, an assessment of the impact on the environment of such development, production, use, application or release, as the case may be;
- (b) require the registrar to examine the conformity of an application to the requirements of this Act;
- (c) require the registrar to maintain a register of all facilities involved in the contained use or the trial release of genetically modified organisms as well as the names and addresses of persons concerned with such contained use or trial release genetically modified organisms;
- (d) require notification by the applicant of any intended change in the type of activities or release involving genetic modification of organisms being undertaken at facilities for which approval was granted in terms of paragraph (g), in which case the Council may require the applicant to apply for a new permit;
- (e) require the registrar to arrange for the inspection by an inspector of facilities where activities with or the release of genetically modified organisms are being undertaken,
- (f) require the registrar to arrange for the inspection of all activities as he or she may deem necessary, including contained use, trial release and general release to ensure that all terms and conditions attached to a permit issued under this Act are complied with:
- (g) after consideration of the risk assessment and, where required the environmental impact assessment referred to in paragraph (a), and in consultation with the Committee, approve, subject to the provisions of this Act and any other law and in accordance with such terms and conditions as the Council may deem necessary, the use of the facilities concerned for the purpose for which the application was made, or the release of genetically modified organisms into the environment, and authorise the registrar to issue a permit accordingly;
- (h)
 - (i) require that the user immediately notify the registrar both orally and in writing of any accident involving genetically modified organisms and require that the registrar be supplied with information on the circumstances of the accident, the identity and quantity of genetically modified organisms released, any information necessary to assess the impact of the accident on the environment and the emergency measures taken to avoid or mitigate any adverse impact of such accident on the environment,
 - (ii) require the registrar to appoint a panel to enquire into and report on the causes of an accident, and to make recommendations to the Minister with a view to avoiding similar accidents in the future and with a view to limiting the adverse impact of such accidents;
- (i) inform any other country of any accident that may have an impact on that country's environment;
- (j) co-operate or enter into agreements with any person or institution upon such conditions as the Council and the person or institution concerned may agree upon;
- (k) promote co-operation between the Republic and any other country with regard to research, development and technology transfer in the field of the genetic modification of organisms;
- (l) with the consent of the Minister approve and publish guidelines for all uses of genetically modified organisms;
- (m) advise the Minister on-
 - (i) prohibitions;
 - (ii) the authorisation and exercise of the necessary control of imports;
 - (iii) the development, production, use, application, release and distribution of genetically modified organisms.
 - (iv) the authorisation or notification of contained uses.
 - (v) the authorisation of trial or general releases;
 - (vi) the control measures to be taken in the event of an accident;
 - (vii) any other matter with regard to genetically modified organisms;
- (n) make recommendations to the Minister on the appointment of members to the Committee.

Vacancies in Council

Section 6

- (1) A vacancy in the Council shall occur when a member-
 - (a) ceases to be an officer:

- (b) is absent without leave from more than three consecutive meetings of the Council;
 - (c) resigns;
 - (d) is removed from the office in terms of subsection (2);
 - (e) dies.
- (2) The Minister may at any time remove a member of the Council from office if the Minister is of the opinion that such Member is no longer competent to fill his or her office or that he or she has misconducted himself or herself.
- (3) A vacancy in the Council shall be filled as soon as practicable in accordance with section 3.
- (4) Whenever the Minister is satisfied that any member of the Council is prevented by illness or any other reason from performing the duties of his or her office, the Minister may appoint any other person whom he or she considers suitable to act as the deputy of that member while such member is so prevented, and such deputy shall during the period he or she so acts, perform the functions of the member in whose stead he or she has been appointed so to act: Provided that a person appointed as the deputy of the chairperson or the deputy chairperson shall only perform the duties of an ordinary member, unless the Minister otherwise directs.

Meetings of Council

Section 7

- (1) Meetings of the Council shall be held at such times and places as the chairperson may determine from time to time: Provided that the first meeting shall be held at a time and place determined by the Minister.
- (2) The quorum for any meeting of the Council shall be a majority of the members.
- (3) A decision of the Council shall be reached on the basis of consensus.
- (4) The Council may determine its own procedures to be followed at its meetings and cause minutes to be kept of its proceedings.
- (5) The Council may co-opt other knowledgeable persons to serve on the Council in order to advise the Council whenever the Council deems it necessary.
- (6) The Council may invite written comment from knowledgeable persons on any aspect of genetic modification which lies within the Council's brief.

Appointment of Registrar

Section 8

- (1)(a) As soon as possible after the composition of the Council and whenever necessary thereafter the Minister shall, after consultation with the Council, appoint a suitably qualified and experienced person as registrar.

- (b) An appointment under paragraph (a)
 - (i) shall terminate if the person resigns as registrar;
 - (ii) may be terminated by the Minister if the registrar does not perform his or her duties satisfactorily.
- (2) The registrar-
- (a) is charged with the administration of this Act;
 - (b) may exercise such powers and perform such duties as may be conferred upon or delegated or assigned to him or her by or under this Act or by the Council.
- (3) Whenever the registrar is for any reason absent or unable to perform his or her functions, or whenever a vacancy in the office of the registrar occurs, the Council may designate a member of its staff act in that capacity until the registrar resumes his or her functions, or a registrar is appointed in terms of subsection (1), and that member has, while so acting, such powers and shall perform such duties of the registrar as may be delayed or assigned to him or her by the Council.
- (4) Any action of the registrar may at any time be withdrawn or amended by the Minister.
- (5) The Director-General shall designate, subject to the provisions of the Public Service Act, 1994 Proclamation No. 103 of 1994), as many officers of the department as may be necessary to assist the registrar in the exercise of his or her powers and the performance of his or her duties.

Functions of Registrar

Section 9

The registrar shall, subject to the instructions of and the conditions laid by the Council-

- (a) issue a permit as required or prescribed under this Act;
 - (b) where he or she has ascertained or suspects on reasonable grounds that genetically modified organisms are being imported or locally produced or used contrary to the provisions of this Act or the conditions of a permit issued thereunder-
- (i) serve a notice upon any person by whom or on whose behalf genetically modified organisms are being so imported into, produced or used in the Republic for the removal of such genetically modified organisms to a place or facility and in a manner prescribed by the Council; and
 - (ii) authorise an inspector to destroy such genetically modified organisms or cause it to be destroyed, subject to procedures and other provisions as set out in this Act;
- (c) amend or withdraw a permit issued under this Act;
 - (d) furnish an inspector with a certificate of appointment;

- (e) require the cessation of any genetic modification activity at facilities where the provisions of this Act the conditions of a permit have not been or are not being complied with: and
- (f) ensure that appropriate measures are undertaken by all users at all times with a view to the protection of the environment from hazards.

