

PLANT PROTECTION PRODUCTS

NEW DEVELOPMENTS FROM A LEGAL PERSPECTIVE

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Abstract: The regulations at national and European level on the legal protection and placing on the market of plant protection products need to update and harmonize the legal structure for the protection of these products. Since 2009, European and national authorities have materialized this update through the enactment of advanced regulations in the matter of authorisation, placing on the market and sustainable use of PPPs. Thus, the latest Spanish regulation paves the way for the control of the marketing of PPPs, developing new mechanisms to follow the course of the commercialization of PPPs in Spain and the Union, and this new legal framework aims to be an example of initiative in the PPPs sector so that the Community authorities adopt these strategies of control and surveillance. Therefore, achieve the objectives of responsible commerce and responsible use of plant protection products in the EU.

Keywords: Plant Protection Products (PPPs), Commercialisation, Authorisation, Agro-industrial sector.

I. INTRODUCTION

Policies oriented towards respect, protection of natural resources and sustainability are fundamental elements in the work to support agricultural activity under the protection of the institutions of Spain and the European Union. New legislative measures on phytosanitary products are one of the best alternatives for the protection of plant products supported by a wide regulatory framework at Community and national level. This legal framework aims to protect plant health through effective and safe phytosanitary products. As well as to protect consumer health and overall, the people who might be involved in the application of each phytosanitary product.

Plant protection products are a fundamental element in the protection of plant health and the good development of the agri-food industry. The implementation of a harmonised legal framework in the European Union is one of the tools available to the European legislator to improve and support innovation and technology in the plant protection sector. The legal protection of plant protection products is underpinned by legislation that insists

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on supporting the free movement of products within the European territory. This has led to a call for Member States to initiate studies on the development and placing on the market of plant protection products, and how they should, through a strong and structured regulatory system, respond to products placed on the market so that they comply with all the safety and quality guarantees set out in Community legislation.

In the following lines of this work, we will analyse the guidelines that Community regulations implement to ensure that the use of these products is sustainable and adapted to the social and environmental needs of the Member States. We will present the most recent Spanish regulatory update in the form of the Royal Decree 285/2021, of 20th April, establishing the conditions for the storage, marketing, import or export of plant protection products.

II. PLANT PROTECTION PRODUCTS (PPPS)

At Community level, Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC defines in its second article as plant protection products all chemical compounds containing one or more active substances together with other ingredients, the objectives of which are to protect plants and plant products against harmful organisms including weeds and to improve agricultural production. Similarly, plant protection products (PPPs) are those compounds that can influence the vital processes of plants by inhibiting, regulating germination, controlling growth, and destroying unwanted plants or plant parts.

In the Spanish national legal framework, the Act 43/2002 of 20 November 2002 on plant health and Royal Decree 971/2014 of 21 November 2014, which regulates the procedure for the evaluation of plant protection products, adapted and continued the conceptual and procedural guidelines on this type of compounds.

Thus, to achieve the objectives of access to food, the protection of the constant production of plant varieties and the defence against the action of pests, plant protection products are an effective tool, which allows the decreases in the production of agricultural products to be smaller each year. They contribute to the stability of production, guaranteeing the quality of crops, with optimum use of harvests and encouraging the creation of new products through research and development of more effective and safer compounds for humans.

The implementation of standards in food and nutrition for people has led to an awareness of the quality of the agricultural products to which they have access. To

achieve a recognised development of agricultural production in the Member States of the European Union, it has been decided to establish measures related to the preservation of agricultural production. This preservation is linked to the quality and safety guarantees that plant protection products authorised for marketing must possess to be used to protect crops. Through advances in innovation resulting from scientific research, new plant protection compounds must be protected by a strong regulatory framework based on the pillars of trust and encouragement of the development of novel inventions, which will be made available to the agricultural sector.

