

# The Patents Regulations 2000, No. 2037

Made ..... 27th July 2000  
Coming into force ..... 28th July 2000

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Whereas a draft of the following Regulations has been approved by resolution of each House of Parliament:

Now, therefore, 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 patents, in exercise of powers conferred by section 2(2) and (4) of the said Act of 1972, hereby makes the following Regulations:—

### **Citation and Commencement**

**1.**—(1) These Regulations may be cited as the Patents Regulations 2000 and shall come into force on the day after the date on which they are made (“the commencement date”).

(2) In these Regulations “the Act” means the Patents Act 1977(*c*).

### **Amendment of the Patents Act 1977**

**2.** The Act is amended as set out in regulations 3 to 8 subject to the transitional provisions set out in regulation 9.

**3.** In section 1 (patentable inventions), for subsections (3) and (4) substitute—

“(3) A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

(4) For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.”.

**4.** In section 60 (meaning of infringement)—

(*a*) in subsection (5), after paragraph (*f*) insert—

“(g) it consists of the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent or with his consent for agricultural use;

(*h*) it consists of the use of an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the proprietor of the patent or with his consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention.”;

(b) after subsection (6) insert—

“(6A) Schedule A1 contains—

(a) provisions restricting the circumstances in which subsection (5)(g) applies; and

(b) provisions which apply where an act would constitute an infringement of a patent but for subsection (5)(g).

(6B) For the purposes of subsection (5)(h), use for an agricultural purpose—

(a) includes making an animal or animal reproductive material available for the purposes of pursuing the farmer’s agricultural activity; but

(b) does not include sale within the framework, or for the purposes, of a commercial reproduction activity.

(6C) In paragraphs (g) and (h) of subsection (5) “sale” includes any other form of commercialisation.”.

5. After section 76 insert—

*“Biotechnological Inventions*

**76A.**—(1) Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of Schedule A2.

(2) Nothing in this section or Schedule A2 is to be read as affecting the application of any provision in relation to any other kind of patent or application for a patent.”.

**6.**—(1) Section 125A (disclosure of invention by specification: availability of samples of micro-organisms) is amended as follows.

(2) In the sidenote, for “micro-organisms” substitute “biological material”.

(3) In subsection (1), for “requires for its performance the use of a micro-organism” substitute “involves the use of or concerns biological material”.

(4) In subsection (2)(a), for “micro-organism” substitute “biological material”.

**7.** In section 130 (interpretation) insert in proper alphabetical order—

““biological material” means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;”;

““biotechnological invention” means an invention which concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used;”.

**8.**—(1) Insert the Schedule set out in Schedule 1 to these Regulations as Schedule A1 to the Act.

(2) Insert the Schedule set out in Schedule 2 to these Regulations as Schedule A2 to the Act.

## Transitional Provisions

9. The amendments effected to the Act by these Regulations shall apply to applications for patents (and to patents granted in pursuance of such applications) made on or after the commencement date.

Kim Howells,  
Parliamentary Under-Secretary of State  
for Consumers and Corporate Affairs,  
Department of Trade and Industry

### SCHEDULE 1

Regulation 8

#### “SCHEDULE A1

Section 60(5)(g)

### DEROGATION FROM PATENT PROTECTION IN RESPECT OF BIOTECHNOLOGICAL INVENTIONS

#### Interpretation

1. In this Schedule—

“Council Regulation” means Council Regulation (EC) No. 2100/94 of 27th July 1994 on Community plant variety rights;

“farmer’s own holding” means any land which a farmer actually exploits for plant growing, whether as his property or otherwise managed under his own responsibility and on his own account;

“the gazette” means the gazette published under section 34 of the Plant Variety and Seeds Act 1964(a);

“protected material” means plant propagating material which incorporates material subject to a patent;

“relevant activity” means the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where the product of the harvest constitutes or contains protected material;

“relevant rights holder” means the proprietor of a patent to which protected material is subject;

“seed” includes seed potatoes;

“seed year” means the period from 1st July in one year to 30th June in the following year, both dates inclusive.

#### Specified Species

2. Section 60(5)(g) applies only to varieties of the following plant species and groups:

*Name*..... *Common Name*

Fodder plants

|                                       |                    |
|---------------------------------------|--------------------|
| <i>Cicer arietinum</i> L. ....        | Chickpea milkvetch |
| <i>Lupinus luteus</i> L.....          | Yellow lupin       |
| <i>Medicago sativa</i> L.....         | Lucerne            |
| <i>Pisum sativum</i> L. (partim)..... | Field pea          |
| <i>Trifolium alexandrinum</i> L. .... | Berseem/Egyptian   |
| .....                                 | clover             |
| <i>Trifolium resupinatum</i> L. ....  | Persian clover     |
| <i>Vicia faba</i> .....               | Field bean         |
| <i>Vicia sativa</i> L. ....           | Common vetch       |

