



REGULATORY IMPACT ANALYSIS REPORT

EXECUTIVE SUMMARY SHEET

Proposing Ministry/body	Ministry of Health (Directorate-General for Public Health and Health Equity), Ministry of Agriculture, Fisheries and Food, and Ministry for the Ecological Transition and the Demographic Challenge	Date	15 December 2025
Title of the regulation	DRAFT ROYAL DECREE REGULATING THE REGISTRATION AND CONDITIONS FOR THE AUTHORISATION, MANUFACTURE, MARKETING AND USE OF BIOCIDAL PRODUCTS.		
Type of report	Normal <input checked="" type="checkbox"/> Abbreviated <input type="checkbox"/>		
TIMELINESS OF THE PROPOSAL			



Subject

The draft royal decree regulating the registration and conditions for the authorisation, manufacture, marketing and use of biocidal products is essentially intended to update national legislation on biocidal products.

All these aspects remain in force in Royal Decree 3349/1983 of 30 November 1983 approving the Technical and Health Regulations for the manufacture, making available on the market and use of pesticides and in Royal Decree 1054/2002 of 11 October 2002 regulating the evaluation process for the registration, authorisation and making available on the market of biocidal products, but it needs updating as a result of changes in the application of the mandates of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

The draft royal decree also makes it necessary to update Royal Decree 830/2010 of 25 June 2010 establishing the regulations governing training in performing treatments using biocidal products, in order to include other recently introduced professional qualifications relating to pest control, as well as other new legislative developments in the field of education.

In addition, the current approach to monitoring products placed on the market in other areas is based on supply chain traceability, which has proven to be a more flexible and effective strategy than registers of movements, such as the previous Official Register of Movements of Hazardous Pesticides (Libro Oficial de Movimientos de Plaguicidas Peligrosos), adapting the context to new technologies; it is therefore appropriate to replace one system with another.

A chapter has been added dedicated to offences and penalties applicable in the event of non-compliance with the provisions laid down in Regulation (EU) No 528/2012 of the European Parliament and of the Council and in this draft royal decree.

Therefore, this draft royal decree updates the existing national regulations on biocidal products and is complementary to Regulation (EU) No 528/2012 of the European Parliament and of the Council.



Objectives pursued	<p>The draft royal decree regulating the registration and conditions for the authorisation, manufacture, marketing and use of biocidal products aims to regulate:</p> <ul style="list-style-type: none"> a) specific conditions for the authorisation, manufacture, packaging, making available on the market, storage and use of biocidal products on national territory; b) the functioning of the Official Register of Biocidal Products; c) training in performing treatments using biocidal products; d) the establishment of responsibilities resulting from the implementation at national level of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ('Regulation (EU) No 528/2012 of the European Parliament and of the Council'); e) the system of offences and penalties applicable for non-compliance with the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council and this Royal Decree; f) the transitional provisions governing national procedures in force during the periods specified in Article 89 of Regulation (EU) No 528/2012 of the European Parliament and of the Council. <p>This draft royal decree applies to biocidal products regulated under Regulation (EU) No 528/2012 of the European Parliament and of the Council and is complementary to that Regulation.</p>
Main alternatives considered	<p>Although the second final provision of Royal Decree 1054/2002 of 11 October 2002 empowers the Minister for Health and Consumer Affairs, the Minister for Agriculture, Fisheries and Food and the Minister for the Environment, within the scope of their powers, to implement the provisions of that Royal Decree, as well as to lay down the rules necessary for updating the technical annexes contained therein and coordinating the requirements for entry in the registers of the Autonomous Communities, determining the conditions of manufacture, storage, making available on the market and application and the conditions and programmes of training courses for staff of biocidal service companies, the amendments required would have a direct impact on the articles of that Royal Decree.</p> <p>It is therefore necessary to repeal the aforementioned royal decree as proposed.</p>
CONTENT AND LEGAL ANALYSIS	
Type of regulation	Royal Decree
Structure of the Regulation	The draft royal decree consists of a preamble, 24 articles, 6 additional provisions, 4 transitional provisions, 1 repealing provision, 3 final provisions and 2 annexes.



Reports received

- In accordance with the provisions of Article 26(5), fourth paragraph, of Law 50/1997 of 27 November 1997 on the Government, reports should be requested from the General Technical Secretariats of the following ministries:
 - Ministry of Health.
 - Ministry of Agriculture, Fisheries and Food.
 - Ministry for the Ecological Transition and the Demographic Challenge.
 - In accordance with the provisions of Article 26(5), first paragraph, of Law 50/1997 of 27 November 1997:
 - Ministry of Education, Vocational Training and Sports.
 - Ministry of Economy, Trade and Business.
 - Ministry of Industry and Tourism.
 - Ministry of Work and Social Economy.
 - Ministry of Defence.
 - Ministry of Social Rights, Consumer Affairs and Agenda 2030.
 - Ministry of Finance.
 - Report of the Ministry of Territorial Policy and Democratic Memory (Article 26(5), sixth paragraph, of Law 50/1997 of 27 November 1997).
 - Prior approval of the Ministry of Digital Transformation and the Civil Service, in accordance with the provisions of Article 26(5), fifth paragraph, of Law 50/1997 of 27 November 1997.
 - Report of the Office of Coordination and Regulatory Quality of the Ministry of the Presidency, Justice and Relations with the Courts (Article 26(9) of Law 50/1997 of 27 November 1997).
 - Report of the Environmental Advisory Council provided for in Article 19(2)(a) of Law 27/2006 of 18 July 2006 regulating the rights of access to information, public participation and access to justice in environmental matters.
 - Report by the Spanish Data Protection Agency (AEPD) in accordance with the provisions of Article 47 of Organic Law 3/2018 of 5 December 2018 on the protection of personal data and the guarantee of digital rights (LOPDGDD).
- Likewise, reports will be received from:
- the Spanish Agency for Medicines and Medical Devices;
 - the Autonomous Communities and the cities of Ceuta and Melilla;
 - the Interterritorial Council of the SNS (Spanish national health system) and the Advisory Committee of the SNS;
 - the Spanish Federation of Municipalities and Provinces (FEMP);
 - the National Institute of Toxicology and Forensic Sciences



	<p>(Ministry of the Presidency, Justice and Relations with the Courts);</p> <ul style="list-style-type: none"> • the Interministerial Commission for Food Management; • the Spanish Council for Consumers and Users. <p>Procedure for the provision of information in the field of technical standards and regulations and of rules on information society services, provided for in Directive 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, as well as in Royal Decree 1337/1999 of 31 July 1999, which incorporates this directive into the Spanish legal system.</p> <p>Opinion of the Council of State, in accordance with the provisions of Article 22(2) and (3) of Organic Law 3/1980 of 22 April 1980 on the Council of State. (pending).</p>	
Prior public consultation procedure	Prior public consultation took place from 10 to 25 July 2024.	
Public hearing and information procedure	The public hearing and information procedure for the affected sectors took place from 21 February to 13 March 2025.	
IMPACT ANALYSIS		
Compliance with the distribution of powers	The regulation is issued under the exclusive State competence for the bases and general coordination of health matters, as well as for the drafting of basic legislation on environmental protection, provided for in Articles 149(1)(16) and 149(1)(23) of the Spanish Constitution.	
Economic and budgetary impact	Overall economic impact.	No significant impact.
	With regard to competition:	<input checked="" type="checkbox"/> The regulation has no significant impact on competition. <input type="checkbox"/> The regulation has positive effects on competition. <input type="checkbox"/> The regulation has negative effects on competition.