The high impact of plant protection products on the increase in agricultural production certainly demonstrates the benefit that is achieved through the application of phytosanitary measures for the protection and preservation of plant varieties and major crops. As for pharmaceuticals and biopharmaceuticals, plant protection products must include in their applications for authorisation a risk-benefit management plan, which must be subject to evaluation by the competent authorities and obtain a balance in which the benefits outweigh the risks. The provisions of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009, indicate that the competent authorities for the risk assessment (Silva *et al.*, 2019, p. 1542), (Weisner *et al.*, 2021, p. 2) of plant protection products and for the toxicological evaluation and classification and the safety assessment are, at national level, the Ministry of Health, and Social Services. Likewise, Royal Decree 1311/2012 of 14 September, which establishes the framework for action to achieve a sustainable use of plant protection products (Helepciuc, 2021, pp. 2-5) enshrines the requirements for the appropriate use of plant protection products with the aim of reducing the risks arising from the application of these compounds. The Directorate-General for Agricultural Production Health is responsible for the control of plant protection products in accordance with Regulation (EU) No. 2017/625 of the European Parliament and of the Council of 15 March 2017 on controls and other official activities to ensure the application of legislation on food and feed, animal health and welfare, plant health and plant protection products.

III. EUROPEAN LEGISLATION ON PLANT PROTECTION PRODUCTS

Developments in the agricultural and phytosanitary industry have given greater prominence to the strengthening of intellectual property rights, such as the importance of patents for the agricultural sector. The substantial increase in crop cultivation and the use of vast areas of land for new agricultural production has led to the emergence of pests and plant diseases that are detrimental to the production of products for consumers. To prevent

these threats from causing substantial losses, the plant protection industry invests heavily in R&D to create new compounds aimed at efficiently eradicating pests and combating diseases that affect agro-industrial production. Research and development of innovative compounds for application in agriculture is on the increase due to production requirements in all EU Member States. The protection of scientific innovation must be backed up by an adequate system for the protection of intellectual property rights, so that technological development in the agricultural sector has effective guarantees of protection for its innovative products.

Over the last four decades, the legal protection of PPPs has been subject to major changes and improvements in the legislation that applies to these products, both at Community and national level, without leaving aside the international provisions on the legal protection of these products. It is important to note that the Community legal system has opted for the strengthening of PPPs related regulations in relation to invention patents, protection through Supplementary Protection Certificates, data exclusivity and test data, as well as controls on the authorisation and marketing of these products. All this regulatory development is aimed at safeguarding and protecting human health and the environment, due to the risks derived from the use of these compounds (Herrera Sebastián, 2019, pp. 63-65).

In these circumstances, to achieve an optimal degree of protection at Community and national level, a regulatory restructuring of the legal protection of plant protection products began at the end of the 2000s. The result of these updates is a set of rules aimed at controlling the safety and efficacy of these products, considering the requirements for authorisation and the forms of post-market review, assessing the risks arising from their nature and purely chemical composition. Similarly, the regulations take into consideration the benefits of plant protection products on crops and the economic, commercial, and sanitary repercussions for the evaluation exercises (Arias Aparicio, 2015, p. 3).

One of the guiding principles of the renewal of Community legislation was the search for harmonisation of legislation concerning the placing of plant protection products on the market. Thus, with the entry into force of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009, the need for reform of the legal structure for the protection of plant protection products materialised, in line with the developments that had occurred since the enactment of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJEC. L.230 of 19.8.91.

We can affirm that this directive served as a starting point for identifying PPPs as one of the most effective methods for the protection of plant products, as well as for promoting more efficient and safer agricultural production. It introduced for the first time the idea of regulatory uniformity on the conditions and procedures for the authorisation and placing on the market of plant protection products. Council Directive 91/414/EEC also provided guidelines on the importance of the evaluation of the intrinsic risks of plant protection products in relation to the protection of human health, animal health and the environment. The Directive introduced a comprehensive definition of plant protection products which has remained almost unchanged until today. One of the most important considerations of this Directive relates to the recognition of authorisations for placing plant protection products on the market by other Member States, to promote the free movement of both plant protection products and plant varieties. Thus, it proposes a community information system in which States allow access to the data obtained from the safety and quality tests submitted in the authorisation processes. These initiatives paved the way for the development of what later became known as the mutual recognition of authorisations, (Regulation (EC) No 1107/2009, art. 40, p.22). It has also pioneered the introduction of new concepts and fundamental requirements for the protection of the PPPs, as well as the protection of human and animal health and the environment.