#### Cereals

|  |              |
|--|--------------|
| <i>Avena sativa</i> .....                              | Oats         |
| <i>Hordeum vulgare</i> L. ....                         | Barley       |
| <i>Oryza sativa</i> L. ....                            | Rice         |
| <i>Phalaris canariensis</i> L. ....                    | Canary grass |
| <i>Secale cereale</i> L. ....                          | Rye          |
| <i>X Triticosecale</i> Wittm. ....                     | Triticale    |
| <i>Triticum aestivum</i> L. emend. Fiori et Paol. .... | Wheat        |
| <i>Triticum durum</i> Desf. ....                       | Durum wheat. |
| <i>Triticum spelta</i> L. ....                         | Spelt wheat  |

#### Potatoes

|                                |          |
|--------------------------------|----------|
| <i>Solanum tuberosum</i> ..... | Potatoes |
|--------------------------------|----------|

#### Oil and fibre plants

|  |                            |
|--|----------------------------|
| <i>Brassica napus</i> L. (partim)..... | Swede rape                 |
| <i>Brassica rapa</i> L. (partim).....  | Turnip rape                |
| <i>Linum usitatissimum</i> .....       | Linseed with the exclusion |
| .....                                  | of flax                    |

### Liability to Pay Equitable Remuneration

3.—(1) If a farmer's use of protected material is authorised by section 60(5)(g), he shall, at the time of the use, become liable to pay the relevant rights holder equitable remuneration.

(2) That remuneration must be sensibly lower than the amount charged for the production of protected material of the same variety in the same area with the holder's authority.

(3) Remuneration is to be taken to be sensibly lower if it would be taken to be sensibly lower within the meaning of Article 14(3) fourth indent of the Council Regulation.

## **Exemption for Small Farmers**

4.—(1) Paragraph 3 does not apply to a farmer who is considered to be a small farmer for the purposes of Article 14(3) third indent of the Council Regulation.

(2) It is for a farmer who claims to be a small farmer to prove that he is such a farmer.

## **Information to Be Supplied by Farmer**

5.—(1) At the request of a relevant rights holder (“H”), a farmer must tell H—

(a) his name and address;

(b) whether he has performed a relevant activity; and

(c) if he has performed such an activity, the address of the holding on which he performed it.

(2) If the farmer has performed such an activity, he must tell H whether he is—

(a) liable to pay remuneration as a result of paragraph 3; or

(b) not liable because he is a small farmer.

(3) If the farmer has told H that he is liable to pay remuneration as a result of paragraph 3, he must tell H—

(a) the amount of the protected material used;

(b) whether the protected material has been processed for planting; and

(c) if it has, the name and address of the person who processed it.

(4) The farmer must comply with sub-paragraphs (2) and (3) when complying with sub-paragraph (1).

(5) If the farmer has told H that he is liable to pay remuneration as a result of paragraph 3, he must (if H asks him to do so) tell H—

(a) whether he used any protected material with the authority of H within the same seed year; and

(b) if he did, the amount used and the name and address of the person who supplied it.

## **Information to Be Supplied by Seed Processor**

6.—(1) On the request of a relevant rights holder, a seed processor shall supply the following information—

(a) the name and address of the seed processor;

(b) the address of the seed processor’s principal place of business; and

(c) whether the seed processor has processed seed of a species specified in paragraph 2 above.

(2) If the seed processor has processed seed of a species specified in paragraph 2 above he shall also supply the following information with the information referred to in sub-paragraph (1)—

(a) the name and address of the person for whom the processing was carried out;

- (b) the amount of seed resulting from the processing;
- (c) the date processing commenced;
- (d) the date processing was completed;
- (e) the place where processing was carried out.

### **Information to Be Supplied by Relevant Rights Holder**

**7.** On the request of a farmer or a seed processor a relevant rights holder shall supply the following information—

- (a) his name and address; and
- (b) the amount of royalty charged for certified seed of the lowest certification category for seed containing that protected material.

### **Period in Respect of Which Inquiry May Be Made**

**8.** A request may be made under paragraphs 5, 6 and 7 in respect of the current seed year and the three preceding seed years.

### **Restriction on Movement for Processing From the Holding**

**9.** No person shall remove or cause to be removed from a holding protected material in order to process it unless—

- (a) he has the permission of the relevant rights holder in respect of that protected material;
- (b) he has taken measures to ensure that the same protected material is returned from processing as is sent for processing and the processor has undertaken to him that the processor has taken measures to ensure that the same protected material is returned from processing as is sent for processing; or
- (c) he has the protected material processed by a seed processor on the list of processors referred to in the gazette as being permitted to process seed away from a holding.

### **Confidentiality**

**10.—(1)** A person who obtains information pursuant to this Schedule shall owe an obligation of confidence in respect of the information to the person who supplied it.