	With respect to administrative burdens:	<input type="checkbox"/> It entails a reduction in administrative burdens. Estimated quantification <input type="checkbox"/> It introduces new administrative burdens. Estimated quantification <input checked="" type="checkbox"/> It does not affect administrative burdens.
	With respect to budgets, the regulation: <input type="checkbox"/> Affects State budgets. <input type="checkbox"/> Affects the budgets of other regional administrations. <input checked="" type="checkbox"/> Does not affect budgets.	<input type="checkbox"/> Involves an expense. <input type="checkbox"/> Involves an income.
Gender-based impact	The regulation has the following gender impact:	Negative <input type="checkbox"/> None <input checked="" type="checkbox"/> Positive <input type="checkbox"/>
Impact on children and adolescents	The regulation has the following impact on children and adolescents:	Negative <input type="checkbox"/> None <input checked="" type="checkbox"/> Positive <input type="checkbox"/>
Impact on the family	The regulation has the following impact on the family:	Negative <input type="checkbox"/> None <input checked="" type="checkbox"/> Positive <input type="checkbox"/>
Climate change impact	The regulation has the following impact on climate change:	Negative <input type="checkbox"/> None <input type="checkbox"/> Positive <input checked="" type="checkbox"/>
Other impacts considered	<ul style="list-style-type: none"> • Environmental impact (POSITIVE) • Impact on equal opportunities, non-discrimination and universal accessibility for persons with disabilities (NONE) • Impact on health (POSITIVE) • Impact on the Single Market (NONE) 	
Ex post evaluation	No	



Other considerations

The regulation essentially does the following:

- updates the national legislation on biocidal products laid down in Royal Decree 3349/1983 of 30 November 1983 and Royal Decree 1054/2002 of 11 October 2002, in aspects such as the registration, authorisation, manufacture, making available on the market and use of biocidal products;
- updates Royal Decree 830/2010 of 25 June 2010 establishing the regulations governing training in performing treatments using biocidal products, in order to include the training requirements for technicians applying biocidal products for use by specialist professionals, as well as the training requirements for technical managers of biocidal products;
- regulates the activities of the competent authorities in Spain in the field of biocidal products;
- establishes the penalty regime applicable in the case of offences breaching the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council and of this draft royal decree.



REGULATORY IMPACT ANALYSIS REPORT ON THE DRAFT ROYAL DECREE REGULATING THE REGISTRATION AND CONDITIONS FOR THE AUTHORISATION, MANUFACTURE, MARKETING AND USE OF BIOCIDAL PRODUCTS

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REGULATORY IMPACT ANALYSIS REPORT

This Report has been written up in accordance with the provisions of Article 26 of Law 50/1997 of 27 November 1997 on the Government and Article 2 of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report.

Its structure corresponds to the model referred to in Article 2 of Royal Decree 931/2017 of 27 October 2017.

I. TIMELINESS OF THE PROPOSAL

1. Rationale

This draft royal decree applies to biocidal products regulated under Regulation (EU) No 528/2012 of the European Parliament and of the Council and is complementary to that Regulation.

This royal decree aims to update the national regulations currently in force on biocidal products.

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market initiated the regulation at EU level of products intended for the control of harmful organisms, structuring them into four groups (disinfectants, preservatives, pesticides and others), and established different authorisation procedures for these products. Said Directive was transposed into the Spanish legal system through Royal Decree No 1054/2002 of 11 October 2002 regulating the evaluation process for the registration, authorisation and making available on the market of biocidal products.

The revision of the Directive, imposed by its own provisions, led to its repeal by Regulation (EU) No 528/2012 of the European Parliament and of the Council, which introduced new authorisation procedures and updated the existing ones in light of scientific and technical progress.

Royal Decree 1054/2002 of 11 October 2002 regulates aspects additional to those derived from that Directive, such as the distribution of powers between the national and regional authorities, the regulation of specific national aspects such as the Official Register of Biocidal Products of the Directorate-General for Public Health and Health Equity of the Ministry of Health, the Official Register of Biocidal Establishments and Services (ROESB), the Official Register of Movements of Biocidal Products and the training of application technicians. All these aspects remain valid, although they need to be updated as a result of changes in the way the mandates of the Regulation are applied, particularly regarding the approval of active substances with biocidal action.

Along the same lines, it is necessary to update the general conditions under which biocidal products, including former non-agricultural pesticides, are manufactured, stored, made available on the market and used, the regulation of which was established in Royal Decree 3349/1983 of 30 November 1983 approving the Technical Health Regulations for the manufacture, making available on the market and use of pesticides.

In Spain, biocidal products have been registered in different official pesticide registers managed by the corresponding ministerial departments in accordance with their competences, as provided for in Article 4(1) of the aforementioned Technical Health Regulations.

The approach of this original fragmented register, the precursor to the current Official Register of Biocidal Products, was changed by Royal Decree 1054/2002 of 11 October 2002, which established that the then Directorate-General for Public Health would be responsible for managing the unified register. The transfer of the biocidal products listed in the various national registers into the Official Register of Biocidal Products is being carried out gradually, such that it began with the launch of the EU procedures for the authorisation of biocidal products in accordance with Directive 98/8/EC of the European Parliament and of



the Council of 16 February 1998 and subsequently with Regulation (EU) No 528/2012 of the European Parliament and of the Council, and will end when the Review Programme for biocidal active substances is finalised, since all of them will have been evaluated, whether or not they are included in the European Union list as provided for in Article 9 of that Regulation.

When biocidal active substances are approved, non-agricultural pesticides must be transferred from the respective national registers to be authorised and entered in the Official Register of Biocidal Products.

The draft royal decree makes it necessary to update Royal Decree 830/2010 of 25 June 2010 establishing the regulations governing training in performing treatments using biocidal products, in order to include other recently introduced professional qualifications relating to pest control, as well as other new legislative developments in the field of education. In this regard, this Royal Decree addresses the types of biocidal products that require training, the minimum training for application technicians (specialist professionals) performing treatments using biocidal products and the training required for technical managers. The training of application technicians is regulated by the vocational training qualification in environmental health or by a professional certificate established in Royal Decree 1157/2024 of 19 November 2024, which establishes the intermediate vocational training qualification of Technician in Applied Environmental Health, setting out the basic aspects of the curriculum and the C, B and A grades included in this qualification.

Another aspect covered by Royal Decree 1054/2002 of 11 October 2002 is that of offences and penalties, which is also updated in this regulation, in order to ensure compliance with the obligations arising from Regulation (EU) No 528/2012 of the European Parliament and of the Council in accordance with Article 87 thereof.

Consequently, this Royal Decree is mainly needed to:

1.º Regulate the specific conditions for the authorisation, manufacture, packaging, making available on the market, storage and use of biocidal products on the national territory.