Furthermore, the risk assessment-oriented procedures allowed Member States to know the harmful elements of this sort of product and to decide according to their own environmental, climatic, and geographical needs and characteristics, the safety and efficacy of allowing the distribution and use of PPPs in their territories. In fact, according to the Spanish Agency for Food Safety and Nutrition, "*risk assessment is the identification of adverse effects on human health that may occur as a result of exposure to food-borne hazards*" (https://www.aesan.gob.es/AECOSAN/web/seguridad_alimentaria).

As a result of technological growth, the development of new plant varieties and the imperative need to maximise crop production, the Community legislator took the initiative to modernise and adapt the legislation in force in accordance with the technological circumstances of the time, through the enactment of a series of regulations aimed at integrating into a common legal framework the matters related to the creation, manufacture, authorisation, marketing and control of plant protection products.

The promotion of the use of plant protection products in the agro-industrial sector is another of the guiding principles of the legislative policies of the European Union authorities. To encourage the sustainable use of these products, and as a way of supporting

the reforms of the regulatory system, Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides was enacted at the same time as Regulation 1107/2009. On the basis that, initiatives to harmonise European legislation are aimed at ensuring the protection of health and the environment, by identifying and reducing the risks arising from the use of plant protection products. In this regard, the intention of the legislator was to set objectives of sustainability and responsibility in the application of PPPs in all the States of the Union (Bonanno *et al.*, 2017, p. 2).

The supervision of the sustainable and respectful use of plant protection products is the responsibility of the state authorities, which must establish systems of measures and controls of use with the aim of reducing the risks of those products containing potentially harmful active substances, or as defined by the Directive itself, substances of particular concern. Hence, as a supporting measure to Regulation 1107/2009, the Directive reaffirms the need for an exchange of information between Member States to achieve the identified risk reduction targets (Herrera Sebastián *op. cit.*, 2019, p. 65).

In addition to the legislative renewal procedures that the Commission had undertaken since 2009, harmonisation of other rules related to aspects of major importance for the approval and placing on the market of plant protection products was necessary. Therefore, in 2013, two Regulations were enacted concerning data requirements for the authorisation of active substances, and for plant protection products. Commission Regulation (EU) No. 283/2013 of 1 March and Commission Regulation (EU) No. 284/2013 of 1 March. Currently, Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/2/EC, 2006/91/EC and 2007/91/EC No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC, laying down the provisions of the Community plant health regime and specifying the plant health conditions, procedures and formalities to be complied with for the introduction of plants and plant products into the Union or their movement within the Union.

Since the adoption of these rules, both, the Commission, and most Member States, have been concerned with further adapting legislation to the technological and legal requirements that arise with the state of the art in the agro-industrial sector.

1. Authorisation for placing plant protection products on the market

The authorisation procedure for placing plant protection products on the market is well defined in the first chapters of the above-mentioned Regulation 1107/2009. At the time, the great initiative at European level was the inclusion of different criteria for the approval of active substances; encouraging each Member State to be responsible, in accordance with the internal provisions of each country, for authorising a product containing the active substances previously approved by the Member State with the aim of controlling the risk of using the plant protection product in its territory.

Once the authorisation has been obtained, the requirements related to the form of placing the plant protection product on the market are established considering the sustainable use guidelines laid down in Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009. Upon compliance with all use and placing on the market requirements, the first authorisation will have a maximum duration of ten years. However, the Regulation includes a provision concerning the possibility to obtain a provisional authorisation for plant protection products containing active substances that have not been approved. In these cases, Member States grant authorisation for a maximum period of three years.

