

**S.I. No. 247 of 2000.**

**European Communities (Legal Protection of Biotechnological Inventions)  
Regulations, 2000**

I, Mary Harney, Minister for Enterprise, Trade and Employment, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998<sup>1</sup> on the legal protection of biotechnological inventions, hereby make the following Regulations:

1. (1) These Regulations may be cited as the European Communities (Legal Protection of Biotechnological Inventions) Regulations, 2000.

(2) These Regulations shall come into operation on 30 July 2000.

2. (1) In these Regulations, unless the context otherwise requires -

“Act of 1980” means the Plant Varieties (Proprietary Rights) Act, 1980 (No. 24 of 1980);

“Act of 1992” means the Patents Act, 1992 (No. 1 of 1992);

“Act of 1998” means the Plant Varieties (Proprietary Rights) (Amendment) Act, 1998 (No. 41 of 1998);

“Controller” means the Controller of Patents, Designs and Trade Marks;

“Controller of Plant Breeders’ Rights” has the meaning assigned to it by the Act of 1980;

“Council Regulation” means Council Regulation (EC) No. 2100/94<sup>2</sup>;

“Directive” means Directive 98/44/EC<sup>3</sup> of the European Parliament and of the Council of 6 July, 1998 on the legal protection of biotechnological inventions;

“holder” has the meaning assigned to it by section 15 of the Act of 1998;

“Rules of 1992” means the Patents Rules, 1992 (S.I. No. 179 of 1992);

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<sup>1</sup> O.J. No. L. 213, 30.07.1998, p.13

<sup>2</sup> O.J. No. L.277, 01.09.1994, p. 1.

<sup>3</sup> O.J. No. L. 213, 30.07.1998, p.13

(2) A word or expression that is used in these Regulations and is also used in the Directive, has, unless the contrary intention appears, the same meaning in these Regulations that it has in the Directive.

(3) In these Regulations -

- (a) a reference to a Regulation is a reference to a Regulation of these Regulations unless it is indicated that reference to some other Regulations is intended,
- (b) a reference to a paragraph or a subparagraph, is a reference to the paragraph or the subparagraph of the provision in which the reference occurs unless it is indicated that reference to some other provision is intended, and
- (c) a reference to any enactment is a reference to that enactment as amended or extended by or under any subsequent enactment including these Regulations.

3. Subject to the provisions of these Regulations, the Act of 1992 and the Rules of 1992 shall apply to patent applications and patents concerning biotechnological inventions.

4. (1) An invention that complies with section 9(1) of the Act of 1992 is patentable even if it concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

(2) Biotechnological inventions shall be patentable, in particular, if they concern -

- (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature,
- (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety, or
- (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

5. (1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, shall not be patentable.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

(3) If an invention concerns the sequence or partial sequence of a gene the industrial application thereof shall be disclosed in the patent application as filed.

6. (1) A patent shall not be granted in respect of a biotechnological invention the commercial exploitation of which would be contrary to public order or morality, provided that the exploitation shall not be deemed to be so contrary only because it is prohibited by law.

(2) Any of the following, in particular, shall not be regarded as a patentable invention, on the basis of paragraph (1)-

- (a) a process for cloning human beings,
- (b) a process for modifying the germ line genetic identity of human beings,
- (c) the use of human embryos for industrial or commercial purposes,
- (d) a process for modifying the genetic identity of animals which is likely to cause them suffering without any substantial medical benefit to man or animal, and animals resulting from such a process.

7. (1) If the subject-matter of a patent is a biological material having specific characteristics as a result of the invention, the protection conferred by the patent shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

(2) If the subject-matter of a patent is a process for the production of a biological material having specific characteristics as a result of the invention, the protection conferred by the patent shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

8. If the subject matter of a patent is a product containing or consisting of genetic information, the protection conferred by the patent shall extend, subject to Regulation 5 (1), to all material in which the product is incorporated and in which the genetic information is contained and performs its function.

9. The protection referred to in Regulations 7 and 8 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the State by the proprietor of the patent or with the consent of the proprietor, where the propagation or multiplication necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for propagation or multiplication.

10. (1) Regulations 7 and 8 shall not extend to-

- (a) the use by a farmer of the product of his harvest for propagation or multiplication by him on his own farm, where there has been a sale or other form of commercialisation of plant propagating material to the farmer by the proprietor of the patent or with the consent of the proprietor of the patent for agricultural use, subject to conditions corresponding to the derogation set out in Article 14 of the Council Regulation, and
- (b) the use for an agricultural purpose by a farmer of protected livestock, where there has been a sale or other form of commercialisation of breeding stock or other animal reproductive material to the farmer by the proprietor of the patent or with the consent of the proprietor of the patent.