Advisory Committee

Section 10

(1) There is hereby established an Advisory Committee which shall consist of not more than ten persons appointed by the Minister after the recommendation of the Council for a period not exceeding five years of whom-

- (a) not more than eight members shall be knowledgeable persons in those fields of science applicable to the development and release of genetically modified organisms;
- (b) two persons shall be from the public sector and shall have knowledge of ecological matters and genetically modified organisms.

(2) The Council shall, in recommending members for appointment to the Committee, endeavour to achieve representation from all the fields of expertise involved with genetically modified organisms.

(3) The Minister shall, after the recommendation of the Council, designate any member of the Committee as chairperson.

(4) In the absence of the chairperson the remaining members of the Committee shall elect an acting chairperson from their number.

(5) The acting chairperson shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to do so.

(6) A member of the Committee whose period of office has expired shall be eligible for reappointment.

Functions of Committee

Section 11

- (1) The Committee shall-
 - (a) act as the national advisory body on all matters concerning or related to the genetic modification of organisms:
 - (b) advise, on request or of its own accord, the Minister, the Council, other Ministries and appropriate bodies, on matters concerning the genetic modification of organisms and, *inter alia*, advise them-

- (i) on all aspects relating to the introduction of genetically modified organisms into the environment;
- (ii) on proposals for specific activities or projects concerning the genetic modification of organisms;
- (iii) on all aspects concerning the contained use of genetically modified organisms;
- (iv) on the importation and exportation of genetically modified organisms; and
- (v) on proposed regulations and written guidelines.

(c) liaise, through the relevant national departments, with international groups or organisations concerned with biosafety, and

(d) invite written comments from knowledgeable persons on any aspect of the genetic modification of organisms which lies within the Committee's brief.

(2) The Committee may appoint subcommittees to deal with specific matters as required.

Funding

Section 12

(1) To members of the Committee, subcommittee members and the member referred to in section 3(2)(c) shall be paid such remuneration as the Minister, with the concurrence of the Minister of Finance, may determine.

(2) The Committee shall annually and in accordance with the departmental budgetary programme submit a budget to the Council.

Conflict of interest

Section 13

A person appointed to the Committee shall immediately recuse himself or herself as a member of the Committee if a subject matter is in issue in which he or she has any direct or indirect interest or if, for any other reason there is or there is likely to be a conflict of interest as a result of his or her participation in the proceedings of the Committee.

Prohibition of activities concerning genetically modified organisms

Section 14

The Minister may, on the recommendation of the Council, by notice in the *Gazette*, prohibit any activity involving genetically modified organisms.

Inspectors

Section 15

(1) The registrar may appoint any officer, or with the approval of the Minister, any person who is not an officer, as an inspector to exercise and perform the functions referred to in subsection (4) and in section 16.

(2) Every inspector shall be furnished with a certificate signed by the registrar stating that he or she has been appointed as inspector under this Act.

(3) An inspector shall, at the request of any person affected by the exercise or performance of a function by such an inspector, exhibit the certificate referred to in subsection (2) to such a person.

(4) An inspector may, on the authority of a warrant issued in terms of subsection (5), conduct an investigation to determine whether the provisions of this Act are being or have been complied with, and may, for that purpose during normal office hours and without giving prior notice, enter any place or facility in respect of which he or she has reason to believe that a contravention of the provisions of this Act is taking place-

- (a) to inspect any activity or process carried out in or upon such place or facility in connection with any activities referred to in this Act;
- (b) to request any information regarding such an activity or process from the owner or person in charge of such place or facility or from any person carrying out or in charge of the carrying out of such activities;
- (c) to seize any appliance, book, statement or document and take samples of material or substances which appear to provide proof of a contravention of any provision of this Act; and
- (d) to give notice to the owner of any material, substance, appliance, book, statement or document seized under paragraph (c) or to the person who had control over it immediately before any seizure under subparagraph (c) to remove the seized items at such person's own cost within a period and to a place specified in such notice.

(5)(a) A warrant referred to in subsection (4) shall be issued by a magistrate who has jurisdiction in the area in which the place or facility in question is situated, and shall only be issued if it appears from information on oath that there are reasonable grounds to believe that any material, substance, appliance, book, statement or document that may relate to a contravention of this Act, is upon or in such place or facility.

(b) A warrant issued in terms of this section shall be executed with strict regard to decency and order.

(6)(a) If no criminal proceedings are instituted in connection with any item referred to in subsection (5)(a), seized in terms of subsection (4), or if it appears that such item is not required at any trial for the purpose of evidence or an order of court, that item shall be returned as soon as possible to the person from whom it was seized.

(b) After the conclusion of criminal proceedings any item seized in terms of subsection (4) and which served as an exhibit in proceedings in which a person was convicted, shall be handed over to the inspector to be destroyed or otherwise dealt with as instructed by the registrar.

Routine inspections by inspectors

Section 16

An inspector may during office hours, without warrant, enter any place or facility registered in terms of this Act in order to-

- (a) open any container found in or upon such place or facility and which the inspector believes on reasonable grounds to contain material of any genetically modified organism;
- (b) examine the material of any genetically modified organism and take samples thereof;
- (c) inspect any activity or process carried out in or upon the place or facility in connection with genetically modified organisms; and
- (d) require the owner or occupier thereof to produce for inspection or for the purpose of obtaining copies or extracts thereof or therefrom any book, label, shipping bill, bill of lading or other document with respect to the administration of this Act.

Determination of risks and liability

Section 17

(1) Users shall ensure that appropriate measures are taken to avoid an adverse impact on the environment which may arise from the use of genetically modified organisms.

(2) The liability for damage caused by the use or release of a genetically modified organism shall be borne by the user concerned: Provided that when such an organism was in the possession of an inspector as set out in section 15(4), the user concerned at the time of such use or release shall not be held liable for any damage unless such user foresaw or should have foreseen such damage and could or should have prevented the damage but failed to take reasonable action to prevent such damage.

