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Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC)

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

(presented by the Commission)



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# EXPLANATORY MEMORANDUM

## INTRODUCTION

1. On 18 June 1992 the Council meeting on the internal market adopted Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products,<sup>(1)</sup> which entered into force on 2 January 1993. When the Council adopted the common position pursuant to the procedure under Article 149(2) of the EEC Treaty, it also adopted, on 19 December 1991, a statement recorded in the minutes of the meeting:

*"The Council requests the Commission to submit to it as soon as possible after this Regulation enters into force a proposal concerning the creation of a supplementary protection certificate for plant health products."*

2. The Commission recalls that, during the discussions on Regulation 1768/92, it argued before the Council and Parliament that it would be possible, at a later stage, to apply the supplementary protection certificate to other products, such as plant protection products, provided the industry concerned demonstrated that it was faced with a situation justifying such a measure.
3. It should also be noted that, on the question of the scope of Regulation 1768/92, the large majority of the Member States took the view at the time that it would be more effective to restrict discussion to the pharmaceutical sector, without prejudice to their respective positions as to the need for subsequent action in respect of other products.
4. The plant protection industry wished the Community to intervene, on the grounds that Community action was necessary to remedy barriers to the free movement of its products, distortions of competition and the erosion of the duration of effective patent protection. Following the Council's request, and after examining the current global situation of the industry in question and noting, in particular, the obvious erosion of the duration of patent protection for plant protection products, the Commission takes the view that Community action is required.

The proposed system prevents barriers to the free movement of plant protection products in the Union and the distortions of competition that would inevitably be caused by different national laws. This is the proposal's first objective. The second is to improve the legal framework for firms in the Union engaged in research and development work on new plant protection products by providing adequate protection for innovations, thereby improving their competitiveness on the world market.

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<sup>(1)</sup> Regulation (EEC) No 1768/92, OJ No L 182, 2.7.1992.

## **PART-ONE: COMPLETING THE INTERNAL MARKET FOR PLANT PROTECTION PRODUCTS**

### **A. HARMONIZING THE DURATION OF PROTECTION FOR INVENTIONS IN THE PLANT PROTECTION SECTOR**

5. The primary objective of this proposal is to harmonize, at Community level, the effective protection afforded to inventions in the plant protection field and, consequently, to ensure the proper functioning of the internal market. At the moment, the theoretical and, above all, the effective duration of protection for inventions in this field varies from Member State to Member State.
6. Where a plant protection product is protected by patent, the duration of this protection is generally twenty years from the date on which the patent application is filed in all the Member States, whether on the basis of national patent law or the European Patent Convention (Munich). However, this duration is theoretical in that marketing authorization procedures, prior to the product's being placed on the market, shorten it considerably and proportionally reduce the length of effective protection.
7. Action to restore adequate, effective duration of protection for these products can be envisaged only if the conditions for supplementary protection and its duration are harmonized between the Member States. Any disparities here, in particular concerning the duration of protection, would lead to restrictions on the free movement of plant protection products which could not be justified under Community law.
8. At the moment, having regard to the operating arrangements of national patent systems, the different patents protecting the same plant protection product in the Member States can commence and expire on different dates owing, in particular, to the existence of a priority period. This is the period of twelve months during which a person who has properly filed an application for a patent in one Member State may file another for the same invention in another Member State without losing the benefit of the novelty of the invention. It follows that the dates on which these different patents take effect and expire may vary between the Member States.
9. In addition, a number of Member States have only recently become members of the European Patent Convention (Munich) and the resulting harmonization is not yet fully effective. Thus, patents issued in Germany before 1978 had a term of eighteen years, former Irish patents one of only sixteen years and patents issued in the United Kingdom before the entry into force of the Patents Act 1977 one of seventeen years from their date of issue. The result is that a product which has entered the public domain in some Member States may still be protected by an exclusive patent right in others, which disrupts the free movement of goods.

- 10.- Lastly, differences in the operation of national registration systems cause an imbalance in the duration of effective protection available to the same plant protection product in different Member States, which interferes with the free movement of these products and free access to the market for competing products. As the Court noted in Case C-341/87 (EMI v Patricia), the problem there stems from the differences between national legislation regarding the period of protection afforded by copyright and by related rights, those differences concerning either the duration of the protection itself or the details thereof, such as the time when the protection period begins to run. In this case, the imbalance -- and the disruption to the internal market -- arises from the different dates on which the different patents covering the same product expire throughout the Union.

Corrective action is therefore needed.

## **B. PREVENTING DISTORTIONS OF COMPETITION**

11. Because of the differences currently existing between the details of the operation of the patent system and of the registration system, a number of producers of plant protection products are subject to unjustified distortions of competition. This is particularly true of producers established in Member States where marketing authorization is obtained much more slowly than in the other Member States.

The erosion of the duration of effective protection is exacerbated by differences in the efficiency of the different national registration systems. Depending on the Member State, the time taken by the national authorities responsible for marketing authorizations to approve an application may vary from one to four years. Faced with the general erosion of the duration of effective patent protection, which disrupts the proper functioning of the internal market, firms are also faced with substantial differences in the time taken to process their applications for marketing authorization, which constitutes a form of distortion of competition.

12. The effort already made at Community level to harmonize the rules on marketing authorizations for plant protection products through the adoption of Directive 91/414/EEC, which is essential to the completion and functioning of the internal market for this sector, must be supplemented by the creation of a corrective mechanism for the inadequacies in the system of protection for plant protection research, which are attributable to the very same requirements of the prior marketing authorization.

This corrective mechanism must be harmonized at Community level, failing which it would only maintain -- possibly worsen -- existing distortions of competition.

13. Putting plant protection products on a footing similar to that which would obtain in the absence of a marketing authorization system means placing them on the terms that obtain in other sectors of technology not subject to marketing authorization. The plant protection sector is experiencing

distortions of competition in relation to other technological sectors because of the very existence of the prior authorization mechanism.

14. The duration of the supplementary protection afforded by the certificate must be sufficient to fulfil the objectives of promoting research pursued by the proposal while maintaining balanced competition. In this respect, plant protection research should not be discriminated against; it should be placed on terms similar to those existing in other sectors. That is why the Commission is proposing that the supplementary certificate should have a maximum term of five years and that the total duration of effective protection (residual period of the basic patent to which is added the supplementary protection certificate) should be a maximum of fifteen years, starting from the first authorization to place the product on the market in the Community. This period is equivalent to that existing in other industrial sectors which are not subject to prior marketing authorization.

### **C. REMEDYING THE EROSION OF PATENT PROTECTION**

#### **(a) Erosion of the duration of effective protection**

15. The available statistics reveal that plant protection products are suffering from increasing erosion of the duration of effective patent protection because of the continuous increase in the time taken to obtain the necessary prior marketing authorizations. This is not just the time taken by the national authorities to examine applications for authorization, but rather the time required by firms to prepare and carry out all the tests and analyses necessary to file the application for authorization.

The duration of *effective* patent protection of plant protection products (period of time between the date of obtaining the marketing authorization and the expiry of the patent protecting the product) has fallen from an average of twelve years in 1978 to some nine years today.

These figures are taken from analyses carried out on a product-by-product basis for each of the Member States. They reflect a situation similar to that of medicinal products when Regulation (EEC) No 1768/92 was adopted in 1992, and justify the adoption of a similar measure for the plant protection sector.

*Table 1: Duration of effective protection for plant protection products (years)*

1978	12,0	1986	11,5
1979	10,75	1987	11,0
1980	9,5	1988	10,5
1981	9,25	1989	10,0
1982	10,0	1990	10,0
1983	11	1991	9,75
1984	11,75	1992	9,25 <sup>(1)</sup>
1985	11,25		

Source: ECPA (European Crop Protection Association)

16. These overall figures are confirmed by the analysis carried out in each Member State. In the United Kingdom, the duration of effective patent protection for plant protection products fell from eleven years in 1980 to just over six years in 1991. In Germany, it has also fallen, from some twelve years in 1980 to nine years at the moment.
17. An imbalance thus arises between the interests of the patent-holder and those of persons wishing to exploit the patented product once the patent has expired. Because of the very nature of plant protection products, they are, like medicinal products, easily reproduced, without the "pirate" having to bear the costs of research and development which went into the original product. This explains the specific value and overwhelming role of the patent in the strategy of the plant protection industry, for which this instrument is of vital importance since there is no alternative.
- (b) Operational differences between authorization systems**
18. With regard to the duration of effective protection, the differences which can exist between Member States at the level of theoretical protection are exacerbated by the operational differences between the systems of marketing authorization for plant protection products. This is where the main obstacles to the proper functioning of the internal market for plant protection products are to be found.
19. Any plant protection product must not only be effective as an insecticide, herbicide, fungicide, etc., but at the same time it must not have any unacceptable effect on health or the environment.

This twofold requirement explains why research and development on new plant protection products requires increasing amounts of time and investment and why these products cannot be placed on the market without having been officially scrutinized and authorized beforehand.

