COMMISSION OF THE EUROPEAN COMMUNITIES

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2003/0161 (CNS)

Proposal for a

COUNCIL REGULATION

amending Regulation (EC) No 2100/94 on Community plant variety rights

(presented by the Commission)

EXPLANATORY MEMORANDUM

Article 29 of Regulation (EC) No 2100/94 on Community Plant Variety Rights is inconsistent with Article 12 of the Biotechnology Patents Directive 98/44/EC on the legal protection of biotechnological inventions.

In February 1998 the Council called on the Commission to examine this inconsistency and to submit an appropriate proposal to amend Regulation (EC) No 2100/94.

A plant variety may be protected by a plant variety right but may also contain one or several biotechnological inventions which are themselves protected by a patent, e.g. patented genetic components. These intellectual property rights may be owned by different persons.

In the case of disagreement between the various intellectual property owners, both legislations provide that compulsory measures (exploitation rights or cross licencing) may be granted to ensure that the plant variety or patent may be exploited, but only when justified.

Under Regulation (EC) No 2100/94 this may be done only on the grounds of 'public interest'. Under Directive 98/44/EC, a compulsory exploitation right can be granted if it would constitute a 'significant technical progress of considerable economic interest', but not a general 'public interest'.

The proposed amendment to Regulation (EC) No 2100/94 will resolve this inconsistency:

1. It will provide coherence of the system of compulsory cross-licencing provided for by Regulation (EC) No 2100/94 on Community plant variety rights and Directive 98/44/EC on biotechnological inventions.

2. To enable the exploitation of a patented biotechnological invention, the Community Plant Variety Office can grant to the patent holder a compulsory licence for the use of a protected plant variety containing his invention. Applicants for the compulsory licences must demonstrate that;

   – they have applied unsuccessfully to the holder of the plant variety right to obtain a contractual licence; and

   – the biotechnological invention constitutes a significant technical progress of considerable economic interest compared with the protected plant variety.

3. The holder of the patent can be granted a cross-licence to exploit the plant variety containing his biotechnological invention, if the holder of a plant variety right has been granted a compulsory licence for the use of this patented invention under Directive 98/44/EC.

The proposal has no new financial implications for the Community budget.

The proposal will have no impact on small or medium sized undertakings.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 308 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Parliament[2],

Whereas:

(1) Regulation (EC) No 2100/94[3] creates a Community regime for plant varieties, co-existing with national regimes, which allows for the grant of industrial property rights, valid throughout the Community ("Community plant variety rights").

(2) The implementation and application of this regime are carried out by a Community Office with legal personality, known as the Community Plant Variety Office ("the Office"),

(3) Only the Office is entitled to grant a compulsory exploitation right for a plant variety which is protected by a Community plant variety right,

(4) The Community's legal framework for the protection of biotechnological inventions, established in Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions[4] lays down in Article 12 rules for the grant of non-exclusive compulsory licences where protected plant varieties incorporate patented inventions, and vice versa,

(5) Article 29 of Regulation (EC) No 2100/94 provides in general for the grant of compulsory exploitation rights for Community plant varieties on grounds of public interest, whereas Article 12 of Directive 98/44/EC does not impose such a requirement in relation to a compulsory cross-licencing between an invention patent and a plant variety right.

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ L 227, 1.9.1994, p. 1.
4 OJ L 213, 30.7.1998, p. 13.

(6) Considering the need to ensure coherence of the system of compulsory cross-licencing in the different fields of industrial and commercial property, the rules established by Regulation (EC) No 2100/94 should be aligned with those provided for in Directive 98/44/EC.

(7) Considering the national scope of the protection for biotechnological inventions under Directive 98/44/EC and the need to ensure that the national patent holder be granted a cross-licence for a plant variety right only in the Member State(s) where he can claim a patent for a biotechnological invention,

(8) For the adoption of this Regulation, the Treaty does not provide for powers other than those conferred by Article 308,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2100/94 is hereby amended as follows:

Article 29 shall be replaced by the following:

"Article 29

Compulsory exploitation right and compulsory cross licencing where a variety incorporates an invention protected by patent

1. Compulsory exploitation rights shall be granted to one or more persons by the Office, on application by that person or those persons, but only on grounds of public interest and after consulting the Administrative Council referred to in Article 36.

2. On application by a Member State, by the Commission or by an organisation set up at Community level and registered by the Commission, a compulsory exploitation right may be granted, either to a category of persons satisfying specific requirements, or to anyone in one or more Member States or throughout the Community. It may be granted only on grounds of public interest and with the approval of the Administrative Council.

3. The Office shall, when granting the compulsory exploitation right under paragraphs 1, 2 or 5, stipulate the type of acts covered and specify the reasonable conditions pertaining thereto as well as the specific requirements referred to in paragraph 2. The reasonable conditions shall take into account the interests of any holder of plant variety rights who would be affected by the grant of the compulsory exploitation right. The reasonable conditions may include a possible time limitation, the payment of an appropriate royalty as equitable remuneration to the holder, and may impose certain obligations on the holder, the fulfilment of which are necessary to make use of the compulsory exploitation right.

4. On the expiry of each one-year period after the grant of the compulsory exploitation right under paragraphs 1, 2 or 5, and within the aforementioned possible time limitation, any of the parties to proceedings may request that the decision on the grant of the compulsory exploitation right be cancelled or amended. The sole grounds for such a request shall be that the circumstances determining the decision taken have in the meantime undergone change.

5. On application, a compulsory exploitation right shall be granted to the holder in respect of an essentially derived variety if the criteria set out in paragraph 1 are met. The reasonable conditions referred to in paragraph 3 shall include the payment of an appropriate royalty as equitable remuneration to the holder of the initial variety.

6. The implementing rules pursuant to Article 114 may specify certain cases as examples of the public interest referred to in paragraphs 1 and 2, and moreover lay down details for the implementation of the provisions of the above paragraphs.

7. Compulsory exploitation rights may not be granted by Member States in respect of a Community plant variety right.

8. The following rules shall apply by way of derogation from paragraphs 1 to 7:

   (a) Where the holder of a patent for a biotechnological invention applies to the Office for a compulsory licence for the non-exclusive use of a protected plant variety under article 12(2) of Directive 98/44/EC, the Office shall grant such a licence, subject to payment of an appropriate royalty, provided that the patent holder demonstrates that

      (i) he has applied unsuccessfully to the holder of the plant variety right to obtain a contractual licence; and

      (ii) the invention constitutes significant technical progress of considerable economic interest compared with the protected plant variety.

   (b) Where, in order to enable him to acquire or exploit his plant variety right, a holder has been granted a compulsory licence under article 12(1) of the above Directive for the non-exclusive use of a patented invention, the Office shall, on application by the holder of the patent for that invention, grant to him a non-exclusive cross-licence on reasonable terms to exploit the variety.

   (c) On granting a licence or cross-licence to a patent holder under sub-paragraph (a) or (b) respectively, the Office shall restrict the territorial scope of the licence or cross-licence to the part or parts of the Community covered by the patent."

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Council
The President