The conditions for the manufacture, making available on the market and use of non-agricultural biocidal pesticides were laid down in Royal Decree 3349/1983 of 30 November 1983 approving the Technical and Health Regulations for the manufacture, making available on the market and use of pesticides. These conditions are updated in this new regulation to take into account new scientific and technical developments arising from the publication of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

For its part, the conditions for the registration, evaluation and authorisation of biocidal products were set out in Royal Decree 1054/2002 of 11 October 2002, which transposed Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998. Similarly, following the publication of the Regulation, although it is directly applicable in Member States, it is appropriate to address certain updates. In particular, the operation of the Official Register of Biocidal Products and of the different non-agricultural pesticide registers, which refers to biocidal products registered in accordance with national regulations, which are applicable by virtue of Article 89 of Regulation (EU) No 528/2012 of the European Parliament and of the Council, and which allows Member States to continue their usual practice until the active substances containing them have been approved at EU level in accordance with the Review Programme.

Likewise, Article 28 of Royal Decree 1054/2002 of 11 October 2002 provides that biocidal products classified as toxic and highly toxic must be the subject of a specific control based on recording each operation. The control of biocidal products classified as toxic and highly toxic was determined by their hazardousness, toxic and highly toxic categories, in accordance with Royal Decree 255/2003 of 28 February 2003 approving the Regulation on classification, packaging and labelling of dangerous preparations. The current legal framework for the classification of chemical products is Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. It is therefore appropriate to align the hazard classes according to that Regulation. In addition, the current approach to monitoring products made available on the market in other areas is based on supply chain traceability, which has proven to be a more flexible and



effective strategy than registers of movements, such as the former Official Register of Movements of Biocidal Products (Libro Oficial de Movimientos de Biocidal Products); it is therefore appropriate to replace one system with another that is more suited to the new technologies to ensure better traceability in the supply chain.

2.º Regulate training in performing treatments using biocidal products.

The training of application technicians in performing treatments using biocidal products, and of the technical manager who performs the diagnosis, evaluates and plans the treatment, was regulated by Royal Decree 830/2010 of 25 June 2010.

This Royal Decree incorporates the provisions of Royal Decree 830/2010 of 25 June 2010, addressing the updates needed regarding the training of application technicians via qualifications or certificates authorising them to perform treatments using biocidal products. The annexes to Royal Decree 830/2010 of 25 June 2010 are not incorporated into this Royal Decree because the new training requirements in the field of education require a professional qualification or certificate to be obtained attesting the professional qualifications for the control of harmful organisms, depending on the type of biocidal product applied.

3.º Penalties regime.

Updates are made in relation to the offences and penalties covered in Articles 30 and 31 of Royal Decree 1054/2002 of 11 October 2002, regulating offences contravening the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council, as well as the provisions of this draft Royal Decree.

2. Objectives

The main objective of this Royal Decree is to protect human health, animal health and the environment by laying down provisions regulating the registration and conditions for the authorisation, manufacture, making available on the market and use of biocidal products. These biocidal products are necessary for the control of organisms harmful to human and animal health, and for the control of organisms harmful to natural or manufactured products.

This proposal for a royal decree updates the existing national legislation on biocidal products laid down in Royal Decrees 3349/1983 of 30 November 1983 and 1054/2002 of 11 October 2002, in the light of scientific and technical progress in the field of biocidal products since the publication of Regulation (EU) No 528/2012 of the European Parliament and of the Council and its entry into force on 1 September 2013.

Royal Decree 830/2010 of 25 June 2010 is being updated. It was issued with the aim of regulating the obligation for persons engaged in performing treatments with pesticides to pass training courses or tests, especially in the case of toxic and highly toxic pesticides for environmental use, a requirement that was established in Royal Decree 3349/1983 of 30 November 1983.

The system adopted to cover the training requirement and the existence of new tools in this area makes it necessary to rethink the previous approach, which was based on the accreditation of courses. A more appropriate approach to meeting the training needs of the sector in this regard is to accredit professional qualifications by recognising vocational training qualifications and professional certificates. Training for those handling biocidal products needs to be regulated in line with scientific and technical advances and thus adapted to the current professional training system, according to the type of biocidal product being applied.

In addition, this Royal Decree includes the powers derived from the application at national level of Regulation (EU) No 528/2012 of the European Parliament and of the Council, such as the actions of the competent authorities in the field of monitoring and control and the exchange of information between the different public administrations.



Finally, the provisions relating to offences and penalties in the field of biocidal products, which were already regulated in Royal Decree 1054/2002 of 11 October 2002 but which require updating in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council and the national provisions regulated in the draft royal decree, are updated.

3. Analysis of alternatives

The nature of the proposed amendments to the provisions of Royal Decree 1054/2002 of 11 October 2002, Royal Decree 3349/1983 of 30 November 1983 and Royal Decree 830/2010 of 25 June 2010 precludes the possibility of maintaining the regulations in their current wording or resorting to other types of documents as alternatives to amending them (guidelines, recommendations, interpretative guidance, etc.), including amending them by means of a regulation of lower status than the royal decree.

Although the second final provision of Royal Decree 1054/2002 of 11 October 2002 empowers the Minister for Health and Consumer Affairs, the Minister for Agriculture, Fisheries and Food and the Minister for the Environment, within the scope of their powers, to implement the provisions of that Royal Decree, as well as to lay down the rules necessary for updating the technical annexes contained therein and coordinating the requirements for entry in the registers of the Autonomous Communities, determining the conditions of manufacture, storage, making available on the market and application and the conditions and programmes of training courses for staff of biocidal service companies, the amendments required would have a direct impact on the articles of that Royal Decree.

This draft Royal Decree repeals:

- Decree 2274/1965 of 15 July 1965 establishing new rules for pest control operations in public establishments;
- Royal Decree 3349/1983 of 30 November 1983 approving the Technical and Health Regulations for the manufacture, making available on the market and use of pesticides, with the exception of Articles 1, 2, 4, 7 and 13 of said Regulations, which shall continue to apply as regards non-agricultural pesticides, pursuant to Article 89 of Regulation (EU) No 528/2012 of the European Parliament and of the Council, until completion of the programme for the systematic examination of existing active substances, set out in Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in the biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council;
- Royal Decree 3360/1983 of 30 November 1983 approving the Technical and Health Regulation on bleaches;
- Royal Decree 1054/2002 of 11 October 2002 regulating the evaluation process for the registration, authorisation and making available on the market of biocidal products, without prejudice to the provisions of the second transitional provision of this Royal Decree and the third transitional provision;
- Royal Decree 830/2010 of 25 June 2010 establishing the regulations regulating training in performing treatments using biocidal products, except for the fourth final provision for as long as Order SCO/3269/2006 of 13 October 2006 establishing the basis for the registration in and operation of the Official Register of Biocidal Establishments and Services remains in force;
- Order SCO/317/2003 of 7 February 2003 regulating the procedure for the approval of training courses for staff involved in the hygienic and sanitary maintenance of the installations covered by Royal Decree 909/2001 of 27 July 2001, without prejudice to the provisions of the fourth transitional provision;
- the Order of 24 February 1993 establishing the regulations governing the Official Register of Movements of Hazardous Pesticides, as regards non-agricultural pesticides;



- the third additional provision of Royal Decree 742/2013 of 27 September 2013 establishing the technical and health criteria for swimming pools.

4. Compliance with the principles of good regulation

The proposed regulation complies with the principles of good regulation set out in Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations.

To this end, compliance with the principles of necessity and effectiveness is demonstrated, given the general interest on which the measures established are based, with the royal decree being the most immediate instrument to ensure that they are achieved.

