# DRAFT ROYAL DECREE REGULATING THE REGISTRATION AND CONDITIONS FOR THE AUTHORISATION, MANUFACTURE, MARKETING AND USE OF 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 ('the Directive'), initiated regulation at EU level of products intended to control harmful organisms, structuring them into four groups (disinfectants, preservatives, pest control and others) and established different authorisation procedures for these products. The aforementioned Directive was transposed into the Spanish legal system through 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.

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 of 22 May 2012 concerning the making available on the market and use of biocidal products ('the Biocidal Products Regulation'), which introduced new authorisation procedures and updated the existing ones in light of scientific and technical advances.

Notwithstanding the direct application of the Biocidal Products Regulation, Royal Decree 1054/2002 of 11 October 2002 remains in force as regards 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 Logbook for Movements of Biocidal Products and the training of application technicians.

The evolution of the implementation of the mandates of the Biocidal Products Regulation, in particular the approval of active substances with biocidal action, makes it necessary to update all those aspects that remain regulated by Royal Decree 1054/2002 of 11 October 2002.

Along the same lines, it is necessary to update the general conditions under which biocidal products are manufactured, stored, made available on the market and used, including old non-agricultural pesticides whose regulation was established 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.

Another aspect included in Royal Decree 1054/2002 of 11 October 2002 is that of infringements and penalties, which is also updated in this regulation, in order to ensure compliance with the obligations arising from the Biocidal Products Regulation in accordance with Article 87 thereof.

At this point, it should be clarified that the terminology imposed by the Directive and the Biocidal Products Regulation may cause confusion when combined with the terms used in national legislation, namely Royal Decree 3349/1983 of 30 November 1983. For this reason, it is appropriate to clarify the terms used in this Royal Decree. Thus, the term biocidal product is defined in the Biocidal Products Regulation, and includes those previously referred to as non-agricultural pesticides, which are the subject of Royal Decree 3349/1983 of 30 November 1983. The term 'non-agricultural pesticides' is used only to define products registered in accordance with

national rules, which are applicable under Article 89 of the Biocidal Products Regulation, and which allow Member States to continue with their usual practice until the active substances contained in them are approved at EU level in accordance with the Review Programme approved by 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 biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.

In Spain, biocidal products have been subject to registration in various Official Pesticide Registers managed by the relevant ministerial departments in accordance with their powers, as provided for in Article 4(1) of the Technical and Health Regulations.

The approach of this original fragmented register, which was the precursor to the current Official Register of Biocidal Products, was modified by Royal Decree 1054/2002 of 11 October 2022, 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 to the Official Register of Biocidal Products is being carried out gradually, starting with the launch of the EU procedures for the authorisation of biocidal products in accordance with the Directive, and subsequently the Biocidal Products Regulation, and ending with the completion of the Review Programme for biocidal active substances, since all of them will have been assessed, whether or not they will be included in the European Union list as provided for in Article 9 of the Biocidal Products Regulation. Once biocidal active substances have been approved and included in the Union list, biocidal products from the different national registers must be transferred to be authorised and registered in the Official Register of Biocidal Products.

On the other hand, it is necessary to address the update of Royal Decree 830/2010 of 25 June 2010, which establishes the regulations governing training in performing treatments using biocidal products, to include other professional qualifications that have recently appeared that are related to the control of harmful organisms, as well as other legislative developments in the field of education.

In turn, for security reasons and bearing in mind the availability of in-house technical managers, an exception must be made regarding staff training in the application of biocidal products in facilities owned or under the supervision or control of the Ministry of Defence.

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 the registration of each operation. 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 the 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, repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. It is therefore appropriate to align the hazard classes according to that Regulation. In addition, the current approach adapted to new technologies ensures better traceability of the supply chain of products made available on the market, 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; it is therefore appropriate to replace one system with another.