Confidentiality

Section 18

(1) No person shall disclose any information acquired by him or her through the exercise of his or her powers or the performance of his or her duties in terms of this Act, except-

- (a) in so far as it is necessary for the proper application of the provisions of this Act;
- (b) for the purposes of any legal proceedings under this Act;

- (c) when ordered to do so by any competent court; or
- (d) if he or she is authorised to do so by the Minister.

(2) The Council shall decide, after consultation with the applicant, which information will be kept confidential and shall inform the applicant of its decision: Provided that the following information shall not be kept confidential-

- (a) the description of the genetically modified organisms, the name and address of the applicant, and the purpose of the contained use or release and the location of use;
- (b) the methods and plans for the monitoring of the genetically modified organisms and for emergency measures in the case of an accident: and
- (c) the evaluation of foreseeable impacts, in particular any pathogenic or ecologically disruptive impacts.

(3) Notwithstanding the provisions of subsection (2), the Council may after consultation with the applicant and if the Council is satisfied on the grounds of information furnished by the applicant that certain information should be withheld in order to protect the intellectual property of the applicant, withhold such information for the period needed to protect such rights.

(4) If, for whatever reasons, the applicant withdraws an application, any party who has knowledge of the details of the application must respect the confidentiality of the information supplied.

Appeals

Section 19

(1) A person who feels aggrieved by any decision or action taken by the Council, the registrar or an inspector in terms of this Act may, within the period and in the manner prescribed and upon the payment of the prescribed fee, appeal against such decision or action to the Minister, who shall appoint an appeal board for the purpose of the appeal concerned.

(2)(a) An appeal board shall consist of the person or persons who, in the opinion of the Minister, has or have expert knowledge and who is or are otherwise suitable to decide on the issues of the appeal concerned.

(b) If an appeal board consisting of more than one person is appointed, the Minister shall designate one of the members as chairperson of that appeal board.

(c) A person appointed under paragraph (a), shall recuse himself or herself as a member of the appeal board if he or she has any direct or indirect interest in the subject matter of the appeal or if, for any other reason, there is or there is likely to be a conflict of interests as a result of his or her participation in the proceedings of the appeal board.

(3) There may be paid to a member of an appeal board who is not in the full-time employment of the State, from money

appropriated by Parliament for such purpose, such remuneration or allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

(4) An appeal board may-

(a) confirm, set aside or amend the decision or action concerned which is the subject of the appeal;

(b) refer the relevant matter back to the registrar for reconsideration by the Council; or

(c) make such other order as it may deem fit.

(5) If a decision or action which is the subject of an appeal-

(a) is set aside, the fee referred to in subsection (1) shall be refunded to the appellant concerned; or

(b) is amended, such portion of the fee referred to in subsection (1) as the appeal board concerned may determine, shall be refunded to the appellant.

(6) The decision of an appeal board, together with the reasons therefor, shall be reduced to writing, and copies thereof shall be furnished to the Minister, whereupon the Minister may take such further action as he or she may deem necessary.

Regulations

Section 20

(1) The Minister may make regulations-

(a) regarding the application for and the issue of permits in terms of this Act:

(b) prescribing the procedure to be followed by an applicant for the purpose of drawing up risk assessments and environmental impact assessments for submission to the Council in terms of this Act:

(c) prescribing the fees payable in respect of any application, matter or document:

(d) regarding the classification and types of genetically modified organisms:

(e) regarding requirements for the contained use of genetically modified organisms:

(f) regarding requirements for laboratory development of genetically modified organisms:

(g) regarding the standards to which facilities for activities involving genetically modified organisms should conform:

(h) regarding requirements for trial release of genetically modified organisms:

(i) regarding requirements for the effective management of waste:

- (j) regarding information to be submitted to the Council in the case of a notification in terms of this Act;
 - (k) regarding requirements for the general release and marketing of genetically modified organisms;
 - (l) regarding the importation and exportation of genetically modified organisms;
 - (m) regarding the registration of a place or facility where activities concerning genetically modified organisms are undertaken;
 - (n) prescribing-
 - (i) the manner in which and period within which an appeal under section 18 should be lodged;
 - (ii) the fee payable in respect of such an appeal;
 - (iii) the procedure at the proceedings of an appeal board: and
 - (iv) the period within which an appeal board shall decide on an appeal;
 - (o) prescribing control measures which shall be complied with by a user;
 - (p) regarding classes of genetically modified organisms exempted from control under this Act; and
 - (q) concerning, generally, any matter which he or she considers necessary or expedient to prescribe in order that the objects of this Act may be better achieved, the generality of the powers conferred by this paragraph not being limited by the provisions of the preceding paragraphs.
- (2) Any regulations made under subsection (1) may provide that any person who contravenes or fails to comply with a provision thereof, shall be guilty of an offence and liable on conviction to a fine, or to imprisonment for a period not exceeding two years.

Offences and penalties

Section 21

- (1) Any person who-
 - (a) contravenes or fails to comply with any condition, restriction, prohibition, reservation or directive imposed or issued in terms of this Act;

- (b) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties in terms of this Act or refuses to furnish information as required in terms of this Act to the registrar;
 - (c) refuses or fails to furnish information or give an explanation or to reply to the best of his or her ability to a question lawfully demanded from or put to him or her by any inspector in the performance of his or her functions in terms of this Act, or furnishes information, an explanation or a reply to any inspector which is false or misleading, knowing that it is false or misleading; or
 - (d) falsely holds himself or herself out to be an inspector or any other officer appointed in terms of this Act, shall be guilty of an offence.
- (2) Any person convicted of an offence under this Act, shall-
- (a) on a first conviction be liable to a fine, or to imprisonment for a period not exceeding two years; and
 - (b) on a second or subsequent conviction be liable to a fine, or to imprisonment for a period not exceeding four years.
- (3) Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty or make any order prescribed by this Act.

Delegation of powers

Section 22

The Minister may, subject to such conditions as he or she may determine, in writing delegate any power conferred upon him or her by this Act, other than a power referred to in section 20, to an officer employed by the department, but shall not be divested of any power so delegated and may amend or set aside any decision of the delegate made in the exercise of such power.

Short title and commencement

Section 23

This Act shall be called the Genetically Modified Organisms Act, 1997, and shall come into operation on a date to be fixed by the President by proclamation in the *Gazette*.