The main need underlying this draft Royal Decree regulating the registration and conditions for the authorisation, manufacture, marketing and use of biocidal products, as reflected in paragraph 1. Motivation of Section I. Timeliness of the proposal, is as follows:

1.º to lay down specific conditions for the authorisation, manufacture, packaging, making available on the market, storage and use of biocidal products on national territory;

2.º to regulate training in performing treatments using biocidal products;

3.º to establish the penalties regime.

The regulation complies with the principle of proportionality, as most of its provisions update existing national legislation on biocidal products, with this regulation complementing Regulation (EU) No 528/2012 of the European Parliament and of the Council, which is directly applicable in all Member States. Thus, the regulation that it contains is essential and proportionate to achieving the intended objectives. Moreover, it improves legal certainty by updating the national legislation, enhancing its clarity and adapting it to the current EU context.

As regards the principle of transparency, while the legislation was being processed, in addition to the public consultation and public hearing and information procedures, broad participation was sought from the sectors concerned (directly seeking the opinions of the organisations or associations identified as most relevant from the sectors affected by the legislation).

Finally, with regard to the principle of efficiency, the regulation does not create new administrative burdens for citizens. On the contrary, it establishes controls on the conditions for making biocidal products available on the market in establishments designated for this purpose, allowing for greater control of biocidal products placed on the market, with the aim of safeguarding human health.

5. Annual Regulatory Plan

For the purposes of Article 25(3) of Law 50/1997 of 27 November 1997 on the Government, this legislation is not in the Annual Regulatory Plan of the General State Administration for 2025, approved by Agreement of the Council of Ministers of 15 April 2025, as it was not expected to be approved this year.

II. CONTENT

1. Structure

As regards the structure of the proposal, the draft royal decree consists of a preamble, 24 articles, 6 additional provisions, 4 transitional provisions, 1 repealing provision, 3 final provisions and 2 annexes.

2. Content

The royal decree is structured as six chapters:



- Chapter I – General provisions. The objective and scope of application of the royal decree are described, along with the applicable definitions and the functions of the competent Spanish authorities responsible for biocidal products.

- Chapter II – Register of biocidal products – regulates the operation of the Official Register of Biocidal Products of the Directorate-General for Public Health and Health Equity for those biocidal active substances approved at EU level and the registers of non-agricultural pesticides within the scope of Royal Decree 3349/1983 of 30 November 1983, while the biocidal active substances remain under evaluation and included in the Review Programme.

The making available on the market and use of biocidal products is regulated in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council and this draft Royal Decree.

- Chapter III – Requirements for manufacture, packaging, storage, making available on the market and use – lays down the manufacturing requirements for facilities at which biocidal products are manufactured or packaged, as well as the conditions for storage premises and the marketing conditions for establishments at which biocidal products are made available on the market for use by the general public, professionals or specialist professionals.

In addition, premises or facilities located on Spanish territory at which biocidal products are manufactured, packaged, stored or made available on the market, as well as companies providing biocidal services, as determined in the implementing legislation of the autonomous communities, must be entered in the Official Register of Biocidal Establishments and Services (ROESB) of each autonomous community.

It also includes an article on the labelling of biocidal products and the obligation for entities manufacturing, packaging, storing and making biocidal products and services available on the market to monitor and keep records of all activities carried out, which must be made available to the competent authorities.

Finally, in this chapter, it is worth highlighting the register of transactions for the most toxic biocidal products described in Article 13. This traceability register replaces the Official Register of Movements of Biocidal Products.

- Chapter IV regulates training in performing treatments using biocidal products. The training needs of biocidal product application technicians that were included in Royal Decree 830/2010 of 25 June 2010 are updated, incorporating the legislative developments in education whereby the training of such technicians applying biocidal products for use by specialist professionals is accredited.

- Chapter V – Monitoring and control activities – describes the functions of the competent authorities, within the scope of their powers, relating to the exchange of information and inspection, monitoring and control activities relating to biocidal products.

- Chapter VI – Penalty regime – describes the offences, which are classified as very serious, serious or minor, as well as the penalties applicable in the event of the infringement of the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council and of this draft Royal Decree currently being processed.

In addition, the Royal Decree includes six additional provisions, notably including:

- the third additional provision, which considers the terms 'sanitising' and 'disinfecting' to constitute biocidal claims;
- the fifth additional provision on the powers of the Ministry of Defence;
- the sixth additional provision on waste regulations.

The Royal Decree includes four transitional provisions:



- The first transitional provision refers to the registers of non-agricultural pesticides covered by Royal Decree 3349/1983 of 30 November 1983, where biocidal products whose active substances have not yet been approved for the type of product in question will continue to be registered; once approved, said biocidal products must be registered in the Official Register of Biocidal Products.

- The second transitional provision, which maintains the marketing notification provided for in the second transitional provision of Royal Decree 1054/2002 of 11 October 2002, for biocidal products not subject to registration pursuant to Royal Decree 3349/1983 of 30 November 1983 containing active substances that have not yet been approved and included in the Union List but have been or are being evaluated in accordance with Regulation (EU) No 1062/2014.

- The third transitional provision grants a period of one year for the implementation of Article 13, which refers to the registration of transactions involving the most toxic biocidal products.

- The fourth transitional provision grants application technicians performing treatments with biocidal products a period of six years to obtain the new qualifications or certificates referred to in Article 16.

The Royal Decree includes a single repealing provision. In particular, the following regulations are repealed.

a) Decree 2274/1965 of 15 July 1965 establishing new rules for pest control operations in public establishments.

b) Royal Decree 3349/1983 of 30 November 1983 approving the Technical and Health Regulations for the manufacture, making available on the market and use of pesticides, with the exception of Articles 1, 2, 4, 7 and 13 of said Regulations, which shall continue to apply as regards non-agricultural pesticides, pursuant to Article 89 of Regulation (EU) No 528/2012 of the European Parliament and of the Council, until completion of the programme for the systematic examination of existing active substances, set out in Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for systematic examination of all existing active substances contained in the biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.

c) Royal Decree 3360/1983 of 30 November 1983 approving the Technical and Health Regulation on bleaches.

d) Royal Decree 1054/2002 of 11 October 2002 regulating the evaluation process for the registration, authorisation and making available on the market of biocidal products, without prejudice to the provisions of the second transitional provision of this Royal Decree and the third transitional provision.

e) Royal Decree 830/2010 of 25 June 2010 establishing the regulations regulating training in performing treatments using biocidal products.

f) Order SCO/317/2003 of 7 February 2003 regulating the procedure for the approval of training courses for staff involved in the hygienic and sanitary maintenance of the installations covered by Royal Decree 909/2001 of 27 July 2001, without prejudice to the provisions of the third transitional provision.

g) The Order of 24 February 1993 establishing the regulations governing the Official Register of Movements of Hazardous Pesticides.

h) The third additional provision of Royal Decree 742/2013 of 27 September 2013 establishing the technical and health criteria for swimming pools. The reason for this is that the training regulated under Royal Decree 742/2012 will be amended by this Royal Decree when it updates the new qualifications established by the Ministry of Education and also grants a period of six years to obtain them. It is therefore mandatory to include this express repeal.

Finally, this Royal Decree contains three final provisions.