Finally, bearing in mind that the definition of biocidal products in the Biocidal Products Regulation also includes the intended use of the biocidal product, and in order to ensure adequate protection of human health, animals and the environment, it is necessary to prevent any product intended for non-biocidal uses that contains any of the active substances approved in accordance with the aforementioned regulation from displaying on its label any biocidal claim included in the list of types of biocidal product set out in Annex V to the Biocidal Products Regulation.

In turn, any national regulations that conflict with the regulation should be repealed, as is the case with Royal Decree 3360/1983 of 30 November 1983, which approves the Technical and Health Regulations on Bleaches.

This Royal Decree complies with the principles of good regulation referred to in Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations. Thus, 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. It meets these criteria by adapting and updating the national regulatory framework on biocidal products to ensure full consistency with the Biocidal Products Regulation and the training requirements for personnel performing biocidal treatments. It also incorporates a clear and systematic penalty regime that makes it possible to ensure effective compliance with the established obligations, thus strengthening the protection of human and animal health and the environment. The legislation complies with the principle of proportionality as it contains rules that are essential and proportionate to achieving the objectives set out, given that most of the provisions contained in the legislation involve updating existing national legislation on biocidal products, and this legislation is complementary to the Biocidal Products Regulation, which is directly applicable in all Member States. Moreover, it improves legal certainty by updating the national legislation, reinforcing its clarity and adapting it to the current EU context. Finally, in accordance with the principle of efficiency, the regulation does not create new administrative burdens for citizens. On the contrary, it streamlines administrative procedures and promotes safer and more effective use of biocidal products.

In compliance with the principle of transparency, prior to the drafting of the Royal Decree, a public consultation was conducted, in accordance with Article 26(2) of Law 50/1997 of 27 November 1997 on the Government. Moreover, the drafting stage also included the public information and hearing processes for the sectors potentially affected and consultation of the autonomous communities and the cities of Ceuta and Melilla, as well as local governments through the Spanish Federation of Municipalities and Provinces. In addition, reports were issued by the Interministerial Commission for Food Regulation, the Consumer and User Council, the Ministerial Commission for Digital Administration of the Ministry of Health, the Spanish Agency for Medicines and Medical Devices, the National Institute of Toxicology and Forensic Sciences, and the Environmental Advisory Council.

Finally, this provision has undergone the 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 (EU) 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, and that set out in Royal Decree 1337/1999 of 31 July 1999 regulating the transmission of information in the field of technical standards and regulations and of rules on information society services, and incorporating this Directive into the Spanish legal system.

This Royal Decree is issued under Article 149(1)(16) and (23) of the Spanish Constitution, which confer on the State powers in matters relating to the basic framework and general coordination of healthcare, and basic legislation on environmental protection, respectively, without prejudice to the autonomous communities' power to establish additional rules of protection. Accordingly, at the proposal of the Minister for Health, the Minister for Agriculture, Fisheries and Food and the Minister for the Ecological Transition and the Demographic Challenge, with the prior approval of the Minister for Digital Transformation and the Civil Service, in accordance with the Council of State and following consideration by the Council of Ministers at its meeting on XXXXX,

THE FOLLOWING IS DECREED:

CHAPTER I

## General provisions

Article 1. *Purpose and scope of application.*

1. The aim of this Royal Decree is to regulate:

a) specific conditions for the manufacture, packaging, storage, making available on the market 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 the powers derived from the implementation at national level of the Biocidal Products Regulation;

e) the system of infringements and penalties applicable for non-compliance with the provisions of the Biocidal Products Regulation and this Royal Decree;

f) the transitional provisions governing national procedures in force during the periods specified in Article 89 of the Biocidal Products Regulation.

2. This provision applies to biocidal products that are regulated by the Biocidal Products Regulation and is complementary to that Regulation.

3. Facilities whose activity is devoted to the manufacture of biocidal products intended exclusively for export to countries outside the European Union are excluded from the scope of application.

4. This Royal Decree shall not apply to antiseptics intended for preoperative surgical use and the disinfection of injection sites, as these are considered medicinal products and must comply with the provisions of their specific legislation.