UNITED KINGDOM

THE PATENTS AND PLANT VARIETY RIGHTS (COMPULSORY LICENSING) REGULATIONS 2002*

The Secretary of State, being a Minister designated

- (a) for the purposes of section 2(2) of the European Communities Act 1972
- (b) in relation to measures relating to the legal protection of biotechnological inventions, in exercise of powers conferred on her by the said section 2(2), and after consultation with the Council on Tribunals pursuant to section 8(1) of the Tribunals and Inquiries Act 1992
- (c) hereby makes the following Regulations (d):

PART I

INTRODUCTORY

Citation, commencement and extent

- 1.(1) These Regulations may be cited as the Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002 and shall come into force on 1st March 2002.
- (2) These Regulations extend to England, Wales, Scotland and Northern Ireland.

Interpretation

- 2.(1) In these Regulations

“the 1977 Act” means the Patents Act 1977(e);

“the 1997 Act” means the Plant Varieties Act 1997(f);

“biotechnological invention” has the meaning given by section 130 of the 1977 Act;

“Breeders’ regulations” means the Plant Breeders’ Regulations as extended and applied by regulation 23, unless and until the Ministers exercise their powers under sections 24, 26(2)(a), 28, 29, 44 and 48(1) of the 1997 Act as extended by regulation 21, at which time “Breeders’ regulations” shall refer to the regulations so made and in force;

“Community plant variety right” means a right granted by the Community Plant Variety Office under the Council Regulation;

“Comptroller General of Patents” means the Comptroller-General of Patents, Designs and Trade Marks appointed under section 63(1) of the Patents and Designs Act 1907(a);

“compulsory patent licence” means a licence ordered to be granted by the controllers under regulation 6;

“compulsory plant variety licence” means a licence granted by the controllers under regulation 13;

“Controller of Plant Variety Rights” means the officer appointed under section 2(1) of the 1997 Act;

“controllers” means the Controller of Plant Variety Rights and the Comptroller General of Patents acting jointly in accordance with the provisions of these Regulations;

“Council Regulation” means Council Regulation (EQ No. 2100/94 of 27th July 1994 on Community plant variety rights(b) as amended by Council Regulation (EQ No. 2506/95 of 25th October 1995(c);

“court” means-

(a) in England, Wales and Northern Ireland, the Patents Court of the High Court,

(b) in Scotland, the Court of Session;

* Statutory Instruments 2002 No. 247. Text provided by the United Kingdom authorities.
Entered into force on March 1, 2002.

(a) SI 2000/738.

(b) 1972 c. 68.

(c) 1992 c. 53.

(d) In accordance with section 88(2) of the Scotland Act 1998, the Secretary of State has consulted the Scottish Ministers.

(e) 1977 c. 37.

(f) 1997 c. 66.

“Ministers” has the meaning given by section 49 of the 1997 Act;

“new plant variety” means the plant variety produced, or to be produced as the case may be, by using an invention protected by a patent;

“patent” has the meaning given by section 130 of the 1977 Act;

“Patents (Fees) Rules” means the fee payable under the Patents (Fees) Rules 1998(d) in force immediately before the coming into force of these Regulations;

“Patents Rules” means the Patents Rules 1995(e) in force immediately before the coming into force of these Regulations;

“plant breeders’ fee” means the fee payable under the Plant Breeders’ (Fees) Regulations as extended and applied by regulation 25, unless and until the Ministers exercise their powers to make regulations under sections 29 and 48(l) of the 1997 Act as extended by regulation 21 and prescribe a fee, at which time “plant breeders’ fee” shall mean that fee in respect of applications under these Regulations;

“Plant Breeders’ (Fees) Regulations” mean the Plant Breeders’ (Fees) Regulations 1998(f) in force immediately before the coming into force of these Regulations;

“Plant Breeders’ Regulations” means the Plant Breeders’ Rights Regulations 1998(g) in force immediately before the coming into force of these Regulations;

“plant breeders’ rights” means rights granted by the Controller of Plant Variety Rights under section 3 of the 1997 Act and existing rights as defined by section 40(4) of the 1997 Act;

“plant variety” has the meaning given by paragraph II of Schedule A2 to the 1977 Act(h); “prescribed fee” means the fee payable under the Patents (Fees) Rules as extended and applied by regulation 24, unless and until the Secretary of State exercises her powers to make rules under section 123 of the 1977 Act as extended by regulation 20 and prescribes a fee, at which time “prescribed fee” shall mean that fee in respect of applications under these Regulations;

“rules” means the Patents Rules as extended and applied by regulation 22, unless and until the Secretary of State exercises her powers under section 123 of the 1977 Act as extended by regulation 20, at which time “rules” shall refer to the rules so made and in force;

“Tribunal” means the Plant Varieties and Seeds Tribunal referred to in section 42 of the 1997 Act; and

“UK” means England, Wales, Scotland and Northern Ireland.

(2) Any reference to a numbered regulation is a reference to the regulation so numbered in these Regulations and any reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation in which the reference occurs.

PART II

COMPULSORY PATENT LICENCES

Applications

3.(1) Where a person cannot acquire or exploit plant breeders’ rights or a Community plant variety right in a new variety without infringing a prior patent, he may apply in accordance with rules to the Comptroller General of Patents for a licence under the patent and on such application shall pay the prescribed fee.

(2) An application under paragraph (1) shall be accompanied by particulars which seek to demonstrate that

(a) the applicant cannot acquire or exploit plant breeders’ rights or a Community plant variety right without infringing a prior patent,

(b) the applicant has applied unsuccessfully to the proprietor of the prior patent concerned for a licence to use that patent to acquire or exploit plant breeders’ rights or a Community plant variety right, and

(c) the new plant variety, in which the applicant wishes to acquire or exploit the plant breeders’ rights or Community plant variety right, constitutes significant technical progress of considerable economic interest in relation to the invention protected by the patent.

(3) If and so far as any agreement purports to bind any person not to apply for a licence under paragraph (1), it shall be void.

Proceedings before controllers

4. On receipt by the Comptroller General of Patents of an application under regulation 3(1) and payment of the prescribed fee, the controllers shall consider and process the application in accordance with rules.

5.(1) The proprietor of the patent concerned or any other person wishing to oppose an application under regulation 3(1) may, in accordance with rules, give to the Comptroller General of Patents notice of opposition and on giving such notice shall pay the prescribed fee.

(a) 1907 c. 29 and see section 130 of the Patents Act 1977.

(b) OJ No. L 227,1.9.1994, p. 1.