The inclusion of Article 40 of the Regulation proposes the mutual recognition of marketing authorisations for the same PPPs. As well as for the same use of the PPPs following agricultural applications in any other Member State. The requirements for applying for this recognition of authorisation are based on the authorisation being granted by a Member State called the reference Member State and belonging to the same zone. The Regulation itself specifies that it is desirable for the efficient organisation and disposal of PPPs to divide the Community into zones. For this zoning, the Regulation emphasises the comparability and similarity of the phytosanitary, agricultural, and environmental conditions of the States in each zone in order to facilitate the assessment of the authorisations requested for recognition.

In addition to mutual recognition, subsection 5 of Regulation (EC) No 1107/2009, on particular cases concerning the placing on the market of plant protection products stipulates guidelines concerning parallel trade of PPPs by obtaining an authorisation for the use in the State of destination of a product which is identical in formulation and composition to a reference product previously authorised in the territory of the State where the new product is to be introduced. A plant protection product will be identical to the reference products if the conditions stipulated in Article 52(3) of the Regulation are

met. The procedure to be initiated by the company that intends to introduce the plant protection product in the State of destination through parallel trade, is marked by the control and surveillance of the sustainable use of PPPs with the aim of not endangering human and animal health and the environment. This is the reason the marketing permit granted by the State of destination obliges the use of this product under the commitments of use granted in the authorisation of the product of reference. Finally, it should be noted that the validity of the product authorised for parallel trade will be the same as the duration of the authorisation of the reference product (Bonanno *et al. op. cit.*, 2017, p. 11).

IV. REGULATORY DEVELOPMENTS IN SPAIN ON PPPS

Concerned to adapt the regulatory framework to the technological and environmental reality, the Spanish legislator has taken the lead in developing new strategies to achieve the objectives of sustainability and responsibility in the use and commerce of phytosanitary products. With the enactment of Royal Decree 285/2021 of 20 April, the conditions for storage, marketing, import or export, official control, and authorisation of tests with phytosanitary products are established. This new regulation introduces an innovative approach to the official control of the marketing of PPPs that is pioneering in the European Union.

The aim is to improve market transparency by means of commercial monitoring of plant protection products in which it is verified that the use of these products complies with the regulations in force in accordance with the parameters of sustainability and protection of health and the environment. It also proposes the creation of a register of all operations conducted by producers and distributors of PPPs in relation to their acquisition and application. It should be noted that the new legislation does not only apply to the internal market; the Royal Decree also aims to cover trade with other Member States and third countries².

The objectives of the Royal Decree include the conditions and measures governing the procedures related to the placing on the market, storage, and use of PPPs. In turn, it makes special reference to the creation of control programs on the systems of trade of plant protection products within and outside the national territory. Finally, it establishes the regulatory policies regarding the tests conducted as requirements for the registration of a plant protection product.

² Articles 1 to 4 sets the general dispositions in terms of the main objectives and content of the new regulation.

As part of the provisions related to the trade of plant protection products for professional use, the Royal Decree lays down the general conditions for storage for subsequent distribution, sale, and agricultural export of PPPs. In parallel, it stipulates conservation and storage requirements for plant protection products for non-professional use. For international trade procedures, the new regulation sets out several innovative provisions on the control of illegal trade, prohibiting electronic trade in plant protection products, except for those purchased for responsible non-professional use³.

One of the new developments in electronic control related to foreign trade⁴ (imports and exports) is the new computerised system for registration and control of activities related to transactions and operations with plant protection products. The Royal Decree 285/2021 requires an important level of documentary transparency of the products in terms of labelling, registration, copies of authorisations, import and export justifications and destination of the products⁵.

This control initiative is linked to the need to avoid parallel trade of plant protection products between Member States for those products whose active substances are concerning. Overall, the new Spanish legislation on the marketing of PPPs is a pioneer in the European Union in the development of this mechanisms of control and surveillance measures.