Article 2. *Definitions.*

1. Without prejudice to the definitions provided for in other legislation and applicable to them, the definitions set out in Article 3 of the Biocidal Products Regulation shall apply. In addition, in relation to evaluation and authorisation under the Official Register of Biocidal Products and other aspects regulated in this Royal Decree, the following definitions shall apply.

a) Manufacturing: production or obtaining of biocidal products in industrial facilities.

b) Storage: activity exclusively involving the stockpiling of biocidal products in premises or sites owned, rented or otherwise made available.

c) Packaging: the procedure whereby a biocidal product is placed in a container or packaging.

d) Specialised professional personnel: user category for personnel engaged in the application of treatments with biocidal products, who have accredited their training in accordance with Article 16. That user shall be included in the authorisation of the biocidal product where so determined by the competent authority. This role is comparable to that of biocidal treatment application technician.

e) Professional personnel: user category for personnel who, in their field of work (not dedicated to treatment using biocidal products), use biocidal products during their working day when they are necessary for their professional activity and who do not have the accreditation indicated in the previous definition. Professional personnel have some knowledge and skills in the handling of chemicals, and can correctly use certain personal protective equipment (PPE). That user shall be included in the authorisation of the biocidal product where so determined by the competent authority.

f) General public: category of user applying biocidal products in the context of their private life and within the domestic sphere. That user shall be included in the authorisation of the biocidal product where so determined by the competent authority. This role is comparable to that of non-professional personnel.

g) Technical manager of biocidal services: person responsible for diagnosing the situation, carrying out the risk assessment, planning and evaluating the treatments, as well as supervising the possible risks involved and defining the necessary measures to be taken to protect people, the environment and the surroundings, in accordance with Article 17. In addition, they shall be responsible for defining the conditions under which the treatments must be performed, as well as for applying the control and verification measures for these treatments, and for signing the certificate for the biocidal service provided.

h) Biocidal service: entity that designs and performs treatments to control harmful organisms in which biocidal products are used by specialised professionals. It can be performed for third parties or on a corporate basis. The service will have a technical manager and treatment application technicians, both with the required training.

i) Biocidal service on a corporate basis: a biocidal service belonging to the entity itself that performs treatments in its own facilities, spaces, premises or means of transport when these are publicly accessible. The service will have a technical manager and treatment application technicians, both with the required training.

j) Biocidal establishments: companies, premises or facilities where biocidal products are manufactured or packaged, and where biocidal products are stored or made available on the market.

k) Fixed treatment facilities: premises with fumigation chambers, immersion tanks and other fixed facilities intended for the application of biocidal treatments by application technicians under the supervision of the technical manager, both with the required training.

2. The competent authority for the registration of biocidal products shall adapt the industrial user category contained in the authorisations granted within the scope of the Biocidal Products Regulation to the categories of professional user, specialised professional user, or both, as defined in paragraph 1.

Article 3. *Competent authorities.*

With regard to compliance with the provisions of this Royal Decree, responsibility shall lie with the following.

1. The Ministry of Health, through the competent body:

a) to act as the competent receiving authority in the procedures established in the Biocidal Products Regulation;

b) to act as competent evaluating authority for applications for the approval and renewal of active substances, and for the authorisation, renewal and modification of biocidal products, as well as in other procedures indicated in the Biocidal Products Regulation, except for the part that corresponds to other departments by virtue of their powers in the matter, in accordance with the following paragraphs;

c) to coordinate actions with other units and bodies of the Public Administrations;

d) to assume, within Spanish territory, any other activity or function that the Biocidal Products Regulation confers on the competent authorities of the Member States, with the exception of those indicated in paragraphs (2) to (5), and without prejudice to the competences of the Ministry of Finance on the approval of public fees and prices, as regards the establishment of fees for the services provided as referred to in Article 80(2) of the Biocidal Products Regulation;

e) to authorise biocidal products intended to be made available and used on the national market;

f) to manage the Official Register of Biocidal Products referred to in Article 4;