(c) OJ No. L 258, 28.10.95, p. 3.

(d) S.I. 1998/1778 as amended by S.I. 1999/1093.

(e) S.I. 1995/2093 as amended by SI 1999/1092, S.I. 1999/1899, SI 1999/3197 and S.I. 2001/1412.

(f) SI 1998/1021 as amended by S.I. 1998/1089 and SI 2001/3630.

(g) S.I. 1998/1027.

(2) On receipt of a notice of opposition under paragraph (1) and payment of the prescribed fee, the controllers, in deciding whether to grant an application under regulation 3(l), shall consider and process any opposition in accordance with rules.

Grant

6. Where, having considered the application made under regulation 3(l), the controllers are satisfied that

- (a) the applicant cannot acquire or exploit plant breeders' rights or a Community plant variety right without infringing a prior patent,
- (b) the applicant has applied unsuccessfully to the proprietor of the patent concerned for a licence to use the prior patent to acquire or exploit plant breeders' rights or a Community plant variety right, and
- (c) the new plant variety, in which the applicant wishes to acquire or exploit the plant breeders' rights or Community plant variety right, constitutes significant technical progress of considerable economic interest in relation to the invention protected by the patent,

the controllers shall order the grant to the applicant (or, where the applicant is a government department, shall order the grant to any person specified in the application) of a licence to use the invention protected by the prior patent in so far as the licence is necessary for the exploitation of the new plant variety on the conditions set out in regulation 7 and on such other terms as the controllers think fit.

Conditions

7.(1) A compulsory patent licence shall

- (a) not be exclusive,
- (b) entitle the proprietor of the patent concerned to an appropriate royalty, and
- (c) entitle the proprietor of the patent concerned to a cross licence on reasonable terms to use the new plant variety.

(2) Where the controllers order the grant of a compulsory patent licence to a person who has been granted plant breeders' rights in the new plant variety, the proprietor of the patent concerned may request, a cross licence on reasonable terms of the plant breeders' rights to use the new plant variety in respect of which the compulsory patent licence has been granted and, on such request, the controllers shall order the grant of such a cross licence to that proprietor (or, where the proprietor of the patent is a government department, to any person specified in the request).

(3) Where the controllers order the grant of a compulsory patent licence to a person who has yet to acquire plant breeders' rights in the new plant variety, the proprietor of the patent concerned may request a cross licence on reasonable terms of

the plant breeders' rights to use the new plant variety in respect of which the compulsory patent licence has been granted and, on such request, the controllers shall order the grant of such a cross licence to that proprietor (or, where the proprietor of the patent is a government department, to any person specified in the request), and the cross licence shall come into effect on the grant to the holder of the compulsory patent licence of plant breeders' rights in the new plant variety.

(4) Where the controllers order the grant of a compulsory patent licence to a person who has been granted a Community plant variety right in the new plant variety, if the proprietor of the patent wishes, the compulsory patent licence shall be subject to the grant to the proprietor of the patent concerned (or, where the proprietor of the patent is a government department, to any person the proprietor specifies) of a cross licence of the Community plant variety right on reasonable terms to use in the UK the new plant variety in respect of which the compulsory patent licence has been granted.

(5) Where the controllers order the grant of a compulsory patent licence to a person who has yet to acquire a Community plant variety right in the new plant variety, the order for grant shall, if the proprietor of the patent wishes, include a condition that, on the grant of the Community plant variety right to such person, in the new plant variety in respect of which the compulsory patent licence has been granted, the proprietor of the patent concerned (or, where the proprietor of the patent is a government department, such person as the proprietor specifies) shall be granted a cross licence on reasonable terms to use in the UK the new plant variety in respect of which the compulsory patent licence has been granted.

Variation

8.(1) On application at any time by a party to the Comptroller General of Patents in accordance with rules, the controllers may extend, limit or in any other respect vary an order for grant of a

- (a) compulsory patent licence, or
- (b) cross licence under regulation 7(2) or 7(3),

and extend, limit or in any other respect vary the licence granted under the order.

(2) On receipt of an application under paragraph (1), the controllers shall consider and process the application in accordance with rules.

Revocation

9.(1) A party may, at any time, apply to the Comptroller General of Patents in accordance with rules to revoke an order for grant of

- (a) a compulsory patent licence, or
- (b) cross licence under regulation 7(2) or 7(3),

if the circumstances which led to the order for grant have ceased to exist or are unlikely to recur.

(2) On receipt by the Comptroller General of Patents of an application under paragraph (1), the controllers shall consider and process the application in accordance with rules and if the controllers are satisfied that the circumstances which led to an order for grant of a –

- (a) compulsory patent licence, or
- (b) cross licence under regulation 7(2) or 7(3),

have ceased to exist or are unlikely to recur, the controllers may revoke the order and terminate the licence granted under the order, subject to such terms and conditions as they think necessary for the protection of the legitimate interests of the holder of the compulsory patent licence or the cross licence ordered to be granted under regulation 7(2) or 7(3).

10. In regulations 8 and 9, “party” means the proprietor of the patent concerned or the applicant, as the case may be, in an application under regulation 3(1) or their respective successors in title.

PART III

COMPULSORY PLANT VARIETY LICENCES

Applications

11.(1) Where a proprietor of a patent for a biotechnological invention cannot exploit a biotechnological invention protected by the patent without infringing prior plant breeders’ rights, he may apply in accordance with Breeders’ regulations to the Controller of Plant Variety Rights for a licence and on such application shall pay the plant breeders’ fee.

(2) An application under paragraph (1) shall be accompanied by particulars which seek to demonstrate that

- (a) the proprietor of the patent for a biotechnological invention cannot exploit the biotechnological invention protected by the patent without infringing prior plant breeders’ rights,
- (b) the proprietor of the patent has unsuccessfully applied to the holder of the prior plant breeders’ rights for a licence, and
- (c) the biotechnological invention protected by patent constitutes significant technical progress of considerable economic interest in relation to, the plant variety protected by the prior plant breeders’ rights.

(3) If and so far as any agreement purports to bind any person not to apply for a licence under paragraph (1), it shall be void.

Proceedings before controllers

12.-(1) On receipt by the Controller of Plant Varieties of an application under regulation 1(1) and payment of the appro-

priate plant breeders’ fee, the controllers shall consider and process the application in accordance with Breeders’ regulations.