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<sup>(1)</sup> estimations



20. On 15 July 1991 the conditions and procedures for authorizing plant protection products were harmonized at Community level by Council Directive 91/414/EEC concerning the placing on the market of plant protection products.<sup>(2)</sup>

The system established by the Directive provides for:

- (a) a positive list of active substances approved at Community level;
  - (b) a system of authorization, by the Member States, of products containing one or more active substances included on the Community positive list;
  - (c) mutual recognition by the Member States of national authorizations provided that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned;
  - (d) a data protection mechanism -- submitted with the applications for marketing authorization -- for the benefit of the first applicant for a period of ten years from first inclusion of an active substance on the positive list.
21. Harmonization of authorizations at Community level and the requirement to register all existing and new active substances is necessary, but not sufficient, for the completion of the internal market, which will be of long-term benefit to the plant protection industry in the Union and to users. The diversity of national requirements concerning marketing authorization for plant protection products represents always a substantial cost to industry.

#### **D. NEED FOR COMMUNITY ACTION**

22. The question of whether the proposed measures are proportionate to the objectives pursued should also be looked at. In so far as one of the objectives is to prevent obstacles to the proper functioning of the internal market which would be created by disparities in the application of national laws, this objective cannot be attained satisfactorily by action taken solely at Member State level. To ensure the proper functioning of the internal market, the laws of the Member States should be harmonized so that the duration of protection for the same plant protection product is identical throughout the Union. Harmonization must deal with not only the duration of protection generally but also with such matters as the date on which protection expires. That is precisely what the mechanism chosen in this proposal does.
23. The data-protection mechanism incorporated into applications for marketing authorization introduced by Directive 91/414/EEC would not, for its part, have the same scope and the same effects as those conferred by a patent or similar instrument. Protection of the registration data is not absolute in that manufacturers of generic products can, if they so wish, themselves carry out

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<sup>(2)</sup> OJ L No 230, 19.8.1991, p. 1.

the tests needed to obtain marketing authorization without waiting for data from the innovating firm. Only a patent or similar instrument can guarantee fully effective protection on the market, enabling the investment made in research and development to be recovered and adequate financial reserves to be set aside for R&D activities.

24. As was the case in 1992 for medicinal products, this proposal seeks to create a specific and sectoral industrial property instrument which is not such as to have any influence on the general patent laws applicable to other technological sectors. Since what is being created is a new industrial property instrument distinct from patents, the optimal harmonization at Community level of its conditions of issue and its method of calculation can be achieved only by using the legal instrument of a Parliament and Council Regulation.
25. The method of calculating the duration of the supplementary certificate -- based on the first authorization to place the product on the market in the Community, and for all the Member States -- means that the different certificates covering the same product will expire on the same date throughout the Union. The date of issue of the marketing authorization in the different Member States has no impact here since the duration of the different certificates is calculated, for all the Member States, on the basis of the first authorization to place the product on the market in the Union. Once the different certificates issued by the different Member States for the same product have expired, the product will enter the public domain at the same time in all the Member States.
26. A heterogeneous and potentially or actually diverging situation with regard to national laws governing the conditions for granting the supplementary protection, its effect or duration would be such as to create distortions of competition in the Union. Not taking the initiative at Community level and leaving to the Member States the task of determining the rules for and duration of an extension of patents for plant protection products would have adverse consequences on the free movement of these products and on the competitive conditions prevailing in this sector.

A Community solution entailing harmonization of the conditions for the application of the system introduced and the rules governing it and standardization of the duration of protection of plant protection products therefore has to be found to secure the establishment and proper functioning of the internal market and the introduction of normal competition.

27. However, with regard to patents, national laws cannot be approximated without also preserving the harmonization between the national systems and the European patent system. That is why the certificate applies to all plant protection products authorized to be placed on the market and protected by patent in their national territory, whatever path -- national or European -- has been followed for that purpose. A uniform solution applying to all patented products, whether the patent was issued under national law or under the European Patent Convention (Munich), can be achieved effectively only by action at Community level.

28. The certificate is a national document issued by a national patent office but whose conditions of issue and duration are harmonized at Community level. In certain aspects it is essentially different from the basic patent. It contributes to facilitating the proper functioning of the European patent system. The result would be completely different if it were possible to obtain a certificate only for plant protection products protected by a national patent. A fortiori, when use is made of the European procedure to obtain a Community patent, it will be all the more necessary for the certificate to apply equally to plant protection products protected by a Community patent. The proposal has been developed with a view to providing now for this prospect.

## **PART TWO: THE NEEDS OF THE PLANT PROTECTION SECTOR WITH REGARD TO COMMUNITY OBJECTIVES**

A detailed profile of the plant protection sector is given in the Annex.

### **A. CHARACTERISTICS OF THE SECTOR**

#### **1. Scale of research and development**

29. The recent trend in the plant protection products industry is for a continuing increase in expenditure on research and development (R&D), both as a percentage of total sales and in absolute terms.

In 1991 R&D expenditure by the fifteen leading firms in the world averaged 10.25 % of turnover. Biotechnology has become, in this respect, a key factor in research, principally in the field of transgenic plants and the development of pesticides. The new plant varieties will be resistant to pesticides, disease, herbicides, frost and drought, and of improved quality. Biotechnology research will not substantially reduce sales volume in the plant protection sector but will produce significant changes in the types of product available and in the competition between different products.

30. Significantly, expenditure by plant protection firms on research and development and the development of new products rose from ECU 25 million per product in 1975 to more than ECU 125 million in 1992, a five-fold increase.

It should be noted that, among the different development stages of a plant protection product (synthesis and screening-formulation, analysis of the product and chemistry-biology-toxicology and environment), it is toxicology and environment which have expanded most: expenditure on studies of the toxicology and environmental impact of new products rose from ECU 4 million per product in 1975 to ECU 50 million in 1992, an eleven-fold increase (Source: Fonds der Chemischen Industrie, Informationsserie No 10 "Pflanzenschutz").

31. However, plant protection research, like pharmaceutical research, is a high-risk activity, involving extremely costly and hazardous investment. It is estimated that some 15 000 chemical compounds must be synthesized and analysed for every new product placed on the market. In addition, it is increasingly difficult to find new plant protection products since solutions to the less complex research objectives have already been found and international competition imposes very high standards. While new plant protection products were introduced at the rate of one major innovation a year in the 1960s, this fell to one every three years in the 1980s. The number of new products placed on the market is therefore much lower in the plant protection sector than in pharmaceuticals, where fifty a year is a normal figure.

32. In addition, whereas European firms were pioneers in the discovery of new products in the 1970s (introduction of Bayer's fungicide triazole), two of the major discoveries in the past decade, imidazoline and sulphonyl, both herbicides, came from American companies (American Cyanamid and Du Pont). Their sales of these two products for 1989 are estimated at 9 % of the world herbicide market. A fourth major new product, however, the insecticide pyrethrin with 6 % of the world market, was a European innovation.
33. This shift in the centres where new products are developed can be illustrated by looking at where the products currently registered as herbicides in France, the most representative part of the European plant protection market in terms of crops and climate, were researched. France currently authorizes 115 herbicide substances. The table below shows where these substances were discovered during previous decades.

*Table 2: Origin of herbicides launched in France*

Time of launch	Europe	United States	Japan
1960s	67 %	33 %	0 %
1970s	52 %	45 %	3 %
1980s	37 %	51 %	12 %

Source: ECPA

These data are significant in that they clearly show the downward trend in new herbicides launched by European firms. If there are no significant changes in the protection given to research by European firms, it is likely that American groups will continue to be the main source of scientific and technical progress in this sector.

34. In many respects, the constraints on research in plant protection are similar to those affecting pharmaceutical and chemical research. None the less, a number of the sector's specific features make it even more vulnerable:
- (a) Plant protection products are used by farmers to increase the profitability of their farms, which reduces the producers' room for manoeuvre with regard to the price levels of their products. The market for plant protection products is highly price-sensitive: prices are not controlled and are the result of market forces; farmers choose between the different products on offer largely on cost.
  - (b) Plant protection research has a narrower range of objectives than pharmaceutical research. The aim is essentially to place on the market products which are more environment-friendly and more efficient from an agricultural point of view.
  - (c) Development costs are very high because of the fact that formulations and instructions for use of plant protection products must take account of regional differences in agronomic conditions.

- (d) Plant protection companies are particularly exposed to market competition (no massive state purchases, as is the case for medicinal products with a number of public health services).

## **2. Impact of environment policy**

35. The scale of research is directly linked to requirements concerning the environment. The industry must balance its role of crop protection with that of not endangering the environment. In this respect, plant protection research is intended not only to limit the risk of major agricultural disasters and the massive losses (some 30 % of world harvests) caused by parasites, disease and weeds. Today, new plant protection products must not only help in avoiding a fall in yields and securing food supplies; they must also involve no unacceptable risk for man and the environment.

The major challenge facing the industry is therefore to find a proper balance between compliance with environmental policies and the production requirements of modern agriculture. Moreover, the high level of environmental requirements further reduces the industry's chances of discovering commercially viable new products.

## **3. Intensity of competition**

36. The industry will have to face an increasingly competitive environment as a result of the completion of the single market, the reform of the common agricultural policy and the GATT agreements on international trade.

The frontier-free single market will, among other things, involve a gradual alignment of prices in the Member States. Until recently, prices in Germany were the highest, almost double those in the United Kingdom, those in France lying between the two. For some three years now, however, firms have been allowing for the single market when introducing products and price differences have fallen to no more than 25 %. This trend will accentuate even further the importance of research as a predominant factor in the competitiveness of firms within the Union.

