

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions

CHAPTER I

Patentability

Article 1

1 Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

2 This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

Article 2

1 For the purposes of this Directive,

- a 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;
- b 'microbiological process' means any process involving or performed upon or resulting in microbiological material.

2 A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

3 The concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94.

Article 3

1 For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of 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.

Article 4

1 The following shall not be patentable:

- a plant and animal varieties;
- b essentially biological processes for the production of plants or animals.

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

3 Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 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, cannot constitute patentable inventions.

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

Article 6

1 Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2 On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

- a processes for cloning human beings;
- b processes for modifying the germ line genetic identity of human beings;
- c uses of human embryos for industrial or commercial purposes;
- d 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.

Article 7

The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.