(2) In proceedings before them in relation to an application under regulation 11(1), 16(1) or 16(2) the controllers, in addition to any powers conferred by Breeders’ regulations, may give such directions as they think fit with regard to the subsequent procedure.

(3) Any person entitled under Breeders’ regulations to make written or oral representations on an application under regulation 11(1), 16(1) or 16(2) shall do so in accordance with Breeders’ regulations and shall pay the appropriate plant breeders’ fee.

Grant

13. Where, having considered the application under regulation 11(1), the controllers are satisfied that

- (a) the proprietor of a patent for a biotechnological invention cannot exploit the biotechnological invention protected by the patent without infringing prior plant breeders’ rights,
- (b) the proprietor of the patent has unsuccessfully applied to the holder of the prior plant breeders’ rights for a licence, and
- (c) the biotechnological invention protected by the patent constitutes significant technical progress of considerable economic interest in relation to the plant variety protected by the prior plant breeders’ rights,

the controllers shall grant to the proprietor of the patent for the biotechnological invention (or, where the proprietor is a government department, to any person specified in the application) a licence to use the plant variety protected by prior plant breeders rights on the conditions set out in regulation 14 and on such other terms as the controllers see fit.

Conditions

14.(1) A compulsory plant variety licence shall

- (a) not be exclusive,
- (b) entitle the holder of the plant breeders’ rights concerned to an appropriate royalty, and
- (c) entitle the holder of the plant breeders’ rights concerned to a cross licence on reasonable terms to use the biotechnological invention protected by the patent.

(2) Where the controllers grant a compulsory plant variety licence to a proprietor of a patent for a biotechnological invention, the holder of the plant breeders’ rights concerned may request the grant of a cross licence on reasonable terms to use the biotechnological invention protected by the patent and, on

such request, the controllers shall grant such cross licence to the holder of plant breeders' rights (or, where the holder is a government department, to any person specified in the request).

Community plant variety rights: cross licences of patents

15.(1) Where the Community Plant Variety Office has granted

- (a) on the grounds specified in Article 12(3) of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions(a), and
- (b) under Article 29 of Council Regulation,

a compulsory exploitation right in respect of a Community plant variety right to a proprietor of a biotechnological invention protected by a patent, who could not otherwise exploit in the UK the biotechnological invention protected by the patent without infringing a Community plant variety right, the holder of the Community plant variety right concerned may, in accordance with rules, apply to the Comptroller General of Patents for a cross licence of the biotechnological invention protected by the patent and on such application shall pay the prescribed fee.

(2) On receipt of an application under paragraph (1) and payment of the prescribed fee, the Comptroller General shall consider and process the application in accordance with rules.

(3) Where the holder of the Community plant variety right concerned has paid the prescribed fee and demonstrates in his application to the satisfaction of the Comptroller General of Patents that

- (a) he has a Community plant variety right, and
- (b) the Community Plant Variety Office has granted, under Article 29 of Council Regulation, a compulsory exploitation right in respect of it which allows a proprietor of a patent for a biotechnological invention to exploit in the UK the biotechnological invention protected by the patent,

the Comptroller General of Patents shall order the grant of a cross licence on reasonable terms to the holder of the Community plant variety right concerned (or, where the holder is a government department, to any person specified in the application) to use in the UK the biotechnological invention protected by the patent.

- (a) OJ No. L 213, 30.7.98, p. 13.

Variation and revocation

16.(1) Any person may at any time apply to the Controller of Plant Variety Rights in accordance with Breeders' regulations to extend, limit or in any other respect vary a compulsory plant variety licence or cross licence granted under regulation 14(2)

and, on making such application shall pay the appropriate plant breeders' fee, and on receipt by the Controller of Plant Varieties of the application and the fee, the controllers shall consider and process the application and may extend, limit or in any other respect vary the compulsory plant variety licence or cross licence granted under regulation 14(2).

(2) Any person may at any time apply to the Controller of Plant Variety Rights in accordance with Breeders' regulations to revoke the grant of a compulsory plant variety licence or a cross licence under regulation 14(2) if the circumstances which led to the grant of the compulsory patent licence or the cross licence under regulation 14(2) have ceased to exist or are unlikely to recur and, on making such application, the applicant shall pay the appropriate plant breeders' fee.

(3) On receipt of an application under paragraph (2) and payment of the appropriate plant breeders' fee, the controllers shall consider and process the application in accordance with Breeders' regulations and if the controllers are satisfied that the circumstances which led to the grant of the compulsory plant variety licence or the cross licence under regulation 14(2) have ceased to exist or are unlikely to recur, the controllers may revoke the grant of the compulsory plant variety licence or the cross licence under regulation 14(2), subject to such terms and conditions as they think necessary for the protection of the legitimate interests of the holder of the compulsory plant variety licence or cross licence granted under regulation 14(2).

(4) On the application of any party at any time in accordance with rules, the Comptroller General of Patents may, having considered and processed the application in accordance with rules, extend, limit or in any other respect vary an order for grant of a cross licence under regulation 15(3) and extend, limit or in any other respect vary the licence granted under the order accordingly.

(5) A party may at any time apply to the Comptroller General of Patents in accordance with rules for an order to revoke a cross licence ordered to be granted under regulation 15(3), if the circumstances which led to an order for grant of the cross licence under regulation 15(3) have ceased to exist or are unlikely to recur.

(6) On receipt of an application under paragraph (5), the Comptroller General of Patents shall consider and process the application in accordance with rules and if the Comptroller General is satisfied that the circumstances which led to an order for grant of a cross licence under regulation 15(3) have ceased to exist or are unlikely to recur, the Comptroller General of Patents may revoke the order and terminate the licence granted under the order, subject to such terms and conditions as they think necessary for the protection of the legitimate interests of the holder of the cross licence.

(7) In paragraphs (4), (5) and (6), "party" means the proprietor of the patent concerned or the applicant, as the case may be, in an application under regulation 15(1) or their respective successors in title.

PART IV

APPEALS AND GENERAL PROVISIONS

Appeals

17.(1) An appeal lies from a decision of the controllers or Comptroller General of Patents under these Regulations.

(2) Where a decision of the controllers relates to a compulsory patent licence or cross licence ordered to be granted under regulation 7(2) or 7(3), or where a decision of the Comptroller General of Patents relates to a cross licence ordered to be granted under regulation 15(3), an appeal may be brought to the court.