g) to coordinate the projects emanating from the Subgroup of the Forum of the European Chemicals Agency (‘ECHA’) for the Biocidal Products Regulation with the autonomous communities and the cities of Ceuta and Melilla and, where appropriate, other ministerial departments, within the scope of their powers;

h) to act as the national focal point and to coordinate actions derived from the information provided by the National Monitoring, Inspection and Control Network and the Rapid Information Exchange System on Chemical Products;

i) to obtain from the competent authorities of the autonomous communities, the National Institute of Toxicology and Forensic Sciences, the Spanish Agency for Medicines and Medical Devices, the Ministry of Agriculture, Fisheries and Food, the Ministry for the Ecological Transition and the Demographic Challenge and other public or private bodies, the information necessary to comply with Article 65(3) of the Biocidal Products Regulation.

2. The Spanish Agency for Medicines and Medical Devices is responsible for issuing reports on the efficacy of biocidal products for human hygiene, repellents for human hygiene, and disinfectants for surfaces, materials, equipment and furniture in clinical and surgical environments.

3. The Ministry for the Ecological Transition and Demographic Challenge, through the Directorate-General for Environmental Quality and Assessment, shall act as the competent evaluating authority for matters relating to environmental protection.

4. The Ministry of Agriculture, Fisheries and Food, through the Directorate-General for Health of Agri-Food Production and Animal Welfare, shall issue a report on the efficacy and safety of biocidal products in relation to animal health.

5. The autonomous communities and the cities of Ceuta and Melilla:

a) to exercise market monitoring, inspection and official control of biocidal products within their territory;

b) to report incidents and non-compliance with the Biocidal Product Regulation identified in their territory that may have an impact on human and animal health and the environment;

c) to exercise, within the scope of their powers, the power to impose penalties;

d) to collaborate with the competent Ministries in disseminating information leading to an appropriate and responsible use of biocidal products;

e) to act as the competent authority for the official control of activities related to the ROESB;

f) to monitor the registration of biocidal product transactions within the scope of their powers.

## CHAPTER II

## **Register of Biocidal Products**

Article 4. *Official Register of Biocidal Products.*

1. The Official Register of Biocidal Products is the national and public register in which all biocidal products authorised to be made available on the market and used in the national territory are entered.

2. All biocidal products whose active substances are included in the EU List of active substances approved for the relevant product type shall be registered in the register.

Biocidal products whose active substances have not yet been approved, but which are included in the Review Programme referred to in Commission Regulation (EU) No 1062/2014 of 4 August 2014, shall comply with the provisions of the first and second transitional provisions of this Royal Decree.

Article 5. *Communications regarding registration.*

Communications from the competent authority responsible for registration with natural and legal persons shall, for the biocidal products referred to in paragraph (1), be carried out through the current version of the ECHA's 'Register for Biocidal Products' (R4BP) platform.

Article 6. *Making available on the market and use of biocidal products.*

1. The making available on the market of a biocidal product shall be subject to the authorisation and registration procedures laid down in the Biocidal Products Regulation and in the other European Union provisions implementing it.

2. Only biocidal products that comply with the provisions of the Biocidal Products Regulation and the provisions laid down in this Royal Decree and that have been previously authorised and registered in the Official Register of Biocidal Products or in one of the Official Registers of Non-Agricultural Pesticides referred to in the first transitional provision may be placed on the market and used in Spain.

3. Without prejudice to the provisions of the previous paragraph, biocidal products which are not subject to authorisation and registration may be made available on the market, following completion of the relevant administrative procedure, provided that notification has been given prior to their being made available on the market in accordance with the provisions of the second transitional provision.

4. Biocidal products must be made available on the market and used in accordance with the conditions contained in their authorisation decision and in the applicable legislation.

## CHAPTER III

## **Requirements for manufacturing, packaging, storage, making available on the market and use**

Article 7. *Official Register of Biocidal Establishments and Services (ROESB).*

1. Premises or facilities located on Spanish territory where biocidal products are manufactured, packaged, stored or made available on the market, as well as companies providing biocidal services as defined in the implementing legislation of the autonomous communities, must be entered in the ROESB of each autonomous community. This authorisation and registration shall not apply when there are specific regulations.