37. In addition, reform of agricultural policy and implementation of the GATT agreements on international trade will reduce the amount of land farmed and agricultural subsidies and will lead to a markedly slower rate of growth in the market for plant protection products in developed countries, offset however by rising demand from developing countries. Whereas the average rate of growth of the market in the Union was some 6 % in 1988, the situation has seriously deteriorated since, with a spectacular fall in sales on the West European market of 18 % in 1992.

The current reform, and the completion of the single market, will increase the intensity of competition in the sector. In particular, the number of plant protection firms in the Union will probably fall, through acquisitions and mergers, involving particularly firms in biotechnology research.

38. We must not ignore the fact that more than half the world market for plant protection products concerns ones which are no longer covered by patents

and which, therefore, will not be able to benefit from the Regulation concerning the supplementary protection certificate. According to available estimates, 55 % of the world herbicide market is for products no longer covered by patents; the figures for insecticides and fungicides are 58 % and 59 % respectively. Accordingly, the plan for a supplementary protection certificate will affect only some of the firms in the sector, to a degree yet to be determined (see below). This incentive for research should also encourage competition between plant protection firms to develop new products.

#### **4. Industry profitability**

39. The aim of the supplementary protection certificate is to protect current profitability levels in the plant protection product industry so as to ensure future research. Profitability in the industry, in particular in the Community, is lower than in industry in general and the pharmaceutical industry in particular, and is falling.

Whereas in 1990, at world level, the industry had average profits of 8.2 % of turnover, companies based in the Union had to be satisfied with only some 6 %, while their American competitors achieved 11.4 %. Since then, margins have shrunk even further, 1992 being a very bad year for sales in Europe. The competitive position of the European industry is therefore considerably weaker than that of its main competitors, American and Asian in the main. In a sector where investment in research is so substantial and risky, an adequate profit margin is essential to ensure the continuity of the R&D process.

40. There are two fundamental reasons for the global reduction in the profitability of plant protection product companies during the 1980s, namely the impact of an increasingly competitive market and the significant increase in costs and time spent on developing new products and getting them authorized.

The figures reveal that the plant protection industry does not generate profits proportionate to the inherently high level of risk associated with its activities, which alone would be able to generate adequate financial reserves to maintain and carry on research activities. They also show the need to extend supplementary protection to certain patented products which are already marketed in the European Union.

41. None the less, the costs of developing plant protection products (up to ECU 125 million for each new product placed on the market) will remain particularly high because of the considerable volume of experimental data required to show that the products are effective and safe. Unlike the case of medicinal products, formulations and instructions for the use of plant protection products must take account of regional variations in agronomic conditions and of effects on the metabolism -- not only of plants but also of animals -- and on the environment in general. It follows that the recovery of the corresponding investments is absolutely vital for the research industry and depends, to a large extent, on it being guaranteed an adequate duration of effective protection for innovations introduced.

## **B. IMPROVING COMPETITIVENESS AND PROMOTING RESEARCH**

42. In its communication to the Council and Parliament of 16 November 1990 on industrial policy,<sup>(1)</sup> the Commission had occasion to stress the vital importance for the position of the Union in the world economy of having a competitive industry, one factor in which is the capacity for innovation. Strengthening the competitiveness of Community industry and promoting research and technological development are now expressly included in Article 3 of the Union Treaty.

43. Support for the research effort in a high-risk industry such as plant protection products depends to a large extent on recovering the cost of investments in R&D on new products, through the sale and exploitation of patented products.

The erosion of the duration of effective protection under patents for plant protection products, as described above (point 15), leads to manifestly inadequate protection which penalizes research precisely in the field which, because of the very nature of the process of innovation, requires the protection of industrial property more than other industries.

44. The Commission White Paper on Growth, Competitiveness and Employment, presented to the European Council in Brussels in December 1993, stresses the need for action to restore the competitiveness of European firms and to encourage growth. These measures are part of an approach to boost the technology/growth/employment cycle. The supplementary protection certificate for plant protection products is a sectoral initiative which is fully consistent with this overall approach.

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<sup>(1)</sup> Industrial Policy in an Open and Competitive Environment, COM(90) 556 final.



## **PART-THREE: THE DIFFERENT INTERESTS INVOLVED**

### **A. ACCESS TO THE MARKET FOR GENERIC PRODUCTS**

45. The very nature of the supplementary protection certificate will ensure that plant protection products benefiting from the provisions of the Regulation will continue to be protected for a longer period of time. Thus, producers of generic plant protection products have access to certain patented products only after several months or perhaps several years.

A number of important points should be made here.

46. First, more than half the plant protection products sold are no longer protected by patent.

*Table 3: Plant protection product market: shares of patented and patented-expired products*

	Current patent	Patent expired
Herbicides	45 %	55 %
Insecticides	42 %	58 %
Fungicides	41 %	59 %
Total	43 %	57 %

Source: Wood Mackenzie Consultants Ltd.

These figures, which were confirmed by a study carried out in 1990 by the UK Ministry of Agriculture, Fisheries and Food (MAFF), show that, in the three most important sectors of the market for plant protection products, products not covered by patents and thus freely accessible to manufacturers of generic products account for more than 50 % of the market.

Of course, none of the products in this category will benefit from the provisions of the proposed Regulation, leaving manufacturers of generic products complete freedom of action. In addition, the patented products which account for the rest of the market will qualify for only one supplementary protection certificate per active substance. Thus, if the same active substance is used in different forms (powder, liquid, etc.), only one certificate can be issued and not as many certificates as there are forms marketed. The certificate protects the active substance which is contained in the different forms or presentations of the product.

47. Second, it should be noted that the supplementary protection certificate is not an automatic mechanism giving five years' additional protection for all patented products. Certificates are granted and their duration calculated on a case-by-case basis, taking account of the duration of patent protection actually lost by the product in question during development and the authorization procedure for placing on the market. Thus, although the supplementary protection certificate can be valid for a maximum of five years,

it will be valid for less than this if marketing authorization was granted less than ten years after the application for a patent was filed.

The non-automatic nature of the certificate also means that it is granted by national patent offices not to all products which might benefit from it, but on application by the holder of the basic patent protecting the product concerned. In certain cases (development of a revolutionary plant protection product within the same group of products), the patent-holder could deliberately choose not to exercise his right to apply for a supplementary protection certificate, thus leaving the product to enter the public domain once the basic patent expires.

The mechanism selected is such that the maximum effective protection of fifteen years (residual duration of the basic patent plus duration of the supplementary protection certificate) is calculated from the date of the first authorization to be placed on the market in the Community, which means that the full fifteen years will be achieved only in the Member State in which the first marketing authorization is obtained. In each Member State in which a marketing authorization is obtained subsequently, the total duration of effective protection will be reduced by the period of time between the first marketing authorization in the first Member State and the subsequent authorization.

48. A third feature of the proposal is to provide a wide range of information to interested third parties -- including manufacturers of generic products -- through publication of details of the application, the decision to grant or reject the application, and the expiry of the certificate. Manufacturers of generic products will thus be able to monitor the development of the market for patented plant protection products and will not suddenly be faced with a fait accompli.
49. Lastly, it should be acknowledged that the generics industry depends to a large extent on the success of research-based industry in that there will be no generics industry to benefit if the research industry does not develop new plant protection products. Today's research findings are the guarantee of the prosperity of tomorrow's generics industry. The supplementary protection certificate should contribute to the appearance of new plant protection products which one day will be accessible to manufacturers of generic products.

## **B. EFFECT ON PRICES OF THE SUPPLEMENTARY CERTIFICATE**

50. A tricky problem posed by the proposal for a Regulation concerns the impact of the supplementary protection certificate on the prices of plant protection products and, consequently, on farmers' expenditure. Taking account of the overall situation of the agricultural world, there are grounds for asking this question and giving a precise answer. Various estimates suggest that the certificate will have a minimal impact on the prices of plant protection products.

- 51.- As mentioned above (point 46), the proposed mechanism will not apply to all plant protection products; the 57 % of the market which has already entered the public domain will not be affected at all. Nor will the granting of a supplementary certificate be automatic, since it is to depend on the merits of each individual case.
52. Plant protection products placed on the market after the entry into force of the Regulation will benefit from a supplementary protection certificate only after ten years, i.e. on the expiry of the basic patent protecting them. During these ten years, the supplementary protection certificate will have no impact on their prices.

The aim of the transitional arrangements -- which concern products already on the market when the Regulation comes into force -- is to strike a fair balance between what is needed to achieve the proposal's objectives and what can reasonably be accepted by society. This balance should not allow all plant protection products already on the market to have a supplementary protection certificate, but should also not exclude all these products from the transitional arrangements.

53. Taking 1 January 1985 as the reference date for the transitional arrangements -- this date defines the size of the group of products already placed on the market when the Regulation comes into force and qualifying for a supplementary protection certificate -- means that only 37 plant protection products could benefit from the transitional arrangements, representing 5.28 % of the total market for such products in the European Union.

Today, these 37 substances represent a market of the order of ECU 285 million. As a rule, it is estimated that the introduction of generic versions of plant protection products (legal copies of products no longer protected by patent) leads to a price reduction of some 25 %. In addition, the 37 substances concerned by the transitional arrangements would benefit from a supplementary protection certificate of 2.5 years on average. That means that the entry into force of the certificate system will put back by 2.5 years a price reduction of the order of 25 % on a market estimated at ECU 285 million, i.e. some ECU 180 million.