(2) The use for an agricultural purpose by a farmer of protected livestock referred to in paragraph 1(b) includes making the animal or other animal reproductive material available for the purposes of pursuing the agricultural activity of the farmer but not sale within the framework or for the purpose of a commercial reproduction activity.

11. (1) Where a holder cannot acquire or exploit in the State a plant breeders' right granted by the Controller of Plant Breeders' Rights without infringing a prior patent for a biotechnological invention, and where the holder has applied unsuccessfully to the proprietor of the patent concerned for a contractual licence under the patent, the holder may apply to the Controller for a licence under the patent to the extent necessary for the exploitation of the plant breeders' right concerned:

Provided that the plant variety protected by the plant breeders' right involves an important technical advance of considerable economic significance in relation to the invention claimed in the patent.

(2) When granting a licence on an application under paragraph (1) the Controller shall ensure that the licence is subject to the payment of an appropriate royalty to the proprietor of the patent.

(3) The Controller shall not grant a licence referred to in paragraph (1) unless the holder is able and willing to grant the proprietor of the patent a cross-licence, on reasonable terms, to use the variety protected by the plant breeders' right.

(4) Part IV of the Act of 1992 shall apply with any necessary modifications to applications for licences and licences under this Regulation.

12. (1) Where the proprietor of a patent for a biotechnological invention cannot exploit it in the State without infringing a prior plant breeders' right, and where the proprietor has applied unsuccessfully to the holder of the plant breeders' right concerned for a contractual licence under the plant breeders' right, the proprietor of the patent may apply to the Controller of Plant Breeders' Rights for a licence under the plant breeders' right to the extent necessary for the exploitation of the patent concerned:

Provided that the patent involves an important technical advance of considerable economic significance in relation to the plant variety protected by the plant breeders' right.

(2) When granting a licence on an application under paragraph (1) the Controller of Plant Breeders' Rights shall ensure that the licence is subject to the payment of an appropriate royalty to the holder of the plant breeders' right.

(3) The Controller of Plant Breeders' Rights shall not grant a licence referred to in paragraph (1) unless the proprietor of the patent is able and willing to grant the holder of the plant breeders' right a cross-licence, on reasonable terms, to use the invention claimed in the patent.

(4) The provisions of section 8 of the Act of 1980 (as amended by section 9 of the Act of 1998) shall apply with any necessary modifications to applications for licences and licences under this Regulation.

13. (1) Where the proprietor of a patent for a biotechnological invention which cannot be exploited in the State without infringing a Community plant variety right has been granted a compulsory exploitation right by the Community Plant Variety Office under Article 29 of the Council Regulation, the holder of the Community plant variety right may apply to the Controller for a cross-licence to use the invention claimed in the patent.

(2) Where an application is made under paragraph (1), the Controller may grant the holder of the Community plant variety right a cross-licence, on reasonable terms, to use the invention claimed in the patent concerned.

(3) Part IV of the Act of 1992 shall apply with any necessary modifications to an application for a cross-licence under this Regulation.

14. (1) Section 19 of the Act of 1992 is amended in subsection (2) by the substitution of "biological material" for "micro-organism".

- (2) Rule 14 of the Rules of 1992 is amended-
- (a) by the substitution of “biological material” for “micro-organism” in each place where it occurs,
  - (b) by the substitution of “sample” for “culture”, and
  - (c) in paragraph (21)(a) by the substitution of “biological material” for “micro-organisms”.

GIVEN under my Official Seal,

**L.S.**

28th July 2000.

Pl. No. 8884

MARY HARNEY,  
Minister for Enterprise, Trade and  
Employment

## **EXPLANATORY NOTE**

(This note is not part of the Instrument and does not purport to be a legal interpretation)

The purpose of these Regulations is to give statutory effect in the State to the requirements of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

Inventions in the field of biotechnology must meet patentability requirements in the same way as inventions in other technical areas. The Regulations contain a non-exclusive list of subject-matter which are considered patentable and non-patentable.

The Regulations include provisions concerning the scope of protection of a patent for self-replicable material or material containing genetic information which permits its multiplication or propagation. The protection conferred by such a patent will extend to all material obtained from the multiplication or propagation. An exemption is made for farmers to whom the Regulations give an implied right to use the seed obtained from their harvest for further propagation on their own farm.

The Regulations also deal with compulsory licences and cross-licences between the proprietor of a patent and the holder of a plant variety right where one cannot be exploited without infringement of the other.

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