2. The ROESB shall be managed by the competent authority of the autonomous communities.

Article 8. *Conditions for the manufacture and storage of biocidal products.*

1. Without prejudice to environmental, industrial, labour or any other applicable legislation, the facilities where biocidal products are manufactured or packaged must have the appropriate means of production, analysis and control to ensure the quality of production and compliance with the requirements laid down in Article 65(2), second paragraph, of the Biocidal Products Regulation, and the provisions established in its implementation.

2. Without prejudice to the provisions of Royal Decree 656/2017 of 23 June, which approves the Regulation of Storage of Chemical Products (APQ) and its Complementary Technical Instructions of the Ministry f Industry and Energy MIE APQ 0 to 10, Law 31/1995 of 8 November 1995 on the Prevention of Occupational Risks, its implementing or supplementary provisions and any other applicable regulations, biocidal product warehouses must comply with the following requirements.

a) The layout, design, construction, location and size of premises for the storage of biocidal products shall be such as to ensure that they are properly maintained, taking into account the following.

1. They must be separated or isolated from the storage of foodstuffs, feed, dwellings or other living quarters; they must also be fitted with an enclosure system preventing access by persons not involved in the activity.

2. The materials and equipment shall be impermeable, and must not promote combustion or react with biocidal products.

3. They must maintain adequate lighting, ventilation, temperature and humidity conditions at all times.

4. They shall not be located near surface water bodies or water extraction wells, nor in areas susceptible to flooding in case of rising water.

5. They shall have adequate systems for the prevention of risks due to breakage and spillage, for detection and for personal and environmental protection, according to the hazard level of the biocidal product, and for the management of the waste generated.

6. They must have containers to store damaged packaging and empty packaging separately; these containers shall be different from those used to collect biocidal product residues or residues from any accidental spills that may occur.

7. They shall have a containment system for liquid products that prevents them from being taken outside.

8. They must be kept clean and in good condition.

9. The biocidal products referred to in Article 13(1) must be stored in spaces with safety measures that restrict access to these products exclusively to authorised persons.

b) The following must be complied with and taken into account in the storage conditions for biocidal products.

1. The information indicated in the decision to enter the biocidal product into the Official Register of Biocidal Products and on the label and safety data sheet of the biocidal product. Biocidal products must be correctly identified and kept in their original packaging at all times, or in containers or receptacles when the characteristics of the treatment require this and the conditions of authorisation so allow, and traceability must be guaranteed at all times.

2. Possible incompatibilities with other biocidal products, chemical products or substances, and materials, due to their physico-chemical characteristics as included in the authorisation decision, where applicable.

3. The distribution or stowage according to the hazard classes and categories of the stored biocidal products, in such a way as to maintain order and cleanliness.

3. Storage in dwellings, garages, any means of transport, and in transit areas or areas intended for other purposes is prohibited.

Article 9. *Conditions for the making available on the market of biocidal products.*

For biocidal products to be made available on the market, the following conditions must be met and taken into account.

a) In warehouses, premises and establishments where biocidal products are sold, they shall be kept in their original packaging, closed and sealed, with their original labelling.

b) Biocidal products made available on the market in establishments shall be stored and displayed for sale in spaces completely separate from those where feed or foodstuffs are stored.

c) In establishments where foodstuffs or animal feed are sold, the biocidal products referred to in Article 13(1) shall be stored and displayed in separate areas equipped with a closure system.

d) Personnel involved in the sale of biocidal products must provide users in the professional and specialised professional categories with all the information necessary for the correct handling and use of biocidal products, including at least the label, safety data sheet and authorisation decision for the biocidal product, given that the authorised uses and the risk mitigation measures to be taken into account are set out in these documents. At all times, the information shall correspond to that which is reflected in the relevant authorisation decision.