This postponement of a price reduction -- it must be regarded as such rather than as a genuine price "rise" -- caused by the supplementary protection certificate must be spread out over a period of ten years. This is because products that obtain marketing authorization after the entry into force of the Regulation will not benefit from a supplementary protection certificate until the expiry of the basic patent protecting them, i.e. on average ten years later.

During this period, only plant protection products already on the market when the Regulation enters into force will be affected.

If the additional expenditure generated by the supplementary protection certificate is spread out over a period of ten years, that gives ECU 18 million a year. This amount represents an increase in expenditure by farmers on plant

protection products of the order of 0.33 % a year. According to data supplied by Eurostat, expenditure by farmers on buying plant protection products accounts for 6.2 % of their total outgoings. The introduction of the supplementary protection certificate will increase this figure to 6.2204 %, which is not a significant rise.

On the industry side, this increase in turnover -- of the order of 6.25 % of the market for products affected by the transitional arrangement -- should generate additional resources to encourage research. These are estimated at ECU 4.86 million a year for each substance concerned during the period of additional protection.

54. It is clear that, by its very nature, the supplementary protection certificate will have an impact -- albeit limited, as shown above -- on prices: however, it should safeguard the future of plant protection research in Europe, and hence the development of products which will be more environment-friendly and adapted to the needs of agricultural efficiency. There is strong demand from farmers for such products.

### **C. MULTILATERAL APPLICATION OF THE SUPPLEMENTARY CERTIFICATE**

55. This proposal for a Regulation, like Regulation (EEC) No 1768/92 concerning medicinal products, may benefit not only firms from within the Union but also firms from outside. In fact, having regard to the geographical distribution of the plant protection research industry, only Swiss, American and Japanese firms are concerned.
56. The obligations which the European Union accepted under the GATT Uruguay Round prevent any other outcome. Article 3 of the TRIPs text (trade-related aspects of intellectual property rights) lays down the "national treatment" principle, which requires the GATT Contracting Parties to grant to natural or legal persons from the other Contracting Parties the same treatment as they give to their nationals.
57. A further consideration is that plant protection firms from the Union benefit from restoration of patents in Japan and Korea, and the advantages inherent in the American system, where the duration of the patent is, in fact, longer than the theoretical 17 years because of the method of calculation. In the United States the duration of patents is 17 years from the date on which the patent is granted and not from the date on which the application is filed, which means that any delay in the procedure for awarding the patent -- very frequent because of the judicial proceedings in that country -- delays the start of protection and means that effective protection ends later.
58. Lastly, according to estimates, if the reference date for the transitional arrangements is 1 January 1985, of the thirty-odd products concerned, less than ten are of American origin, while the rest are European. It is thus clear that the proposed measure will not be of greater benefit to firms from outside Europe. In the context of an open market, in normal circumstances it will apply both to European firms and those from outside the Union.

## **PART FOUR: DETAILS AND CHARACTERISTICS OF THE PROPOSED SYSTEM**

### **A. OPERATION OF THE SUPPLEMENTARY CERTIFICATE**

59. The supplementary protection certificate is a *sui generis* industrial property instrument which takes effect on the expiry of the basic patent protecting an invention in the plant protection field. The rules governing its granting and its duration are harmonized at Community level, although the certificates are issued by the national patent offices. The same plant protection substance patented and authorized to be placed on the market in a number of Member States is the subject of the same number of applications for certificates, filed with corresponding national patent offices. At national level, the competent patent office is that of the State which granted the basic patent or on whose behalf it was granted and in which a marketing authorization was obtained.
60. The supplementary protection certificate applies to all patents existing at national level, whether granted under national law, the European Patent Convention (Munich) or, subsequently, the Community Patent Convention (Luxembourg). Only legislative action at Community level, in the form of a Regulation, can achieve the degree of harmonization needed at this triple level.
61. As was decided for medicinal products in 1992, this proposal for a Regulation harmonizes the conditions for granting supplementary protection certificates and their duration; it does not create a single application or a body specifically responsible for issuing supplementary protection certificates at Community level.
62. With a view to maintaining as broad as possible a degree of harmony in the field of industrial property, the Commission takes the view that a proposal concerning the creation of a supplementary protection certificate for plant protection products should not, in principle, differ from Council Regulation 1768/92 concerning medicinal products.

This means that the basic rules, the procedure and the overall mechanism for the supplementary protection certificate, in particular its duration, should be identical. Moreover, this approach was preferred by the national experts attending the meeting of the Group of experts on industrial property held, at the Commission's initiative, on 1 October 1992. The few changes in relation to Regulation 1768/92 are highlighted in the section on examination of the provisions (see Part Five).

63. Because of the very high research costs in the plant protection sector, it is usual practice to protect any invention in all the Member States (in fact, protection is generally wider since patent applications cover the entire industrialized world). With regard to the European Union, that means that the same plant protection substance protected in all the Member States will have its protection extended by a maximum of five years and that this protection

- will expire on exactly the same day throughout the Union. The detailed procedures provided for in this proposal are a powerful force for harmonization of the conditions of protection granted to inventions in the plant protection sector and, through competition, a means of ensuring the establishment and proper functioning of the internal market.
64. Putting plant protection products on a footing similar to that which would obtain in the absence of authorization means placing them on the terms that obtain in other sectors of technology not subject to authorization. The Commission puts the average period from when the patent application for a given product is filed to when it is placed on the market at five years. The duration of protection under the certificate thus calculated (the period "lost" less five years) takes effect on the day after the basic patent lapses.

If the duration of protection under the certificate (the period "lost" less five years) is added to the period of effective protection under the basic patent, i.e. from the date marketing authorization is obtained to the end of the patent's term, a total period of effective protection for the product concerned is obtained of a maximum of fifteen years, starting from the first authorization to be placed on the market in the Community.

## **B. LEGAL BASIS**

65. The introduction of a different period of protection for plant protection products in each of the Member States of the Union would create obstacles to their free movement within the internal market and distort conditions of competition.

The introduction of a standard, adequate period of protection for the results of plant protection research will help avoid problems in the internal market, encourage innovation and technical progress at Union level, and promote intra-Community trade in plant protection products. In addition, because of the method of calculation, the certificate is a powerful force for harmonization and will facilitate the free movement of plant protection products in so far as one and the same patented product protected by certificates in a number of, or all, the Member States will enter the public domain on the same day throughout the Union.

However, this proposal does not create, at Community level, any new body responsible for issuing certificates; they will be issued by national patent offices.

The Commission proposes that Article 100a of the EC Treaty be taken as the legal basis for this proposal.

In drafting the proposal, the Commission has taken due account of the provisions of Article 7c of the Treaty and has found that there is no need to provide for special or exceptional provisions for the time being.

Similarly, the Commission has considered the question of the high level of protection required in the field of health, safety, environmental protection and

consumer protection under Article 100a(3) of the Treaty. In order to introduce a high level of protection, meeting both the requirements of the internal market and the need to create a legal environment conducive to the unhampered development of research activities in the plant protection sector, the duration of effective protection for plant protection products should be harmonized at fifteen years from the date of the first authorization to be placed on the market in the Union.

## PART-FIVE: EXAMINATION OF THE PROVISIONS

### Article 1

66. "Plant protection products" are defined in Article 2 of Directive 91/414/EEC concerning the placing of plant protection products on the market. The terms "substances", "active substances" and "preparations", also taken from Directive 91/414/EEC, help to identify better what is covered by the definition of plant protection product.

However, since the objectives of the patent system are different from those of the system of marketing authorization, it is important to stress that, for the purposes of the certificate, the term "product" is not understood to mean an agro-chemical product or a plant protection product in the wider sense, as presented for purchase by the final consumer, but in the narrower sense of active substance or combination of active substances contained in a plant protection product.

The purpose of the expression "basic patent" is to specify what types of invention may serve as a basis for a certificate: the proposal does not provide for any exclusions. All plant protection research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new preparation, a new process for obtaining a new or known product, a new application of a new or known product, or a new combination of substances containing a new or known product, must be encouraged, without any discrimination, and must be eligible for a supplementary protection certificate provided that all of the conditions governing implementation of the Regulation are fulfilled.

It is for the holder of the patents for the product, the process for obtaining the product, the application of the product or the combination containing the product, to choose which of these patents is to be regarded as the "basic patent" for the purpose of obtaining a supplementary protection certificate.

### Article 2

67. This Article determines the scope of the proposal. It refers to any product that is the subject of both a system of protection by patent and a system of administrative authorization prior to its being placed on the market.

It is specified that the authorization concerned is that provided for in Directive 91/414/EEC or in equivalent national law, thereby making it clear that the proposal applies only to plant protection products which have been authorized to be placed on the market pursuant to current Community or national law.

With regard to the twelve Member States, Directive 91/414/EEC came into force in July 1993. However, applications for marketing authorization filed before that date in these Member States, on the basis of the relevant



provisions of the different national laws, will be governed, even once authorization has been granted, by those same national laws and not by Directive 91/414/EEC. The reason for this is that the period between the application for marketing authorization and the date of issue can run to several years. This explains why the proposal lays down that products covered by national law -- those in respect of which the application for authorization to be placed on the market was filed before the entry into force of Directive 91/414/EEC -- will also be able to benefit from a supplementary protection certificate under the conditions laid down by the Regulation.

