

Regulation (EC) No 1610/96 of the European Parliament and  
of the Council of 23 July 1996 concerning the creation of a  
supplementary protection certificate for plant protection products

REGULATION (EC) No 1610/96 OF THE  
EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 23 July 1996

concerning the creation of a supplementary  
protection certificate for plant protection products

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Acting in accordance with the procedure referred to in Article 189b of the Treaty<sup>(3)</sup>,

- (1) Whereas research into plant protection products contributes to the continuing improvement in the production and procurement of plentiful food of good quality at affordable prices;
- (2) Whereas plant protection research contributes to the continuing improvement in crop production;
- (3) Whereas plant protection products, especially those that are the result of long, costly research, will continue to be developed in the Community and in Europe if they are covered by favourable rules that provide for sufficient protection to encourage such research;
- (4) Whereas the competitiveness of the plant protection sector, by the very nature of the industry, requires a level of protection for innovation which is equivalent to that granted to medicinal products by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products<sup>(4)</sup>;
- (5) Whereas, at the moment, the period that elapses between the filing of an application for a patent for a new plant protection product and authorization to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research;
- (6) Whereas this situation leads to a lack of protection which penalizes plant protection research and the competitiveness of the sector;

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*Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 1610/96 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)*

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- (7) Whereas one of the main objectives of the supplementary protection certificate is to place European industry on the same competitive footing as its North American and Japanese counterparts;
- (8) Whereas, in its Resolution of 1 February 1993<sup>(5)</sup> on a Community programme of policy and action in relation to the environment and sustainable development, the Council adopted the general approach and strategy of the programme presented by the Commission, which stressed the interdependence of economic growth and environmental quality; whereas improving protection of the environment means maintaining the economic competitiveness of industry; whereas, accordingly, the issue of a supplementary protection certificate can be regarded as a positive measure in favour of environmental protection;
- (9) Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to hinder the free movement of plant protection products within the Community and thus directly affect the functioning of the internal market; whereas this is in accordance with the principle of subsidiarity as defined by Article 3b of the Treaty;
- (10) Whereas, therefore, there is a need to create a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a plant protection product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;
- (11) Whereas the duration of the protection granted by the certificate should be such as to provide adequate, effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the plant protection product in question first obtains authorization to be placed on the market in the Community;
- (12) Whereas all the interests at stake in a sector as complex and sensitive as plant protection must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years;
- (13) Whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection;
- (14) Whereas the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them;
- (15) Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community plant protection industry to catch up to some extent with its main competitors, while making sure that the arrangements do not compromise the achievement of other

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legitimate objectives concerning the agricultural policy and environment protection policy pursued at both national and Community level;

- (16) Whereas only action at Community level will enable the objective, which consists in ensuring adequate protection for innovation in the field of plant protection, while guaranteeing the proper functioning of the internal market for plant protection products, to be attained effectively;
- (17) Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, *mutatis mutandis*, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) (c) and 17 of Council Regulation (EEC) No 1768/92,

HAVE ADOPTED THIS REGULATION:

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- (1) OJ C 390, 31. 12. 1994, p. 21 and OJ C 335, 13. 12. 1995, p. 15.
- (2) OJ No C 155, 21. 6. 1995, p. 14.
- (3) Opinion of the European Parliament of 15 June 1995 (OJ C 166, 3. 7. 1995, p. 89), common position of the Council of 27 November 1995 (OJ C 353, 30. 12. 1995, p. 36) and decision of the European Parliament of 12 March 1996 (OJ C 96, 1. 4. 1996, p. 30).
- (4) OJ No L 182, 2. 7. 1992, p. 1.
- (5) OJ No C 138, 17. 5. 1993, p. 1.

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