About the storage of plant protection products, the Royal Decree sets out the conditions for professional use in distribution and sales. Furthermore, it elaborates the conditions to the storage of PPPs for non-professional use⁶. This second chapter sets out the requirements for compliance with storage conditions for professional use in treatment facilities. The same applies to professional use in agricultural holdings, and the requirements for manufacturing establishments, storage and application premises for plant protection products are presented.

³ Article 14 of the Real Decree 285/2021 sets out the conditions for the distance selling of PPPs.

⁴ Articles 10 to 12 include a series of conditions and obligations that both importers and exporters of PPPs must comply with to meet the requirements of the free movement of plant protection products in the EU. Among the import obligations, there are the imperative elements of registration in the official Register of Producers and Operators (ROPO), to keep a strict control on the phytosanitary elements entering the country; this registration is also mandatory for the import of active substances. These articles of the Royal Decree also set out the control measures for inspections at border checkpoints, which are the responsibility of the Directorate General for Agricultural Production Health of the Ministry of Agriculture, Fisheries and Food.

⁵ Article 13 sets out the commitments of exporters in accordance with the authorisation of the export regime, which is not subject to border control, as is the case for imports, except in cases where this is requested by the third country of destination.

⁶ Chapter II, articles 4 to 9.

As regards the marketing and sale of PPPs, the Royal Decree outlines the conditions for distance selling of these products. Distance selling may only be carried out for products for non-professional use. In order to accomplish the sale, the fulfilment of the requirements expressed in the Royal Decree must be guaranteed⁷. The legislation then provides for the establishment of the Electronic Register of Transactions and Operations with Plant Protection Products (RETO). Operators registered in the supply and phytosanitary treatment sectors of the Official Register of Producers and Operators (ROPO), shall keep an up-to-date record of all placing on the market, import or export operations conducted by them⁸.

At this point, the Royal Decree makes progress in the field of testing with plant protection products by presenting the requirements and conditions necessary for interested companies to be able to conduct quality and safety tests with this type of product. The introduction of an official Register of companies, a compulsory registration to obtain authorisation to conduct tests with commercially available PPPs, is another of the novel initiatives included in the Royal Decree. With the purpose of having a systematised control of the marketing activities conducted with these products, the database corresponding to the registration of companies will be public and will include all the data provided by the company concerned in the application for authorisation of trials with phytosanitary products⁹. Another of the characteristics of this provision, related to the authorisation of tests with phytosanitary products, refers to the obligation to register all those public entities that have the infrastructure and capacity to conduct certain types of tests with these products.

It is therefore intuitive that, this Royal Decree is a first approach for the Community authorities to take into consideration the creation of this sort of control database, through the registration of private and public companies for conducting tests with phytosanitary products, with a view to improving the safety and quality of products for professional and non-professional use throughout Europe. In parallel to the inspection and control of tests with phytosanitary products, Royal Decree 285/2021 includes the provision for the evaluation of public or private laboratories in charge of conducting non-clinical tests on phytosanitary products, aimed at certifying good practices in this kind of tests.

⁷ Chapter IV, articles 14 to 16.

⁸ Article 15.

⁹ Chapter V. Articles 17 to 24.

V. FINAL REMARKS

The European legal framework related to the development, authorisation, placing on the market and control of plant protection products and active substances may require a process of modernisation with respect to the modern technologies and commercial requirements of our globalised society. As a result, some Member States' legislations have taken the initiative to adapt their regulations to current needs. Spain, for example, as a pioneering country in the development of regulations on the marketing of plant protection products, has set the tone for the countries around it to join this legislative initiative and seek to achieve the Community objectives of unified regulation. The consensus of the Member States of the European Union to guarantee sustainable use while respecting the environmental characteristics of each country, means that phytosanitary development has grand expectations for the marketing and circulation of quality, safe and effective products throughout the Community.

VI. REFERENCES

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