- The first final provision establishes the title of competence, referring to the exclusive competence of the State for the bases and general coordination of health matters, and basic legislation on environmental protection, without prejudice to the autonomous communities establishing additional protection regulations.
- The second final provision grants the power of implementation to the heads of the Ministry of Health, the Ministry of Agriculture, Fisheries and Food, and the Ministry for the Ecological Transition and the Demographic Challenge.
- The third final provision refers to the *entry into force*, establishing its entry into force on the second day of January of the year following its publication in the Official State Gazette.

3. Main developments

In addition to introducing aspects dedicated to regulating the operation of the Official Register of Biocidal Products by updating existing national biocidal product regulations, it is worth highlighting the introduction of a system of offences and penalties applicable for non-compliance with the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council, in accordance with Article 87 of Regulation (EU) No 528/2012 of the European Parliament and of the Council. Clarification is provided of the transitional provisions governing national procedures in force during the periods specified in Article 89 of Regulation (EU) No 528/2012 of the European Parliament and of the Council, which have hitherto been dispersed across various pieces of legislation, and updates are made to the requirements for training in performing treatments using biocidal products in accordance with the new legislation on education.

III. LEGAL ANALYSIS

1. Legal basis and regulatory status

The regulatory status of the regulation is that of a royal decree, as its purpose is to repeal various regulations of the same status.

Although the second final provision of Royal Decree 1054/2002 of 11 October 2002 empowers the Minister for Health and Consumer Affairs, the Minister for Agriculture, Fisheries and Food and the Minister for the Environment, within the scope of their powers, to implement the provisions of that Royal Decree, as well as to lay down the rules necessary for updating the technical annexes contained therein and coordinating the requirements for entry in the registers of the Autonomous Communities, determining the conditions of manufacture, storage, making available on the market and application and the conditions and programmes of training courses for staff of biocidal service companies, the amendments required would have a direct impact on the articles of that Royal Decree. The amendments contained in the proposal would exceed the scope of the *regulatory authorisation* of the second final provision.

This draft Royal Decree repeals not only the aforementioned Royal Decree 1054/2002 of 11 October 2002 (with the exception of its second and third transitional provisions), but also Royal Decree 3349/1983 of 30 November 1983 (with the exception of Articles 1, 2, 4, 7 and 13 of that Regulation, which shall continue to apply as regards non-agricultural pesticides, in compliance with Article 89 of Regulation (EU) No 528/2012 of the European Parliament and of the Council, until the end of the programme for the systematic examination of existing active substances, set out in the Regulation on the Review Programme) and Royal Decree 830/2010 and others and it is therefore appropriate to draw up this new Royal Decree.

2. Consistency with the Spanish legal system

The proposal is a technical and health regulation adopted within the regulatory framework of:



1. Law 14/1986 of 25 April 1986, the General Health Law, which established the obligation of public health administrations to focus their actions primarily on the promotion of health and the prevention of diseases (Article 3).

2. Law 33/2011 of 4 October 2011, the General Public Health Law, which imposes on public administrations, within the scope of their competences, the duty to protect the health of the population through activities and services that act on the risks present in the environment and in food, for which purpose services and activities shall be developed to manage health risks that might affect the population (Article 27(2)).

This regulation complements Regulation (EU) No 528/2012 of the European Parliament and of the Council.

3. Consistency with the legal order of the European Union.

This draft legislation is respectful of European Union law since it merely brings the national legislation in force into line with the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

The repeal of Royal Decree 1054/2002 is imposed by the repeal of Directive 98/8/EC repealed by the Regulation itself. In accordance with the transitional period laid down in Article 89 of the Regulation, the national registers established in Royal Decree 3349/1983 remain in force until the completion of the Review Programme set out in the Regulation, as well as the notification system established in the transitional provision of Royal Decree 1054/2002.

Furthermore, in accordance with Article 87 of Regulation (EU) No 528/2012 of the European Parliament and of the Council, the system of offences and penalties set out in Royal Decree 1054/2002 of 11 October 2002 has been updated.

4. Entry into force and validity period

In its third final provision, *Entry into force*, the regulation provides for entry into force on the second day of January of the year following its publication in the Official State Gazette, with the exception of the provisions laid down in paragraph h) of the sole repealing provision, which shall take effect on the day following that of its publication in the Official State Gazette.

The third transitional provision grants a period of six months from the entry into force of this Royal Decree for the application of Article 13(2), relating to the registration of transactions involving the most dangerous biocidal products, given that, as a result of the amendment of the CLP Regulation (Commission Delegated Regulation (EU) 2023/1434 of 25 April 2023 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures), new hazard classes and categories were introduced that deserve consideration in the registration of transactions, such as endocrine disruptors, which were not included in the legislation currently in force.

The fourth transitional provision grants biocidal product application technicians a period of six years to obtain the new professional qualifications. The draft requires application technicians to obtain new qualifications or certification, so a generous time frame is necessary to ensure that they can continue to offer the service while obtaining the relevant qualifications or certification.

5. Repeal of regulations

This proposal repeals any provisions of a similar or lesser scope that oppose the provisions of this Royal Decree and, in particular:

a) Decree 2274/1965 of 15 July 1965 establishing new rules for pest control operations in public establishments;



b) Royal Decree 3349/1983 of 30 November 1983 approving the Technical and Health Regulations for the manufacture, making available on the market and use of pesticides, with the exception of Articles 1, 2, 4, 7 and 13 of said Regulations, which shall continue to apply as regards non-agricultural pesticides, pursuant to Article 89 of Regulation (EU) No 528/2012 of the European Parliament and of the Council, until completion of the programme for the systematic examination of existing active substances, set out in Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for systematic examination of all existing active substances contained in the biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council;

c) Royal Decree 3360/1983 of 30 November 1983 approving the Technical and Health Regulation on bleaches;

d) Royal Decree 1054/2002 of 11 October 2002 regulating the evaluation process for the registration, authorisation and making available on the market of biocidal products, without prejudice to the provisions of the second transitional provision of this Royal Decree and the third transitional provision;

e) Royal Decree 830/2010 of 25 June 2010 establishing the regulations governing training in performing treatments using biocidal products;

f) Order SCO/317/2003 of 7 February 2003 regulating the procedure for the approval of training courses for staff involved in the hygienic and sanitary maintenance of the installations covered by Royal Decree 909/2001 of 27 July 2001, without prejudice to the provisions of the third transitional provision;

g) the Order of 24 February 1993 establishing the regulations governing the Official Register of Movements of Hazardous Pesticides;

h) the third additional provision of Royal Decree 742/2013 of 27 September 2013 establishing the technical and health criteria for swimming pools.

IV. ADAPTATION OF THE REGULATION TO THE ORDER OF DISTRIBUTION OF POWERS

1. Titles of competence: identification of the prevalent title

This Royal Decree is issued pursuant to the provisions of Article 149(1)(16) and (1)(23) of the Spanish Constitution, which confer on the State the power to lay down basic rules and general coordination of health and basic legislation on environmental protection, without prejudice to the autonomous communities respectively laying down additional protection regulations, and to Article 40 of Law 14/1986 of 25 April 1986, the General Health Law, which makes the State Administration responsible, without prejudice to the powers of the autonomous communities, for implementing the following actions: determining, in general, the methods used for analysis and measurement and the technical requirements and minimum conditions, in the field of health control of the environment and the determination of the health requirements of technical and health regulations on foodstuffs, services or products directly or indirectly related to human use and consumption (Article 40(2)).