With regard to the countries which are soon to become members of the European Union, the proposal allows for enlargement by laying down that any product which has been the subject of an application for marketing authorization filed before the entry into force of Directive 91/414/EEC **for the Member State in question** will be able to benefit, under the conditions laid down by the Regulation, from the supplementary protection certificate. If, in the future, a new Member State joins the European Union, Directive 91/414/EEC will enter into force in that Member State at a later date than that laid down for the current Member States. It is possible that the authorization to be placed on the market obtained in this new Member State will be the first marketing authorization to be obtained in the enlarged Community; this authorization must also enable a supplementary protection certificate to be obtained. The proposal allows for this type of situation.

Since the proposal does not state under what kind of law patent protection is given, it follows that the proposal applies to all plant protection products with a patent in any Member State, whether this be a national patent, a European patent or, in due course, a Community patent.

Only patented products are covered, whatever the legal source of the patent. The aim here, with a view to the single market, and in accordance with the solution adopted in Regulation (EEC) No 1768/92 concerning medicinal products, is to prevent the illogical situation whereby, in one and the same Member State, a new plant protection product may or may not benefit from a supplementary protection certificate depending on whether the corresponding patent was obtained nationally or at European level.

The requirement for harmonization on two levels, in addition to the urgency in this specific instance in view of the constantly increasing periods required to obtain authorizations to place plant protection products on the market, calls for the adoption of a legal solution that maintains such harmonization and enables it to be implemented simply and swiftly. That is why the proposal for a Regulation provides for a system identical to that in force since 2 January 1993 for medicinal products, i.e. a supplementary protection certificate, the conditions and the rules for obtaining which are laid down in a uniform manner for all of the Member States of the European Union.

### Article 3

68. This Article lays down the substantive conditions to be met by a product in order to obtain a certificate.

As the certificate is a national document, compliance with these conditions must be examined with respect to the Member State in which the application for a certificate is submitted and to the date of application.

First, it must be ascertained that the product is protected by a current patent. It is this patent that serves as the basis for the certificate for the purposes of the Regulation.

It may be that the same product is protected by more than one patent, e.g. one for the product and another for the process for obtaining the product. In this case, it is for the holder of the patents concerned to choose one of them as the basic patent. This choice is particularly important in that the subject and the content of the protection granted by the certificate are limited, respectively, by the subject and content of the basic patent.

The product must have obtained a valid marketing authorization in accordance with Article 4 of Directive 91/414/EEC. That Directive adopts a two-stage system of authorization: first, the authorization is restricted to plant protection products containing certain active substances on a Community list of authorized active substances; next, the final product is subject, as a final product, and before it is actually marketed, to a separate authorization to be placed on the market. Only plant protection products which have successfully completed these two stages qualify for a supplementary protection certificate.

In addition, because of the special features of the registration system for plant protection products (long delay between the filing of the application and the issue of the certificate by the competent authorities in the Member States), there is a need to ensure that a product authorized on the basis of an equivalent provision of national law can also benefit from the proposal.

It is frequently the case that one and the same product is successively granted several authorizations to be placed on the market, in particular every time a modification is made affecting dose, composition or use, and every time a new use for the product is developed. In such a case, only the first authorization to place the product on the market in the Member State in which the application is lodged is taken into account for the purposes of the Regulation, in particular for calculating the period of six months available to the holder of the basic patent to submit an application for a certificate. Furthermore, if the first authorization given is also the first authorization to place the product on the market in the Union, it serves as the sole reference for all of the Member States for calculating the duration of each of the certificates they grant for the same product (see Article 13).

Lastly, the product must not have already been the subject of a certificate in the Member State concerned. The certificate is designed to encourage

research into new plant protection products so that the duration of protection it affords, together with the duration of effective protection by patent, is sufficient to enable the investments made in the research to be recovered. However, it would not be acceptable, in view of the balance required between the interests concerned, for this total duration of protection for one and the same plant protection product to be exceeded. This might be the case if one and the same product were able to be the subject of several successive certificates.

This calls for a strict definition of the product as laid down in Article 2. If a certificate has already been granted for the active substance itself, a new certificate may not be granted for that active substance, whatever changes may have been made regarding other features of the plant protection product (use of a different salt, different excipients, different presentation, etc.).

In conclusion, it should be noted that, although one and the same substance may be the subject of several patents and several authorizations to be placed on the market in one and the same Member State, the supplementary protection certificate will be granted for that substance only on the basis of a single patent and a single authorization to be placed on the market, namely the first granted in the State concerned (the first authorization in the Union being taken only to calculate a uniform duration of different certificates for one and the same product).

#### Article 4

69. The supplementary protection certificate is a *sui generis* protection instrument inasmuch as it is linked to both an authorization to place the product on the market (the first granted in the State concerned) and to a previous patent (the basic patent). This is already evident from the conditions for obtaining the certificate, which require both that the basic patent is a current one and that the authorization is valid, failing which the certificate is void.

The delimitation of the subject protected by the certificate also illustrates this duality since the protection afforded by the certificate is limited in two ways.

It is often the case in the plant protection field that a patent protects a series of products based on the same formula. However, only some of these products will subsequently be developed and only one might be placed on the market. In such a case, the certificate will protect only the product covered by the authorization and not all of the products protected by the patent.

At the same time, the product authorized will itself be limited by the patent's subject-matter. If the basic patent protects a compound x, where the authorized product consists of a combination of compound x and another active principle, only compound x will be protected by the certificate.

Furthermore, the certificate will protect only the product covered by the authorization, namely the product within the strict meaning of Article 2.

Lastly, the fact that the certificate is based on both the basic patent and the authorization can also be seen in the link between the protection afforded and the use of the product. A new product patent normally gives the product absolute protection so that any use of the patented product, even for non-patented applications, constitutes an infringement, i.e. the patent protects all possible uses that the product may have.

The certificate does not give such protection. On the one hand, the link with the authorization system implies protection of the product covered by the first authorization, while limiting it to the uses of the product successively authorized prior to the expiry of the protection certificate.

Plant health firms frequently develop new uses of the same product, which are the subject of new marketing authorizations. The marketing authorization is actually granted several years after the patent is filed, during which time the plant protection product undergoes multiple tests for one or more very specific uses. In view of this, it would seem to be logical to protect it, by means of the certificate, for the successive uses which have been the subject of authorizations.

Furthermore, only uses in the plant protection field as defined in Directive 91/414/EEC come under the protection of the certificate (authorized use of the product as an additive in animal feedingstuffs, for example, would not be protected under the certificate).

On the other hand, the protection granted by the certificate is limited by that of the basic patent. In the case of a product patent, the limitation under the patent will not apply since this type of patent protects all possible uses of the product. However, in the case of an application patent, the certificate will protect only the use or uses claimed in the patent, provided that they were authorized prior to the expiry of the certificate.

#### Article 5

70. The effects of the certificate on the subject to which it refers as described in Article 4 are the same as those of the basic patent. The patent system has hitherto been the best way yet found of encouraging research. It is therefore not surprising, in view of the objective of this Regulation, that the certificate grants the same rights, subject to the same limitations.

In the case of a basic patent covering a product, the rights conferred by the certificate will be the same as those conferred by the basic patent, but limited to any use of the product authorized prior to the expiry of the certificate.

In the case of a basic patent covering a use of the product, the rights conferred by the certificate will be the same as those conferred by the basic patent, but limited to the use covered by the patent and authorized prior to the expiry of the certificate.

In the case of a basic patent covering a process for obtaining the product, the rights conferred by the certificate will be the same as those conferred by the

basic patent, but limited to the process for obtaining the authorized product. The rights conferred by the certificate will be extended to the product if the law applicable to the basic patent lays down that the protection of a process for obtaining a new product extends to the product directly obtained by that process.

Lastly, the certificate is subject to the same restrictions as the basic patent. Restrictions on private acts for non-commercial purposes, restrictions on acts for experimental purposes relating to the subject of the certificate and restrictions on obligatory licences relating to the subject of the certificate are some of the possible restrictions on the rights conferred by the certificate if these are also included in the basic patent.

#### Article 6

71. The right to apply for a supplementary protection certificate belongs to the holder of the basic patent; it is for him, or his successor in title, to choose whether or not to exercise this right.

#### Article 7

72. This Article concerns the time during which the application for the certificate must be submitted.

A period of six months is provided from the date on which the first authorization to place the product on the market in the State concerned was obtained. This solution takes account of the various interests involved; those of the patent holder who, after having applied for the certificate, may, if he so wishes, forgo the certificate if his product proves to be unsuccessful on the market, and those of third parties who have every interest in knowing as early as possible whether or not the product concerned will be protected by a certificate once the patent has expired.

Furthermore, there is no danger of applications for a certificate being routinely and systematically filed each time authorization to place a product on the market is given, since the conditions laid down in Article 3 for obtaining the certificate are strict and allow only one certificate per substance.

It may be that authorization is obtained before the basic patent is granted, in particular in the field of biotechnology products, where patent applications may be left pending for quite a long time. In such cases, the period of six months begins on the date on which the patent is granted and not on the date on which the first marketing authorization is obtained.