(3) Where a decision of the controllers relates to a compulsory plant variety licence or cross licence of a patent for a biotechnological invention granted under regulation 14(2), an appeal may be brought to the Tribunal as if the decision of the controllers were one made by the Controller of Plant Variety Rights under section 17, and referred to in section 26(1)(c), of the 1997 Act and section 45 of the 1997 Act shall apply accordingly.

18. The Secretary of State shall draw up and from time to time revise a panel of persons who have specialised knowledge of biotechnological inventions.

19.(1) Subject to paragraph (2), appeals to the Tribunal under regulation 17(3) shall be governed by the provisions of Part 11 of the 1997 Act and Breeders' regulations.

(2) The provisions of Schedule 3 to the 1997 Act shall apply to appeals under regulation 17(3) with the following modifications

- (a) paragraph I (b) of Schedule 3 shall be treated as if it referred to a member of the panel constituted under regulation 18; and
- (b) the panels referred to in paragraph 8(1) of Schedule 3 to the 1997 Act shall be treated as including the panel constituted under regulation 18.

Extension of powers to make rules and regulations

20. The power of the Secretary of State to make rules under section 123 of the 1977 Act shall be extended so as to permit her to make rules regulating the business of the Patent Office in respect of

- (a) applications for the grant of licences under regulations 3(1) and 15(1),
- (b) applications under regulations 8 and 16(4) for variation and under regulations 9 and 16(5) for revocation of compulsory patent licences and cross licences,
- (c) proceedings before the controllers or the Comptroller General of Patents as the case may be in relation to applications in sub-paragraphs (a) and (b),
- (d) fees, and

- (e) other matters related to or arising under these Regulations,

and section 124 of the 1977 Act shall apply accordingly.

21. The powers of the -Ministers to make regulations under sections 24, 126(2)(a), 28., 29, 44~, and 48(1) of the 1997 Act shall be extended so as to permit them to make regulations in respect of-

- (a) applications for the grant of licences under regulation I 1 (1),
- (b) applications under regulation 16(1) for variation and under regulation 16(2) for revocation of compulsory plant variety licences and cross licences,
- (c) proceedings before the controllers in relation to applications in sub-paragraphs (a) and (b),
- (d) appeals from the decisions of the controllers in relation to such applications,
- (e) fees, and
- (f) other matters related to or arising under these Regulations,

and section 48(2) to (5) of the 1997 Act shall apply accordingly.

Application of existing rules and regulations

22.(1) Subject to the exercise by the Secretary of State of her powers under section 123 of the 1977 Act as extended by regulation 20, the Patents Rules in respect of

- (a) applications for the grant and revocation of compulsory licences under section 48(1) of the 1977 Act including forms,
- (b) proceedings before the Comptroller General of Patents in relation to
 - (i) the grant of such applications, and
 - (ii) the revocation of compulsory licences granted under section 48(1) of the 1977 Act, and
- (c) other matters provided for in the Patents Rules related to applications and proceedings in respect of such compulsory licences,

shall, subject to paragraph (2), extend and apply to and be taken to make corresponding provision in respect of applications for the grant of licences under regulation 3(1), proceedings before the controllers in relation to the grant of such applications, the variation or revocation of compulsory patent licences and cross licences under regulations 7(2), 7(3) and 15(3), and other matters related to or arising under these Regulations.

(2) For the purposes of paragraph (1), the Patents Rules shall have effect as if a reference to the Comptroller General of Patents in the Patents Rules were to the controllers, other than in rule 7 1 (1) of the Patents Rules and in relation to an application under regulation 15(1), and with any other necessary modifications.

23. Subject to the exercise by the Ministers of their powers under sections 24, 26(2)(a), 28, 29, 44 and 48(1) of the 1997 Act as extended by regulation 2 1, the Plant Breeders' Regulations in respect of

- (a) applications for the grant, variation and revocation of compulsory licences under section 17(1) of the 1997 Act,
- (b) proceedings before the Controller of Plant Variety Rights in relation to (i) the grant of such applications, and
 - (ii) the variation or revocation of compulsory licences granted under section 17(1) of the 1997 Act,
- (c) appeals to the Tribunal, and
- (d) other matters provided for in the Plant Breeders' Regulations related to applications

and proceedings in respect of such compulsory licences, shall, subject to paragraphs (2) and (3), extend and apply to and be taken to make corresponding provision in respect of applications under regulation I I (I), proceedings before the controllers in relation to such applications, the variation or revocation of compulsory plant variety licences and cross licences granted under regulation 14(2), appeals to the Tribunal and other matters related to or arising under these Regulations.

(2) For the purposes of paragraph (1), the Plant Breeders' Regulations shall have effect as if a reference to the Controller of Plant Variety Rights in the regulations were to the controllers and with any other necessary modifications.

(3) Regulation 10 of the Plant Breeders' Regulations shall not extend and apply to and shall not be taken to make corresponding provision in these Regulations.

24. Subject to the exercise by the Secretary of State of her powers under section 123 of the 1977 Act as extended by regulation 20, the Patents (Fees) Rules in respect of:

- (a) making an application for the grant of compulsory licences under section 48(1) of the 1977 Act, and
- (b) giving a notice of opposition to an application made under section 48, shall extend and apply to and be taken to make corresponding provision in respect of an application for a licence under regulation 3(1) or 15(1), and giving a notice of opposition under regulation 5(1).

25. Subject to the exercise by the Ministers of their powers under sections 29 and 48(1) of the 1997 Act as extended by regulation 21, the Plant Breeders' (Fees) Regulations in respect of

- (a) applications for the grant of compulsory licences under section 17(1) of the 1997 Act,
- (b) applications to extend, limit, vary or revoke such licences,
- (c) making representations in writing to the Controller, and
- (d) attending to be heard by the Controller, shall extend and apply to and be taken to make corresponding provision in respect of an application for a licence under regulation I I (I), applications to extend, limit, vary or revoke compulsory plant variety licences and cross licences granted under regulation 14(2), and proceedings before the controllers referred to in regulation 12.