2. Most relevant issues of competence raised by the draft.

The regulation does not encroach on the competences of the autonomous communities, or the cities of Ceuta and Melilla.

3. Regional and local participation in preparing the draft.

The draft has been drawn up with the participation of the autonomous communities both in the initial phase, within the framework of the Environmental Health Committee of the Interterritorial Council of the National Health System, and in the public hearing and information procedure. Finally, the Spanish Federation of Municipalities and Provinces (FEMP) has been asked for a report.



V. DESCRIPTION OF THE PROCESS

In accordance with the provisions of Article 26(2) of Law 50/1997 of 27 November 1997 on the Government, the corresponding **prior public consultation** was conducted via this Ministry's website from 10 July to 25 July 2024. During this period, 13 contributions were received from:

- Spanish Confederation of Business Organizations (CEOE)
- MYLVA
- Spanish Marine Saltworks Association (SALIMAR)
- Spanish Business Association of the Animal Health and Nutrition Industry (VETERINDUSTRIA)
- Catalan Association of Environmental Health Companies (ADEPAP)
- Association for Health Self-Care (ANEFP)
- Association of Detergent and Cleaning, Maintenance and Related Product Companies (ADELMA)
- Professional Association of Application Technicians (APTA)
- National Federation of Associations of Manufacturers and Distributors of Disinfectant Products (FEDESLIM)
- National Cleaning Associations, Federations and Companies (AFELIN)
- Canary Islands Health Service, Directorate-General for Public Health
- GRAPHENTOWER
- LStyker Iberia, S.L.

The contributions have mainly focused on the following.

- The training required to perform treatments with biocidal products, depending on the user profile and product types. This requirement is addressed in Chapter IV of the draft legislation, clarifying the training required for application technicians (specialist professionals) according to the type of product, adapted to the new regulations published by the Ministry of Education, Vocational Training and Sports. Training requirements for technical managers are also regulated. Furthermore, the definitions of users in Royal Decree 830/2010 of 25 June 2010 have been incorporated into this draft Royal Decree.

- Ensuring that biocidal products are made available on the market according to the type of user or training required to apply them. In this regard, Article 9 of the draft legislation addresses the conditions for making available biocidal products on the market, laying down different measures for making the biocidal product available on the market in such a way that it is accessible only to the user for whom it is authorised.

- Correctly defining the authorised uses, categories of users and modes of use of biocidal products. In this respect, it should be noted that the reference legislation in the field of biocidal products is Regulation (EU) No 528/2012, which is directly applicable in all Member States and which regulates and harmonises at EU level the making available on the market and use of biocidal products. This regulatory draft is complementary to the Regulation and does not regulate those aspects already covered by the Regulation. In addition, the authorisation resolution for each biocidal product includes the authorised uses, the category of users for whom the biocidal product is intended and the instructions for use, among other information.

- Development towards a register covering all entities providing environmental health services, regardless of whether or not biocidal products are used. In this regard, this draft regulation only regulates



biocidal products as defined in Regulation (EU) No 528/2012, in order to update national aspects that are not included in EU legislation.

In accordance with the provisions of Article 26(6) of Law 50/1997 of 27 November 1997, **as part of the public information procedure, it was published on the Ministry of Health's website from 21 February to 13 March 2025**, with responses received from:

- Provincial Delegation of the Regional Ministry of Health, Albacete
- Asociación Biocidas Europa Consorcio (ABEC)
- Catalan Association of Environmental Health Companies (ADEPAP)
- ADIQUIMICA
- Association of Environmental Health Companies of the Community of Madrid (AESAM)
- Extremadura Association of Comprehensive Hygiene Companies (AEXEHI)
- Madrid Association of Disinfection Companies (AMED)
- Association for Health Self-Care (ANEFP)
- Spanish Aquaculture Business Association (APROMAR)
- Spanish Association of Manufacturers of Paints and Printing Inks (ASEFAPI)
- Association for Animal Health (ASEMAZ-ASA)
- Association of Pesticide Companies of the Basque Country (ASEPLA EUSKADI)
- Spanish Association of Beef Producers (ASOPROVAC)
- Centre for Environmental Health Studies (CEDESAM)
- General Council of the Official Colleges of Pharmacists (CGCOF)
- Agri-food Cooperatives of Spain
- COSEMAR OZONO
- ECOPLAGAS DEL MEDITERRÁNEO
- Federation of Interior Environmental Quality Companies (FEDECAI)
- Canary Islands Health Service
- OZONO ESPAÑA
- PID MEDIOAMBIENTAL
- PREVENCIÓN BIO AMBIENTAL
- Spanish Marine Saltworks Association (SALIMAR)
- Subdirectorato-General for Public Health of the Madrid Health Autonomous Body (Madrid City Council)
- Urdí-Solé & Associats, S.L. (US SOLUTIONS)

Likewise, the organisations or associations identified as most relevant to the sectors affected by the proposed amendment have been approached directly for their opinions:

- Association of Detergent and Cleaning, Maintenance and Related Product Companies (ADELMA)



- National Association of Environmental Health Companies (ANECPLA)
- Spanish Confederation of Business Organizations (CEOE)
- National Federation of Associations of Manufacturers and Distributors of Disinfectants, Cleaning Products and Related Items (FEDESLIM)
- Business Federation of the Spanish Chemical Industry (FEIQUE)
- National Association of Timber Protection Companies (ANEPROMA)
- Spanish Water Company Association (AQUA ESPAÑA)
- Federation of Professionals, Micro-Enterprises and SMEs in the Chemical Sector (QUIMELTIA)
- Spanish Business Association of the Animal Health and Nutrition Industry (VETERINDUSTRIA)

In accordance with Article 26(5) of Law 50/1997 of 27 November 1997 on the Government, the following reports have been received:

- In accordance with the provisions of Article 26(5), fourth paragraph, of Law 50/1997 of 27 November 1997, report of the General Technical Secretariat for the following ministries:
 - Ministry of Health, dated 19 November 2025;
 - Ministry of Agriculture, Fisheries and Food, dated 18 March 2025;
 - Ministry for the Ecological Transition and the Demographic Challenge, dated 24 April 2025.
- In accordance with the provisions of Article 26(5), first paragraph, of Law 50/1997 of 27 November 1997:
 - Ministry of Education, Vocational Training and Sports, dated 7 March 2025;
 - Ministry of Economy, Commerce and Business, dated 2 April 2025;
 - Ministry of Industry and Tourism, dated 11 March 2025;
 - Ministry of Labour and Social Economy, dated 11 March 2025;
 - Ministry of Defence, dated 6 March 2025;
 - Ministry of Social Rights, Consumer Affairs and Agenda 2030, dated 10 March 2025;
 - Ministry of Finance, dated 20 March 2025.
- Report of the Ministry of Territorial Policy and Democratic Memory (Article 26(5), sixth paragraph, of Law 50/1997 of 27 November 1997), received on 5 March 2025.
- Report of the Environmental Advisory Council provided for in Article 19(2)(a) of Law 27/2006 of 18 July 2006 regulating the rights of access to information, public participation and access to justice in environmental matters (requested on 25 April 2025).
- Report of the Office for Coordination and Regulatory Quality of the Ministry of the Presidency, Justice and Relations with the Courts (Article 26(9) of Law 50/1997 of 27 November 1997), reiterated on 25 April 2025.