(2) Sub-paragraph (1) shall not have effect to restrict disclosure of information—

- (a) for the purposes of, or in connection with, establishing the amount to be paid to the holder of rights pursuant to paragraph 3 and obtaining payment of that amount,
- (b) for the purposes of, or in connection with, establishing whether a patent has been infringed, or
- (c) for the purposes of, or in connection with, any proceedings for the infringement of a patent.

## Formalities

**11.**—(1) A request for information under this Schedule, and any information given in response to such a request, must be in writing.

(2) Information requested under this Schedule must be given—

(a) within 28 days; or

(b) if the request specifies a longer period, within the specified period.

## Remedies

**12.**—(1) If, in response to a request under this Schedule, a person—

(a) knowingly fails to provide information which he is required by this Schedule to give, or

(b) refuses to provide any such information,

the court may order him to provide it.

(2) Sub-paragraph (1) does not affect any of the court's other powers to make orders.

(3) A person who knowingly provides false information in response to a request under this Schedule is liable in damages to the person who made the request.

(4) In any action for damages under sub-paragraph (3) the court must have regard, in particular to—

(a) how flagrant the defendant was in providing the false information, and

(b) any benefit which accrued to him as a result of his providing false information, and shall award such additional damages as the justice of the case may require.”.

## SCHEDULE 2

Regulation 8

### “SCHEDULE A2

Section 76A

## BIOTECHNOLOGICAL INVENTIONS

**1.** An invention shall not be considered unpatentable solely on the ground that it concerns—

(a) a product consisting of or containing biological material; or

(b) a process by which biological material is produced, processed or used.

**2.** Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

**3.** The following are not patentable inventions—

(a) 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;

- (b) processes for cloning human beings;
- (c) processes for modifying the germ line genetic identity of human beings;
- (d) uses of human embryos for industrial or commercial purposes;
- (e) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;
- (f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.

**4.** Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

**5.** 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.

**6.** The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application as filed.

**7.** The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention 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.

**8.** The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention 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.

**9.** The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided for in paragraph 3(a) above, in which the product is incorporated and in which the genetic information is contained and performs its function.

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

**11.** In this Schedule:

“essentially biological process” means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection;

“microbiological process” means any process involving or performed upon or resulting in microbiological material;

“plant variety” means a plant grouping within a single botanical taxon of the lowest known rank, which grouping can be:



(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes; and

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics; and

(c) considered as a unit with regard to its suitability for being propagated unchanged.”.

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## EXPLANATORY NOTE

*(This note does not form part of the Regulations)*

These Regulations amend the Patents Act 1977 in order to make provision for the implementation of Articles 1 to 11 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (“the Directive”) and for implementation of article 27(2) of the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) annexed to the Agreement establishing the World Trade Organisation (Cm. 2556-59, 2561-69, 2571-74). Implementation of Articles 12 to 14 of the Directive is to be by way of other statutory instruments.

The following changes are made to the Patents Act 1977—

(a) in section 1 (patentable inventions), new subsections are substituted for subsections (3) and (4). The provision in the Directive which is implemented by this amendment to the Act, (exclusions on the grounds of morality or public policy), corresponds to article 27(2) of TRIPS. However, article 27(2) of TRIPS, and the new subsections, apply to all inventions (regulation 3);

(b) in section 60 (meaning of infringement), after subsection (5) paragraph (f) are inserted two paragraphs providing a derogation from infringement of a patent where an otherwise infringing act consists of the use by a farmer of:

(i) the product of his harvest for propagation or multiplication by him on his own farm, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent or with his consent for agricultural use subject to conditions set out in new Schedule A1 to the Act;

(ii) an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the proprietor of the patent or with his consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention (regulation 4);

(c) after section 76 is inserted a new section 76A which provides that any provision of, or made under, the Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of new Schedule A2 (regulation 5);

(d) section 125A (disclosure of invention by specification: availability of samples of micro-organisms), is modified so as to substitute “biological material” for “micro-organism” where it occurs (regulation 6);

(e) in section 130 (interpretation) definitions of “biological material” and “biotechnological invention” are inserted in proper alphabetical order (regulation 7);

(f) two new schedules are inserted into the Act. Schedule A1 contains detailed provision for the operation of the derogation contained in section 60(5) (g) (use by a farmer of the product of his harvest for propagation or multiplication by him on his own farm). Schedule A2 contains provisions in accordance with which all other provisions of the Act must be interpreted when they are to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention (regulation 8).

A regulatory impact assessment is available, copies of which have been placed in the libraries of both Houses of Parliament. Copies of the assessment are also available from the Intellectual Property Policy Directorate of the Patent Office, Room 3B38, Concept House, Cardiff Road, Newport NP10 8QQ.