Application of 1977 and 1997 Acts

26.(1) Subject to paragraphs (2) and (3), the provisions of the 1977 Act in respect of

- (a) proceedings before the Comptroller General of Patents,
- (b) decisions of the Comptroller General of Patents including orders for grant of compulsory licences,
- (c) legal proceedings in respect of appeals from the Comptroller General of Patents, and (d) other matters,

as and to the extent they relate to compulsory licences under section 48(1), shall extend and apply to and be taken to make corresponding provision in the UK in respect of proceedings before the controllers, decisions of the controllers including orders for the grant, variation and revocation, of compulsory patent licences and cross licences ordered to be granted under regulations 7(2), 7(3) and 15(3), legal proceedings in respect of appeals from the controllers and other matters related to compulsory patent licences and cross licences ordered to be granted under regulations 7(2), 7(3) and 15(3) arising under these Regulations.

(2) An application for a licence under regulation 3(1) is additional to any application an applicant may make under section 48 of the 1977 Act but the provisions of sections 48, 48A, 48B, 49, 50 and 52 do not extend and apply to and shall not be taken to make corresponding provision in respect of compulsory patent licences and cross licences ordered to be granted under these Regulations.

(3) For the purposes of paragraph (1), the provisions of the 1977 Act shall have effect as if a reference to the Comptroller General of Patents were to the controllers, other than in relation to applications under regulations 15(1), 16(3) and 16(4), and with any other necessary modifications.

27.(1) Subject to regulation 19(2) and paragraphs (2) and (3) of this regulation, the provisions of the 1997 Act in respect of

- (a) proceedings before the Controller of Plant Variety Rights,
- (b) decisions of the Controller of Plant Variety Rights in relation to compulsory licences,

- (c) appeals from the Controller of Plant Variety Rights to the Tribunal,
- (d) appeals from the Tribunal, and
- (e) other matters,

as and to the extent they relate to compulsory licences under section 17(1), shall extend and apply to and be taken to make corresponding provision in respect of proceedings before the controllers, decisions of the controllers including the grant, variation and revocation of compulsory plant variety licences and cross licences granted under regulation 14(2), appeals from the controllers and other matters related to compulsory plant variety licences and cross licences granted under regulation 14(2) arising under these Regulations.

(2) An application for a licence under regulation I 1 (1) is additional to any application an applicant may make under section 17 of the 1997 Act but the provisions of sections 17 and 23 of the 1997 Act do not extend and apply to and shall not be taken to make corresponding provision in respect of compulsory plant variety licences and cross licences under these Regulations.

(3) For the purposes of paragraph (1), the provisions of the 1997 Act shall have effect as if a reference to the Controller of Plant Variety Rights were to the controllers and with any other necessary modifications.

EXPLANATORY NOTE

(This note does not form part of the Regulations)

These Regulations implement Article 12 of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (OJ No. L 213, 30.7.98, p. 13). Articles I to I I of that Directive have been implemented by the Patents Regulations 2000 (S.I. 2000/2037) and Articles 13 and 14 by the Patents (Amendment) Rules 2001 (S.I. 2001/ 1412).

These Regulations enable the Comptroller General of Patents, Designs and Trade Marks and the Controller of Plant Variety Rights, acting jointly, to grant non-exclusive compulsory licences and cross licences where the exploitation of a patent would infringe a plant variety right and vice versa (regulations 6 and 13).

In these circumstances an applicant for a compulsory patent or plant variety licence must show that he has applied unsuccessfully to the respective patent or plant variety right holder to obtain a licence (regulations 3(2)(b) and 11(2)(b)).

In the case of an application for a compulsory patent licence, the applicant must also show that the new plant variety, in which he wishes to acquire or exploit the plant breeders' rights or a Community plant variety right, constitutes significant technical progress of considerable economic interest in relation to the invention protected by a prior patent (regulation 3(2)(c)).

In the case of an application for a compulsory plant variety licence, the proprietor of a patent for a biotechnological invention must also show that his invention constitutes significant technical progress of considerable economic interest in relation to the existing plant variety protected by prior plant breeders' rights (regulation I 1(2)(c)).

Where a compulsory licence has been granted, the holder of plant breeders' rights or proprietor of a patent for a biotechnological invention, in respect of whose rights the compulsory licence has been granted, is entitled to payment of an appropriate royalty and the grant of a cross licence on reasonable terms (regulations 7 and 14).

Where the Community Plant Variety Office has granted a compulsory exploitation right in respect of a Community plant variety right to a proprietor of a patent for a biotechnological invention who could not otherwise exploit his invention in the UK without infringing the prior Community plant variety right, the holder of the Community plant variety right concerned may apply to the Comptroller General of Patents, Designs and Trade Marks for a cross licence to use the biotechnological invention protected by the patent (regulation 15).

Part IV of these Regulations makes provisions for appeals (regulations 17 to 19). The route of appeal depends upon the nature of the main compulsory licence which forms the subject matter of the controllers' decision appealed from.

If the decision appealed from relates to the grant of a compulsory patent licence, the appeal is to the Patents Court of the High Court. An appeal lies also to the Patents Court of the High Court in respect of a cross licence granted under regulation 7(2) or 7(3) as a condition of the grant of the compulsory patent licence.

If the decision appealed from relates to the grant of a compulsory plant variety licence or cross licence of a patent for a biotechnological invention (granted under regulation 14(2) as a result of the grant of the compulsory plant variety licence), the appeal is to the Plant Variety and Seeds Tribunal (regulations 17 to 19) and subsequently, on points of law only, to the High Court.

The respective powers of the Secretary of State and Ministers to make rules and regulations under the relevant primary legislation have been extended so as to permit them to make rules and regulations governing applications and proceedings under these Regulations (regulations 20 and 21).

Subject to the exercise of extended powers, existing procedures and fees for applications and proceedings in the relevant primary and subordinate legislation relating to compulsory licences apply to applications for compulsory licences under these Regulations as if these applications were made under section 48(1) of the Patents Act 1977 and section 17(1) of the Plant Varieties Act 1997 respectively (regulations 22 to 25).

The provisions of primary legislation extend and apply to matters provided for in these Regulations with any necessary modifications (regulations 26 and 27).

A regulatory impact assessment and transposition note are available, copies of which have been placed in the libraries of both Houses of Parliament. Copies of the assessment and transposition note are also available from the Intellectual Property Policy Directorate of the Patent Office, Room 31338, Concept House, Cardiff Road, Newport NP10 8QQ.

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**GENERAL INTRODUCTION
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DISTINCTNESS, UNIFORMITY AND STABILITY
AND THE DEVELOPMENT OF HARMONIZED DESCRIPTIONS
OF NEW VARIETIES OF PLANTS**