The draft has also been the subject of a report by:

- the Spanish Agency for Medicinal Products and Medical Devices (AEMPS), received on 28 March 2025;



- the National Institute of Toxicology and Forensic Sciences (Ministry of the Presidency, Justice and Relations with the Courts), received on 1 April 2025;
- the Interministerial Commission for Food Management (**pending**);
- the Council of Consumers and Users (CCU), received on 10 March 2025;
- the Spanish Data Protection Agency, received on 20 May 2025.

Reports are also collected from the autonomous communities and the cities of Ceuta and Melilla, through the Technical Secretariat of the Interterritorial Council of the National Health System, as well as a report from the Interterritorial Council of the National Health System and its Advisory Committee. On 20 February 2025, a report was also requested from the Spanish Federation of Municipalities and Provinces (FEMP).

All of the above, together with the relevant responses, are contained in separate reports attached to this Regulatory Impact Analysis Report.

Procedure for the provision of information in the field of technical standards and regulations and of rules on information society services, provided for in Directive 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, as well as in Royal Decree 1337/1999 of 31 July 1999, which incorporates this directive into the Spanish legal system. (**pending**).

Pursuant to the provisions of Article 22(2) and (3) of Organic Law 3/1980 of 22 April 1980 on the Council of State, the opinion of the Council of State will be requested. (**pending**).

VI. IMPACT ANALYSIS

1. Economic impact

a) Overall economic impact

The analysis was carried out pursuant to Article 26(3)(d) of Law 50/1997 of 27 November 1997 on the Government and Article 2(1)(d)(1) of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report. In principle, this draft Royal Decree updates the general conditions under which biocidal products are manufactured, packaged, stored, made available on the market and used, the regulation of which was established in Decree 3349/1983 of 30 November 1983, which approves the Technical and Health Regulations for the manufacture, making available on the market and use of pesticides.

Records of non-agricultural pesticides are maintained by the relevant ministerial departments in accordance with their powers, as provided for in Article 4(1) of the aforementioned Technical Health Regulations, while the biocidal active substances are being evaluated in the Review Programme. Once approved, biocidal products must be registered in the Official Register of Biocidal Products.

With this regulation, the Official Register of Movements of Biocidal Products, which identifies the biocidal products that must be the subject of specific controls, has been replaced. The control of these products was determined by their hazardousness, toxic and highly toxic categories, in accordance with Royal Decree 255/2003 of 28 February 2003 approving the Regulation on classification, packaging and labelling of dangerous preparations. This regulation implements a traceability system for the most toxic biocidal products referred to in Article 13(1), which replaces the Official Register of Movements of Biocidal Products.

The training requirements for technicians applying biocidal products for use by specialist professionals, which were already established in Royal Decree 830/2010, are updated in accordance with the new training



requirements established by the Ministry of Education and Vocational Training in Royal Decree 1157/2024 of 19 November 2024, establishing the intermediate vocational training qualification of Technician in Applied Environmental Health, sets out the basic aspects of the curriculum and the C, B and A grades included in this qualification.

And the penalty regime applicable in the case of offences infringing the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council and this draft Royal Decree is hereby established.

In view of the above, it is considered that this draft Royal Decree updates the national legislation on biocidal products and that it is issued in complement to Regulation (EU) No 528/2012 of the European Parliament and of the Council, and does not have a significant overall economic impact greater than the previous regulations that it repeals.

b) Effects on competition

This draft does not have an effect on competition, since it does not limit the number or variety of operators or reduce the incentives of operators or their ability to compete.

2. Budgetary impact

The analysis was carried out pursuant to Article 26(3)(d) of Law 50/1997 of 27 November 1997 on the Government and Article 2(1)(d)(1) of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report.

In relation to the *General State Budget*. With regard to the Ministry of Health, there are no direct or indirect associated costs for those activities that fall within the scope of the Directorate-General for Public Health and Health Equity. The situation is the same in the Ministry of Agriculture, Fisheries and Food and the Ministry for the Ecological Transition and the Demographic Challenge, which are in turn responsible for administrative procedures relating to biocidal products.

With respect to *the regional budgetary impact*, the activities of the competent public health authorities in relation to the monitoring and control of activities associated with the manufacture, making available on the market, storage and improper use of biocidal products have not significantly changed in relation to the current legislation.

The approval of this draft Royal Decree will not entail any additional economic cost for the health authorities in performing official controls to ensure compliance with the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council and this regulation.

3. Analysis of administrative burdens

The analysis has been carried out pursuant to Article 26(3)(e) of Law 50/1997 of 27 November 1997 on the Government and Article 2(1)(e) of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report. The adoption of this regulation would not result in any change in administrative burdens, which would remain at the same level as those currently assumed for the application of Royal Decree 3349/1983 of 30 November 1983, which approves the Technical and Health Regulations for the manufacture, making available on the market and use of pesticides, Royal Decree 1054/2002 of 11 October 2002 regulating the evaluation process for the registration, authorisation and making available on the market of biocidal products and Royal Decree 830/2010 of 25 June 2010 establishing the regulations governing training in performing treatments using biocidal products.

4. Gender impact

As provided for in Article 26(3)(f) of Law 50/1997 of 27 November 1997 and Article 19 of Organic Law 3/2007 of 22 March 2007 on the effective equality of women and men, this report must contain a reference to the gender impact, which will analyse and assess the results that may ensue from the adoption of the regulation from the perspective of eliminating inequalities and its contribution to achieving the



objectives of equal opportunities and treatment between women and men, based on the indicators for the initial situation, for the forecast results and for the forecast impact.

In accordance with the provisions of Article 2(1)(f) of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report, this report must analyse and assess the results that may ensure from the adoption of the draft from the perspective of eliminating inequalities and its contribution to achieving the objectives of equal opportunities and treatment between women and men, based on the indicators for the initial situation, for the forecast results and for the forecast impact, as set out in the Methodological Guide.

In turn, in accordance with Article 19 of Organic Law 3/2007 of 22 March 2007 on effective equality between women and men, this draft Royal Decree, when submitted to the Council of Ministers, must include a report on its gender impact.

It is therefore appropriate to divide this gender impact analysis into the following sections:

1.º Identification of the equal opportunities objectives that apply: the draft Royal Decree has no impact on equal opportunities as its primary objective is to protect the population from possible risks arising from the making available on the market and use of biocidal products. For this reason the draft has no impact on gender, since its implementation affects women and men equally.

2.º Gender impact analysis:

- Description of the initial situation.

The draft Royal Decree has no gender impact, since, as has been indicated, it seeks only to protect the population from possible risks arising from the making available on the market and use of biocidal products.

The starting point for this measure is not a situation of pre-existing discrimination, as it aims to protect people's health by establishing specific conditions for the authorisation, manufacture, packaging, making available on the market, storage and use of biocidal products on national territory.

- Expected results: no gender impact is expected; this draft Royal Decree seeks only to protect the population from possible risks arising from the manufacture, making available on the market and use of biocidal products on national territory.

- Gender impact assessment: the gender impact of the draft Royal Decree, in line with the above, is zero.