e) In establishments where biocidal products intended for use by the general public are made available on the market together with other products intended for professional or specialised professional use, the necessary measures must be put in place to ensure that the biocidal product is accessible only to the user for whom it is authorised.

f) When biocidal products intended for professional users are sold in establishments, the purchaser must, at the time of the first supply, provide proof of their professional status through a declaration of responsibility in order to obtain these products and use the biocidal product in the workplace. In this case, the establishment shall provide the corresponding safety data sheet as required under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, at the time of the first acquisition of the biocidal product and upon subsequent revisions thereof, together with the authorisation decision of the biocidal product. Annex I contains a declaration of responsibility template for the purchase of biocidal products for professional or specialised professional use.

g) Where biocidal products intended for users classified as specialised professionals are made available on the market in establishments, the purchaser shall, at the time of the first supply, ensure, by means of a declaration of responsibility, that they are purchased for the purpose of performing a treatment with biocidal products and that they have the necessary training. Where applicable, the establishment shall provide the corresponding safety data sheet as required under the REACH Regulation at the time of the first acquisition of the biocidal product and upon subsequent revisions thereof, together with the authorisation decision for the biocidal product. Annex I contains a declaration of responsibility template for the purchase of biocidal products for professional or specialised professional use.

h) Biocidal products intended to be made available on the market online, without prejudice to the general regulations applicable in this area, must comply with the advertising conditions set out in Article 72 of the Biocidal Products Regulation and Article 48 of Regulation (EU) No 1272/2008 of the European Parliament and of the Council of 16 December 2008. The information indicated on the internet portal must be in accordance with the authorisation decision. Persons responsible

for making biocidal products available on the market for professional or specialised professional use shall lay down the necessary requirements for their purchase to be restricted to such users. Prior to the completion of the purchase of the biocidal product, the purchaser must accept the conditions set out in paragraph (f) for professionals and in paragraph (g) for specialised professionals. Where applicable, the supplier shall provide the corresponding safety data sheet as required under the REACH Regulation at the time of the first purchase of the biocidal product and upon subsequent revisions thereof.

Article 10. *Labelling.*

1. The labelling of biocidal products must be expressed at least in the official Spanish language of the State.

2. Without prejudice to the provisions of Regulation (EU) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, during the period established in Article 89 of the Biocidal Products Regulation, the provisions of Article 69(2) of the Biocidal Products Regulation shall apply to biocidal products made available on the market within the national territory.

3. Without prejudice to the provisions of the applicable regulations, the labelling of a product intended for non-biocidal uses and containing any of the active substances approved or under review for biocidal use shall not refer to the uses listed in Annex V of the Biocidal Products Regulation.

Article 11. *Basic requirements of biocidal services to perform treatments with biocidal products.*

1. An initial diagnosis must be made by the technical manager of the biocidal service for treatments with biocidal products performed by specialised professional personnel on the basis of information collected during a prior inspection of the site (area, premises or facility) or object to be treated. This diagnosis will determine and justify the biocidal treatment to be performed. In turn, the technical manager must carry out a risk assessment and define the measures necessary for the protection of human, animal and environmental health.

2. Biocidal treatments shall be performed only if all necessary safety measures are taken before, during and after such treatments, where so specified in the conditions of use of the products, in order to avoid any direct or indirect adverse effect on human, animal and environmental health, in accordance with the risk assessment carried out.

3. During the application of a biocidal treatment, it is necessary to ensure that no persons other than those performing the treatment are present, that animals or non-target organisms are absent and that the safety period for biocidal products is respected, where so established by their authorisation and whenever deemed necessary, in the area where the application has been performed and throughout the area affected by the treatment.

4. Prior to performing the service, the biocidal service must provide the contracting party or client of the service, alongside a record of the dates of delivery and receipt, with documentation on the plan, programme or action with the control strategy to be implemented, including the necessary data, as well as the biocidal products to be used, sufficiently in advance to enable the safety measures indicated therein to be adopted.