#### Article 8

73. This Article concerns the content of the application for a certificate.

Few documents are required. Apart from the request itself, a copy of the first authorization to place the product on the market in the State concerned is required as this enables the product to be identified. If this authorization is not also the first authorization to place the product on the market in the Union, a copy of the latter also has to be attached since the duration of the certificate will be calculated, in all Member States in which an application for a certificate is lodged, by reference to this criterion alone. Information enabling the basic patent to be identified must also be provided.

The authority responsible for granting the certificate will have to verify that the authorization(s) and the patent refer to one and the same product.

Lastly, the application must contain a summary of the product's features as defined at points A(1) or B(1) of Annex II to Directive 91/414/EEC or by equivalent national legislation. These are the features which enable it to be characterized as a plant protection product and, consequently, which help to provide a better description of the product. It is also a requirement that is easy to meet once all the tests on the product have been completed.

#### Article 9

74. The application for a certificate must be submitted to the patents offices of the Member States. The office responsible for each application for a certificate is that in the State which granted the basic patent or on whose behalf it was granted and in which the first authorization to place the product on the market for that State was obtained. For one and the same plant protection product patented and authorized to be placed on the market in several Member States, as many applications for certificates must be submitted to the corresponding patents offices.

The application for a certificate must be published by the patents office. This important formality ensures that third parties are informed as soon as possible.

#### Article 10

75. This Article refers to the conditions governing the grant of the certificate or the rejection of the application.

The procedure is simple; its application should not give rise to any particular difficulties. All patent offices must, in particular, be able to verify the conditions referred to in Article 3 under which the certificate was obtained. Contacts may, if necessary, be provided for between the patents office and the authority responsible for authorizing the product to be placed on the market.

### Article 11

76. With a view to providing the best possible information to interested third parties, the proposal for a Regulation provides for publication of the decision to accept or reject applications for supplementary protection certificates. This publication must be accompanied by a series of details intended to provide information which is as complete as possible to third parties.

### Article 12

77. This Article states that the Member States may provide that renewal of the certificate is subject to the payment of a fee. It is for the Member States to establish the amount if they decide to introduce such fees, failure to pay causing the certificate to lapse.

### Article 13

78. The duration of protection granted by the certificate is established on the basis of several factors.

First, the duration of protection must be sufficient to meet the proposal's objectives of promoting research. In this respect, there is a need to avoid discriminating against plant protection research and to subject it to conditions similar to those which would obtain if plant protection products were not subject to authorization to be placed on the market.

The duration of the certificates covering the same product in a number of Member States must be calculated on the basis of specific reference dates, the effect of which, in particular, is that all the supplementary protection certificates protecting one and the same product in the different Member States expire on the same date throughout the Union. The proposal for a Regulation will therefore exercise a powerful harmonizing effect on the total duration of protection for plant protection products throughout the Union. This harmonization also means that one and the same plant protection product, covered by supplementary certificates, will enter the public domain on the same day in all the Member States, whereas this is not the case under the current patent system.

However, it is also essential to take account of the objectives of Community policy as a whole and, in particular, to prevent the duration of protection of plant protection products from becoming a barrier to them.

Lastly, the system must be kept simple, while allowing for a certain degree of balance between all the interests involved.

The Commission therefore proposes that the duration of the certificate be calculated on the basis of the protection period "lost" under the patent, i.e. the period between the date on which the patent application is filed and the date on which the first authorization to place the product on the market in the Community is obtained.

As the authorization dates for one and the same plant protection product differ from one Member State to another, the later authorization is given, the shorter the period of effective protection will be. The Community's policy on authorizations should nevertheless gradually reduce the gaps between Member States and therefore improve the levelling of the durations of effective protection afforded to plant protection products.

Putting plant protection products on a footing similar to that which would obtain in the absence of an authorization system means placing them on the terms that obtain in other sectors of technology not subject to authorization. The Commission puts the average period in Europe from the date on which the patent application for a given product is filed to the date on which it is marketed at five years. The duration of protection under the certificate thus calculated (the period "lost" less five years) takes effect on the day after the basic patent lapses.

It should be stressed that, if the effective period remaining under the basic patent, i.e. from obtaining the marketing authorization to the expiry of the patent, is added to the duration of protection under the certificate -- the period lost less five years -- a total period of effective protection for the plant protection product concerned of fifteen years is obtained, below which, in the Commission's view, the objectives of this proposal for a Regulation will not be attained.

Lastly, it should be pointed out that the proposal also provides for a deadline after which the plant protection product enters the public domain. The duration of the certificate may not exceed five years from the date on which it takes effect.

The simplicity of the system means that it is not possible to take account of certain factors, such as the diligence that the innovating firm has shown throughout the tests required to obtain authorization. The proposal compensates for this shortcoming by restricting the certificate in cases in which authorization was obtained very late. For example, if the authorization was obtained eighteen years after the application for the corresponding patent was filed, the duration of the certificate is not thirteen years (eighteen minus five) but five years, after which there is no further protection.

It should be noted that fixing the maximum duration of the certificate at five years begins to have a restrictive effect if the marketing authorization for the plant protection product concerned is obtained more than ten years after the date on which the application for the patent was filed, which is, however, the norm in this sector. Thus, an authorization obtained twelve years after the corresponding patent application was filed does not produce a certificate of seven (twelve minus five) years' duration, but a certificate of maximum five years' duration.



#### Article 14

79. This Article provides for four cases of extinction of the certificate: expiry of the certificate itself; surrender of the certificate by its holder; non-payment of the annual fees, and the fact that the product no longer has authorization to be placed on the market obtained in accordance with Community law.

#### Article 15

80. The proposal lays down three grounds for invalidity of the certificate.
- (1) The certificate is void if the conditions for obtaining the certificate as laid down in Article 3 have not been complied with. This will in particular concern cases where the authorization to place the product on the market was not valid or was not the first in the Member State concerned, where the basic patent was no longer in force when the certificate was applied for and, lastly, where one and the same product was the subject of several certificates in the same Member State, in which case only the certificate granted in respect of the first authorization to place the product on the market in the State concerned will be valid.
  - (2) The certificate is void if the basic patent is not valid when its lawful term expires. Where renewal of a patent until its term expires is indicative of the value of the product it protects, this ground for invalidity will play an important selective role. Furthermore, the exclusive protection granted by the certificate over a given period is not lawful unless the product concerned meets not only the specific conditions for obtaining the certificate laid down by Article 3, but also the criteria of patentability for the basic patent. It is therefore necessary to specify that the certificate is void if the basic patent or at least that part of the basic patent that corresponds to the product covered by the certificate has been revoked. It is therefore necessary to specify expressly that an application for revocation of the basic patent, with a view to the revocation of the certificate, may be submitted even after the lawful term of the basic patent has expired.
  - (3) The certificate is void if the subject that it protects is not covered by the basic patent. The aim is to prevent a given product not protected by a patent from enjoying the exclusive protection of a certificate without having to fulfil the conditions and obligations specific to the patent system. This ground for invalidity is therefore based on the same principle as the previous ground. It should also be stressed that, if the subject of the certificate is only partially covered by the basic patent, the declaration of invalidity of the certificate may take the form of a corresponding limitation of the certificate, this being in accordance with the principle of proportionality. Lastly, the Article specifies that any person may request a declaration of invalidity of the certificate from the authority which granted it, i.e. the corresponding patents office. The decision of the office will be subject to appeal, as provided for in Article 17.

#### Article 16

81. Pursuing its objective of making information widely available to interested third parties, the proposal lays down that notice be given of the lapse or invalidity of the certificate.

#### Article 17

82. This Article provides that any decisions of the patents office to which the application for a certificate was made are open to the same appeals as provided for in national law against similar decisions in respect of patents. This is an essential legal guarantee, claims under which are subject to the national patents law of the State in which the certificate was granted.

#### Article 18

83. Where the proposal for a Regulation lays down procedural provisions, these will apply. If it does not, the applicable provisions are those laid down by the national law applicable to the corresponding basic patent, unless that law has laid down special procedural provisions.

In addition, the proposal states that it is not possible to oppose a certificate which has been issued.

#### Article 19

84. In accordance with the general principles of law, the proposal for a Regulation will apply to any product protected by a valid patent and which has not yet obtained the authorization to be placed on the market when the Regulation comes into force.

The aim of this Article is to lay down transitional arrangements concerning products already authorized when the Regulation comes into force, a particularly important and sensitive part of the proposal. The Commission takes the view that certain criteria have to be satisfied in order to arrive at a balanced solution.

It is essential to strike a balance between all of the interests concerned if the desire is to find a solution acceptable to everyone: the aim is neither to cover all products already being marketed nor to exclude them totally.

The proposed solution must avoid any distortion to the system for granting authorization to place a product on the market that might make certain firms delay submitting an application for such authorization.

Lastly, the solution must be free of uncertainty in order to enable all firms to plan ahead.

That is why the Commission proposes that the Regulation apply to all products authorized since 1 January 1985 and protected by a valid patent on the date on which it enters into force.

The choice of 1 January 1985 as a single reference date for obtaining the first marketing authorization should enable European industry to close the gap between itself and its foreign competitors. Furthermore, if the date of entry into force of the Regulation can be envisaged as the beginning of 1996, a product for which a patent application was filed in 1976 will not be able to benefit from a certificate unless the corresponding authorization was given more than nine years after the application was filed (after 1985).