5. Impact on children and adolescents

The analysis is carried out in accordance with the provisions of Article 22 quinquies of Organic Law 1/1996 of 15 January 1996 on the Legal Protection of Minors, partially amending the Civil Code and the Civil Procedure Act, and with Article 2(1)(f) of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report.

In the light of the above, it is concluded that this regulation has no impact on children and adolescents.

6. Impact on the family

The analysis has been carried out in accordance with the tenth additional provision of Law 40/2003 of 18 November 2003 on the Protection of Large Families and with Article 2(1)(f) of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report.

In light of the above, it is concluded that this regulation has no impact on the family.

7. Climate change impact

Assessment of the climate change impact is based on Article 26(3)(h) of Law 50/1997 of 27 November 1997 on the Government, the amendment made by the fifth final provision of Law 7/2021 of 20 May 2021



on climate change and energy transition, which must be assessed in terms of mitigation and adaptation, and Article 2(1)(g) of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report.

The impact in terms of mitigation can be considered low or practically nil, as it does not entail a reduction in greenhouse gas (GHG) emissions.

In terms of adaptation to climate change, the effect of the proposed measures can be considered positive, since the monitoring obligations imposed in respect of the manufacture, storage, making available on the market and use of biocidal products, as well as the traceability record for the most dangerous biocidal products, entail a positive impact on the management of these products and their impact at an environmental level.

8. Other impacts

a) Environmental impact

The analysis was carried out in accordance with Article 26(3) of Law 50/1997 of 27 November 1997 on the Government and Article 2(1)(g) of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report. The environmental impact of this regulation can be considered positive, as it establishes conditions for the storage of biocidal products that guarantee their safe preservation and prevent any accidental leaks, spills or discharges that might occur. Furthermore, under storage conditions, biocidal products must comply with the provisions of the Resolution on Registration in the Official Register of Biocidal Products, the label and safety data sheet of the biocidal product being correctly identified and kept in their original packaging at all times.

This regulation is ultimately intended to ensure the protection of human health, animal health and the environment.

In order to achieve a high level of protection for human and animal health and the environment, active substances with the worst hazard profiles should not be approved for use in biocidal products, except in specific situations, such as those in which approval is justified on the grounds that the risk of exposure to the substance is negligible, on grounds relating to human or animal health or the environment, or on the grounds that it entails the non-approval of disproportionate negative effects on society. When deciding whether such active substances can be approved, the availability of sufficient suitable alternative substances or technologies must also be taken into account.

b) Impact on equal opportunities. Impact on persons with disabilities

This was assessed in accordance with the fifth additional provision of Law 26/2011 of 1 August 2011 on regulatory adaptation to the International Convention on the Rights of Persons with Disabilities, Article 26(3) of Law 50/1997 of 27 November 1997 on the Government and Article 2(1)(g) of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Analysis Report.

In light of the above, it is concluded that the measure has no impact on equal opportunities and will not have any impact on persons with disabilities.

c) Impact on health

This was assessed in accordance with Article 26(3) of Law 50/1997 of 27 November 1997 on the Government. The impact on health is positive, as it implies an improvement in the control of activities associated with the manufacture, making available on the market and use of biocidal products and, consequently, in protection of the health of the population.



VII. EX POST EVALUATION

It is not considered that this regulatory draft need be subject to implementation analysis.



VIII. SME TEST

DRAFT ROYAL DECREE /2025 OF XX XXXX REGULATING THE REGISTRATION AND CONDITIONS FOR THE AUTHORISATION, MANUFACTURE, MARKETING AND USE OF BIOCIDAL PRODUCTS

IDENTIFICATION OF THE POPULATION OF COMPANIES AFFECTED

1. Estimate of the number of companies in the sector concerned and their turnover, differentiating them by size:

Companies by size	No of companies (September 2025)
SME (0-249 employees)	2 948 994
SME with no employees	1 622 032
SME with employees (1-249 employees)	1 326 962
Micro-enterprises (1-9 employees)	1 124 068
Small enterprises (10-49 employees)	174 481
Medium-sized (50-249 employees)	28 413
Large enterprises (\geq 250 employees)	5 959
Total number of companies	2 954 953

Source: SME figures (Ministry of Industry, Trade and Tourism).¹

2. Estimated number of workers employed in SMEs in the sector: 11 379 188 (SMEs) and 7 142 882 (LEs) workers.

Remarks: at national level, the number of companies stood at 2 954 953. It should be borne in mind that, apart from the making available on the market, the use of biocidal products affects companies in all production sectors. The resulting heterogeneity means that it is not feasible to make a brief approximation for the total number of companies, by sectoral distribution.

CONSULTATION OF THE SECTOR CONCERNED

3. Have SMEs in the sector concerned or the business associations representing them been consulted on the design of the regulation and regulatory options before starting the process?

YES

4. During the hearing process, will at least those business associations representing the majority of SMEs in the affected sector be consulted?

YES

Remarks: ---

ASSESSMENT OF THE IMPACT ON SMES

5. Have the administrative burdens arising from compliance with the proposed measures been quantified?

NO

6. Have the most relevant financial costs or substantive costs of the proposed regulation been quantified?

¹ <https://industria.gob.es/es-es/estadisticas/paginas/estadisticas-y-publicaciones-sobre-pyme.aspx>



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NO

7. Has it been ensured that the costs incurred for SMEs do not entail competitive disadvantages in relation to larger companies?

NO

8. Has it been ensured that SMEs can operate under conditions of fair competition in the market?

YES

Remarks: The draft royal decree aims to update aspects of the current national legislation on biocidal products in order to bring it into line with the current requirements on the making available on the market and use of biocidal products imposed by Regulation (EU) No 528/2012, as well as the distribution of powers and the updating of the legislation on education in relation to the training needed to perform treatments using biocidal products, thus being complementary to that Regulation, without entailing significantly higher costs than at present or greater administrative burdens.

ASSESSMENT OF SPECIFIC MEASURES FOR SMES

9. Has any option been assessed that simplifies compliance with the regulation for smaller companies, or makes it more flexible for them, while achieving the public goals pursued?

YES

Some examples are:

- a. temporary exemptions or longer transitional periods;
- b. temporary or partial exemptions;
- c. reductions or discounts on fees and direct financial aid;
- d. simplification of information obligations;
- e. information campaigns, user guides, specific training, user support or other measures to improve access to information;
- f. other measures that particularly benefit SMEs.

10. Have any of these more flexible regulatory options for SMEs been adopted in the regulatory proposal?

NO

11. Has the proposal been drafted in simple language that is comprehensible to a person without specific legal training?

YES

12. Does it contribute to simplifying the regulatory framework for the sector in order to make it more accessible?

YES



DRAFT ROYAL DECREE /2025 OF XX XXXX REGULATING THE REGISTRATION AND CONDITIONS FOR THE AUTHORISATION, MANUFACTURE, MARKETING AND USE OF BIOCIDAL PRODUCTS

Remarks: It should be noted that, although a more flexible regulatory option for SMEs has not been adopted in the current regulatory proposal, such options were already provided for prior to it, deriving from the direct application of Article 81 of Regulation (EU) No 528/2012, whereby specialist advice is provided, particularly to SMEs, through the biocidal products technical assistance service - Helpdesk.

IX. ANNEX

- Report on the contributions received from interested parties during the public hearing and information phase.
- Report on the contributions of the autonomous communities.
- Report on the contributions of the ministries.