5. At the end of the treatment, the biocidal service shall provide the contracting party, client or person designated by them with the documentation containing the certificate of the biocidal service performed in accordance with Annex II. This obligation shall not apply where there are specific regulations with respect to the template or certificate requirements of the biocidal service performed. Such documentation must be signed by the technical manager responsible for biocidal treatments, and the contractor or client of the service, or the person designated by them, must give their approval upon receipt of this information. In the case of documents in electronic format, the digital signature must be valid in accordance with the legislation in force. Only biocidal services that comply with the requirements of this Royal Decree and its implementing regulations may issue certificates for biocidal treatments performed.

6. Biocidal treatments will be subject to subsequent evaluation by the biocidal service to determine their effectiveness and, where appropriate, possible resistance, and to establish possible corrective measures if necessary.

Article 12. *Retention of the documentation of the activities carried out.*

1. Without prejudice to Article 65(2) of the Biocidal Products Regulation, entities performing manufacturing, packaging, storage and making available on the market activities and biocidal services falling within the scope set out in Article 1(2) must keep and make available to the competent authority, upon request, the following documentation, so that retrospective monitoring can be carried out at any time.

a) Registration of the entity or company in the ROESB of the relevant autonomous community, in compliance with Article 7.

b) Information relating to the authorisations of biocidal products in relation to the activities they carry out (manufacturing, packaging, storage or making available on the market): authorisation decision, labels, technical information and safety data sheets. The making available on the market of biocidal products intended for the general public user category is excluded from this obligation.

c) Accreditation of the training of personnel, as required in accordance with the current regulations in this regard in the field of education.

d) Documentation on the control of the activity and the actions of the biocidal service including:

1. situation diagnoses, planning and assessment of risks carried out;
2. service reports issued;
3. prior communications of the actions and precautionary measures to be adopted before, during and after the treatments;
4. continuous monitoring and control location plans;
5. records of incidents related to the activity being carried out;
6. accreditation of the technical manager and the application technicians.

e) Register of biocidal product transactions in accordance with the provisions of Article 13.

f) Maintenance plan for materials and equipment, in the case of entities that perform biocidal treatment activities, and records of related incidents.

2. This documentation must be available to the competent authorities for a period of at least five years.

Article 13. *Register of biocidal product transactions.*

1. The following categories of biocidal products classified in accordance with Regulation (EU) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 shall be monitored in the corresponding register of transactions.

a) Acute toxicity, categories 1, 2 and 3.
b) Specific target organ toxicity (STOT). Single exposure, category 1.
c) Specific target organ toxicity (STOT). Repeated exposure, category 1.
d) Carcinogenic, Mutagenic or Toxic for Reproduction (CMR), category 1A or 1B.
e) Respiratory sensitisation, category 1 and subcategories 1A and 1B.
f) Endocrine disruptors for human health and the environment, category 1.
g) Persistent, Bioaccumulative and Toxic (PBT) or very persistent and very bioaccumulative (vPvB).
h) Persistent, mobile and toxic (PMT) or very persistent and very mobile (mPmM).

2. The biocidal products referred to in paragraph 1 shall be made available on the market and applied under a traceability control system based on a register of transactions involving the acquisition, transfer or application of the biocidal products, which shall preferably be electronic and shall always be available to the competent authority.

The minimum information that must be included in the register is as follows.

a) Transaction type.
b) Transaction date.
c) Identification of the biocidal product: trade name, number in the Official Register of Biocidal Products, if applicable, and identifier of the biocidal active substance (EC number or CAS number), and manufacturing batch reference.
d) Quantity, fraction or subunits of the biocidal product subject to the transaction.
e) Identification of the supplier, recipient or client, and the ROESB.
f) Identification reference of the document evidencing the movement (invoice or delivery note, service certificate, etc.).

Transactions involving the sale of biocidal products intended for the general public are excluded from this obligation.

Article 14. *Export.*

Biocidal products intended exclusively for export to third countries must be clearly identified, packaged and labelled at all times in such a way as to ensure that the biocidal product will not be made available on the market or used within national or EU territory, and must be labelled with the words ‘for export’.