However, Directive 91/414/EEC concerning the placing of plant protection products on the market entered into force only in mid-1993; this means that few products which could qualify for the transitional arrangements of this proposal for a Regulation have an authorization to be placed on the market granted on the basis of Directive 91/414/EEC. Before this Directive entered into force, the procedures for authorization to be placed on the market for plant protection products were a matter for national laws. It is therefore necessary to specify in the transitional arrangements that plant protection products authorized after 1 January 1985 on the basis of either Directive 91/414/EEC (a limited number of products) or an equivalent provision of national law (the majority of products) are eligible for a supplementary protection certificate, provided that the other conditions for obtaining a certificate are met. Of course, in order to qualify for the transitional arrangements, these products must still be validly protected by a current patent on the date on which the Regulation comes into force.

As regards the transitional arrangements, the proposal for a Regulation lays down that the application for a certificate must be filed during the six months following the entry into force of the Regulation.

## PROFILE OF THE PLANT PROTECTION SECTOR

The agro-chemicals industry comprises two principal sectors: fertilizers and chemical products protecting crops, also known as plant protection products, which include herbicides, insecticides, fungicides and plant growth regulators.

Firms in the plant protection sector can be split into two broad groups: those which base their activities on substantial research, with a view to placing new plant protection products on the market, and those which do not carry out research but depend on the first group for making lawful copies of products no longer protected by patent: these latter firms are commonly called manufacturers of generics.

### A. The market for plant protection products

The world market for plant protection products is estimated at ECU 22 000 million (1992 figure). The United States accounts for some 27 % of this market, the twelve Member States of the European Union for 26 %, the Far East for 25 %, and the rest of the world for 22 %.

*Table 1: Plant protection products: market size by region (1992)*

(ECU million)	Herbicides	Insecticides	Fongicides	Other	Total
USA	3649	1311	456	286	5702
Western Europe	2275	878	1510	1022	5685
Far East	1606	2160	1475	197	5438
Latin America	976	606	406	52	2040
Eastern Europe	293	297	142	122	854
Rest of World	765	931	133	39	1868
<b>Total</b>	<b>9564</b>	<b>6183</b>	<b>4122</b>	<b>1718</b>	<b>21587</b>

Source: County NatWest WoodMac.

In terms of the value of plant protection products, it is estimated that the European Union, with some 36 % of world production, remains the largest producer, the United States lying second with almost 28 %. They are followed by Japan (14 %) and the rest of Western Europe (10 %).

The current position of the European industry is based on experience over the last forty years in developing products initially aimed at the markets of Europe, Africa, Australasia and Latin America.

France, Germany, Italy and the United Kingdom are the largest producers of plant protection products in the Union; with Spain, these countries are the largest consumers since between them they use more than 80 % of the herbicides and fungicides, and more than 75 % of the insecticides consumed in Europe.

In 1992 France, along with the United States and Japan, accounted for 55 % of the world market for herbicides and, on its own, for 8 % of world sales. Today, herbicides form the largest production and market in the Union, with

the exception of Italy, where sales of fungicides have been greater than those of herbicides since 1990, and Spain, where sales of insecticide exceed those of herbicides.

## B. Trade balance

The trade balance is very favourable to the Union since its exports run at twice the level of its imports although, since 1985, imports have been increasing more strongly than exports (see Table 2). The market for plant protection products in the European Union generates a positive trade balance of some ECU 850 million (1991).

Whereas in 1986 the Soviet Union was the Union's largest export market (19 %), in 1991 its successor States accounted for only 11 % of sales. The countries of central Europe and EFTA have taken over, even if it is the rest of the world which accounts for the highest percentage of Community exports (46 %). With regard to imports, the major competitors of Community firms are in the EFTA countries, with more than 50 % of total Community imports, followed by the United States (33 %).

*Table 2: Plant protection products: external trade*

(ECU million)	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991
Exports extra-EC	1074.7	1242.6	1527.1	1732.9	1599.9	1380.0	1342.9	1404.2	1423.0	1478.7
Imports extra-EC	257.1	301.3	374.2	426.3	378.5	392.0	461.2	571.0	593.6	633.2
Trade balance	817.6	941.3	1152.9	1306.6	1221.5	988.1	881.7	833.2	829.5	845.5
Ratio of exp/imp	4.1	4.12	4.08	4.07	4.23	3.52	2.91	2.46	2.4	2.34
Intra-EC trade	979.6	1091.9	1413.0	1518.3	1521.9	1476.9	1628.4	1932.5	2162.0	2111.0

Source: Panorama of European Industry and Eurostat 1991

However, these figures reveal a decline in the relative position of the European plant protection industry at international level. Whereas the ratio of exports/imports was 4.18 in 1982 -- which indicates that exports of plant protection products from the Union were more than four times higher than imports -- this fell to 2.34 in 1991. During this period, the amount of plant protection products bought outside the Union rose from ECU 257 million to ECU 633 million, an increase of 146 %, while exports rose from ECU 1 074 million to ECU 1 478 million, an increase of 37 %.

## C. Leading firms

Most of the main producers of plant protection products -- estimated to be forty worldwide -- are located in the United States (9), Japan (11), or in Western Europe (14). Almost all are part of multinational chemical firms and the plant protection sector represents only a small fraction of the total group sales.

Monsanto (USA) is regarded as the leading producer of herbicides (14 % of the world market), followed by Ciba (Switzerland) with 12 %, Rhône-Poulenc (France) and BASF (Germany) with 6 % each. In the field of insecticides, Bayer (Germany) and Rhône-Poulenc (France) are the leaders, followed by FMC (USA) and Hoechst (Germany). The main producers of fungicides are Bayer (18 % of the world market), Ciba, Rhône-Poulenc, Du Pont (USA) and BASF (see Table 3).

Table 3: Plant protection industry: leading firms

Firm	Sales of plant protection products (ECU million)	Plant protection products as % of total sales
Ciba (CH)	2416	18.6
Du Pont (USA)	1669	5.2
Bayer (D)	1595	7.3
Rhône-Poulenc (F)	1572	12.5
Zeneca (ex-ICI) (GB)	1465	28.5
Monsanto (USA)	1405	21.2
Dow Elanco (USA)	1349	100.0
Hoechst (D)	1138	4.7
BASF (D)	975	4.2
American Cyanamid (USA)	854	19.0

Source: County NatWest WoodMac -- 1992 figures

In terms of the breakdown of turnover of plant protection products by product group, it is estimated that herbicides account for 45 % of the total, insecticides 29 %, fungicides 19 %, plant growth regulators and other products 7 %.

Proposal for a  
**EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC)**  
concerning the creation  
of a supplementary protection certificate for plant protection products

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**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>

- (1) Whereas plant protection research contributes to the continuing improvement in crop production;
- (2) Whereas plant protection products, especially those that are the result of long, costly research, will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;
- (3) 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 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;
- (4) Whereas this situation leads to a lack of protection which penalizes plant protection research and the competitiveness of the sector;
- (5) Whereas, in its Resolution of 1 February 1993<sup>(3)</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 competitiveness of industry; whereas, accordingly, the issue of a supplementary protection certificate can be regarded as a positive measure in favour of environmental protection;

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(1) OJ No C

(2) OJ No C

(3) OJ No C 138, 17.5.1993, p. 1.

- (6) 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 create obstacles to the free movement of plant protection products within the Community and thus directly affect the establishment and the functioning of the internal market; whereas this is in accordance with the principle of subsidiarity as defined by Article 3b of the Treaty on European Union;
- (7) Whereas, therefore, the creation of 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;
- (8) 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;
- (9) 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; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a plant protection product;
- (10) 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 legitimate objectives concerning the agricultural and environment policies pursued both at national and Community level;
- (11) Whereas only action at Community level can be effective in attaining 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;

**HAVE ADOPTED THIS REGULATION:**



## Article 1 Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. 'plant protection products': active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:
  - 1.1. protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;
  - 1.2. influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators);
  - 1.3. preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;
  - 1.4. destroy undesired plants; or
  - 1.5. destroy parts of plants, check or prevent undesired growth of plants;
2. 'substances': chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;
3. 'active substances': substances or micro-organisms including viruses, having general or specific action:
  - 3.1. against harmful organisms; or
  - 3.2. on plants, parts of plants or plant products;
4. 'preparations': mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection products;
5. 'plants': live plants and live parts of plants, including fresh fruit and seeds;
6. 'plant products': products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves as defined at point 5;
7. 'harmful organisms': pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;

8. 'product': the active substance is defined at point 3 or combination of active substances of a plant protection product;
9. 'basic patent': a patent which protects a product as defined at point 8 as such, a preparation as defined at point 4, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
10. 'certificate': the supplementary protection certificate.

## Article 2 Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorization procedure as laid down in Article 4 of Council Directive 91/414/EEC<sup>(4)</sup>, or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorization was lodged before the entry into force of Directive 91/414/EEC for the Member State concerned, may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

## Article 3 Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted, at the date of that application:

- (a) the product is protected by a basic patent in force;
- (b) a valid authorization to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law;
- (c) the product has not already been the subject of a certificate;
- (d) the authorization referred to in (b) is the first authorization to place the product on the market as a plant protection product.

## Article 4 Subject-matter of protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorizations to place the

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<sup>(4)</sup> OJ No L 230, 19.8.1991, p. 1.

corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorized before the expiry of the certificate.

#### Article 5 Effects of the certificate

Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

#### Article 6 Entitlement to the certificate

The certificate shall be granted to the holder of the basic patent or his successor in title.

#### Article 7 Application for a certificate

1. The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3(b) to place the product on the market as a plant protection product was granted.
2. Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

#### Article 8 Content of the application for a certificate

1. The application for a certificate shall contain:
  - (a) a request for the grant of a certificate, stating in particular:
    - (i) the name and address of the applicant;
    - (ii) if he has appointed a representative, the name and address of the representative;
    - (iii) the number of the basic patent and the title of the invention;
    - (iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3(b) and, if this authorization is not the first authorization to place the product on the market in the Community, the number and date of that authorization;

- (b) a copy of the authorization to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Part A.I or B.I of Annex II to Directive 91/414/EEC or in equivalent national laws of the Member State in which the application was lodged;
  - (c) if the authorization referred to in (b) is not the first authorization to place the product on the market as a plant protection product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the Official Journal or any other document including the information required.
2. Member States may provide that a fee is payable upon application for a certificate.

#### Article 9

##### Lodging of an application for a certificate

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.
2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:
- (a) the name and address of the applicant;
  - (b) the number of the basic patent;
  - (c) the title of the invention;
  - (d) the number and date of the authorization to place the product on the market, referred to in Article 3(b), and the product identified in that authorization;
  - (e) where relevant, the number and date of the first authorization to place the product on the market in the Community.

#### Article 10

##### Grant of the certificate or rejection of the application

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.

2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.
3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.
4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.
5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(c) and (d) are met.

#### Article 11 Publication

1. Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9(1). The notification shall contain at least the following information:
  - (a) the name and address of the holder of the certificate;
  - (b) the number of the basic patent;
  - (c) the title of the invention;
  - (d) the number and date of the authorization to place the product on the market referred to in Article 3(b) and the product identified in that authorization;
  - (e) where relevant, the number and date of the first authorization to place the product on the market in the Community;
  - (f) the duration of the certificate.
2. Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9(1). The notification shall contain at least the information listed in Article 9(2).

#### Article 12 Annual fees

Member States may require that the certificate be subject to the payment of annual fees.

Article 13  
Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years.
2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

Article 14  
Expiry of the certificate

The certificate shall lapse:

- (a) at the end of the period provided for in Article 13;
- (b) if the certificate-holder surrenders it;
- (c) if the annual fee laid down in accordance with Article 12 is not paid in time;
- (d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place it on the market in accordance with Article 4 of Directive 91/414/EEC or equivalent provisions of national law. The authority referred to in Article 9(1) may decide on the lapse of the certificate either on its own initiative or at the request of a third party.

Article 15  
Invalidity of the certificate

1. The certificate shall be invalid if:
  - (a) it was granted contrary to the provisions of Article 3;
  - (b) the basic patent has lapsed before its lawful term expires;
  - (c) the basic patent is revoked or limited so that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.
2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent.

Article 16  
Notification of lapse or invalidity

If the certificate lapses in accordance with Article 14(b), (c) or (d), or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9(1).

Article 17  
Appeals

The decisions of the authority referred to in Article 9(1) or of the body referred to in Article 15(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

Article 18  
Procedure

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless that law lays down special procedural provisions for certificates.
2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

**TRANSITIONAL PROVISIONS**

Article 19

1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a plant protection product in the Community was obtained after 1 January 1985 under Article 4 of Directive 91/414/EEC or an equivalent national provision may be granted a certificate.
2. An application for a certificate as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force.

## FINAL PROVISION

### Article 20 Entry into force

This Regulation shall enter into force three months after its publication in the Official Journal of the European Communities.

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

Done at ,

For the Parliament  
The President

For the Council  
The President



# **FINANCIAL STATEMENT**

## **TITLE**

Proposal for a Parliament and Council Regulation concerning the creation of a supplementary protection certificate for plant protection products.

## **DESCRIPTION OF THE MEASURE**

The objective is to promote research in a high-risk sector by creating a new industrial property instrument, the supplementary protection certificate. The measure also harmonizes the conditions for granting the supplementary protection certificate and calculating its duration at Community level.

The measure has no financial impact on the Community budget.

# **IMPACT OF THE PROPOSAL ON FIRMS**

## **(in particular SMEs)**

### **1. WHY IS COMMUNITY LEGISLATION NECESSARY?**

In order to harmonize at Community level the arrangements for granting and calculating the duration of the supplementary protection certificate, in pursuit of the following objectives:

- (a) improving the functioning of the internal market for plant protection products by ensuring their freedom of movement;
- (b) preventing the distortions of competition currently facing plant protection firms;
- (c) ensuring that plant protection research can benefit from better protection through a single measure with direct and uniform effect throughout the Community;
- (d) improving the competitiveness of the plant protection industry by supporting European research.

### **2. WHICH SECTORS WILL BE AFFECTED?**

- (a) Firms manufacturing plant protection products, essentially those which base their activities on research, will benefit from the measure, provided that the products concerned are protected by a valid basic patent when the Regulation comes into force.
- (b) Most of these firms belong to international groups operating in several sectors of the chemical industry (basic chemistry, plant protection products, colorants, plastics, etc.) and human or animal health. Plant protection generally accounts for a relatively small percentage of their total activities, but it is characterized by a very high level of risk. However, the proposed measure is such as to apply to all plant protection firms irrespective of size.

The rights to supplementary protection must be respected by third parties, such as manufacturers of generic plant protection products. However, the proposal contains limitations, in particular concerning the maximum duration of the supplementary protection certificate, intended to prevent any undue effect on the activities of manufacturers of generics in the sector.

- (c) There are no grounds for supposing that certain geographical areas will profit more than others from the measure.

### **3. WHAT MUST FIRMS DO TO COMPLY WITH THE MEASURE?**

The supplementary protection certificate will be granted to plant protection firms which apply for it, provided that all the necessary conditions are met.

All applications for a supplementary certificate must be submitted to national patent offices: the application may be subject to the payment of a fee to be set by the competent authorities of the Member States.

### **4. WHAT ARE THE LIKELY ECONOMIC EFFECTS OF THE MEASURE?**

#### **(a) On employment.**

The creation of the supplementary protection certificate will provide innovating firms in the plant protection sector with an incentive to maintain, even increase, their investment in research. It will help to establish an appropriate legal framework for protecting innovation in the sector; it will thus have a positive effect on employment, in particular in research.

#### **(b) On investment and the creation of new firms.**

Harmonization at Community level of the conditions for granting the certificate and the method of calculating its duration should provide the firms concerned with more certainty about recovering their costs, thus encouraging them to invest. Since patents are the best instrument for encouraging research, it is certain that the supplementary protection certificate -- a sui generis instrument providing similar protection to a patent -- will be regarded as an incentive to research in the plant protection industry.

#### **(c) On the competitiveness of firms.**

By placing the plant protection industry in a competitive situation comparable to that prevailing in the other important regions of the world, the supplementary protection certificate should be an incentive for maintaining investments in Union territory. The European plant protection industry, which makes a substantial contribution to the European Union's positive balance of payments, will thus have the opportunity of better establishing its competitive position on domestic and international markets.

## 5. DOES THE PROPOSAL CONTAIN MEASURES TAKING ACCOUNT OF THE SPECIAL CIRCUMSTANCES OF SMES?

The measures contained in the proposal are not specifically aimed at small and medium-sized businesses, although they can also take advantage of it in so far as they meet the conditions required for a supplementary protection certificate to be granted.

## 6. CONSULTATION

A meeting of national experts was held on 1 and 2 October 1992 at the Commission's initiative. The experts examined the need for supplementary protection for patents for plant protection products in the light of a Commission working document. The main subjects discussed were determination of the scope of a Community measure and the transitional arrangements. This proposal takes account of the initial approach emerging from that meeting.

In addition, Commission departments have contacted the various organizations representing the interests concerned by the proposal.

The organization representing the research-based plant protection industry, the **ECPA**,<sup>(1)</sup> supplied the Commission with data which established with certainty that the industry was suffering from substantial erosion of the duration of effective patent protection, which has a negative impact on the sector's research activities. The ECPA estimates that the supplementary protection certificate will help to ensure that innovating industries will be able to recover over a long enough period the increasingly large investments needed to develop new products.

Commission departments also received a contribution from **GAME**,<sup>(2)</sup> an informal grouping of several (currently four) producers of generic products, which takes the view that the proposed measure will delay free access to protected products and, consequently, is opposed to any extension of patent protection or of supplementary protection. **GAME** is eager to see generic products appearing on the market as quickly as possible after the expiry of a patent in order to promote competition, in particular price competition.

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(1) European Crop Protection Association.

(2) Generic Agrochemical Manufacturers of Europe.

Lastly, **COPA-COGECA**<sup>(3)</sup> submitted its position, voicing its concerns about the effects of the supplementary protection certificate on the prices of plant protection products and, as a result, on expenditure by farmers on buying these products. Commission departments have made estimates to assess, where possible, the effects of the proposed measure on farmers' outgoings.

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<sup>(3)</sup> Committee of Agricultural Organizations in the European Community; General Committee for Agricultural Cooperation in the EC.





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