## CHAPTER IV

## **Training for performing biocidal treatments**

Article 15. *Types of biocidal products that require training in order to perform treatments.*

1. For the performance of treatments with biocidal products by users in the specialised professional user category for the biocidal product types defined in Annex V to the Biocidal Products Regulation indicated below, the training laid down in Article 16 shall be required.

a) Main group 1: Disinfectants

1. Product type 2 (PT 2): Disinfectants and algaecides not intended for direct application to humans or animals.
2. Product type 3 (PT 3): Veterinary hygiene.
3. Product type 4 (PT 4): Food and feed area.
4. Product type 5 (PT 5): Drinking water.

b) Main group 2: Preservatives

1. Product type 8 (PT 8): Wood preservatives.
2. Product type 11 (PT 11): Preservatives for liquid-cooling and processing systems, exclusively in facilities susceptible to proliferation of Legionella and other harmful organisms.

c) Main group 3: Pest control

1. Product type 14 (PT 14): Rodenticides.
2. Product type 15 (PT 15): Avicides.
3. Product type 16 (PT 16): Molluscicides, vermicides and products to control other invertebrates.
4. Product type 17 (PT 17): Piscicides.
5. Product type 18 (PT 18): Insecticides, acaricides and products to control other arthropods.
6. Product type 19 (PT 19): Repellents and attractants.
7. Product type 20 (PT 20): Control of other vertebrates.

d) Main group 4: Other biocidal products

Product type 22 (PT 22): Exclusively liquids for embalming.

2. Such training shall not be required for the application of biocidal products authorised for the general public user category or for the professional user category.

Article 16. *Minimum training of application technicians (specialised professional personnel) to perform treatments with biocidal products.*

Persons who have received the following training or certifications shall be authorised to apply the various biocidal treatments.

a) Holders of the Technician in Applied Environmental Health qualification, as established in the regulations governing it, may apply the following biocidal treatments: PT 2, 3, 4, 5, 8, 11, 14, 15, 16, 17, 18, 19 and 20.

b) Holders of the professional certificate (Grade C) in Pest and Harmful Organism Control Services, as established in the regulations governing it or the corresponding qualification, may apply the following biocidal treatments: PT 14, 16, 17, 18, 19 and 20.

c) Holders of the professional certificate (Grade C) in Hygienic and Sanitary Maintenance of Facilities Susceptible to the Proliferation of *Legionella* and Other Harmful Organisms, as

established in the regulations governing it or the corresponding qualification, may apply biocidal treatments: PT 11, 2, 4 and 5.

d) Holders of the professional certificate (Grade C) in Control of Harmful Organisms through Disinfection and Algaecidal Treatments, as established in the regulations governing it or the corresponding qualification, may apply biocidal treatments PT 2 (except in Legionella treatments provided for in paragraph (c), and in the maintenance of swimming pools provided for in paragraph (g)), Pt 3 and PT 4.

e) Holders of the professional certificate (Grade C) in Control of Birds Harmful to Human Activity, as established in the legislation governing it or the corresponding qualification, may apply the biocidal treatment PT 15.

f) Holders of the professional certificate (Grade C) in the Control of Organisms, including Insects, that Degrade or Alter Wood and its Derivatives, as established in the legislation governing it or the corresponding qualification, may apply the biocidal treatment PT 8.

g) Holders of the professional certificate (Grade C) for the Maintenance of Swimming Pools and other Aquatic Facilities, as established in the legislation governing it or the corresponding qualification, may apply the biocidal treatment PT 2 except in the disinfection processes and algaecide treatments provided for in paragraph (d).

h) Holders of the professional certificate (Grade C) in the Operation of Water Treatment Plants, established in Annex II to Royal Decree 1536/2011 of 31 October 2011 which establishes two professional certificates in the professional field of Safety and Environment, included in the National Catalogue of Professional Certificates or their corresponding qualification, may apply biocidal treatments PT 4 and 5.

i) Holders of the professional certificate (Grade C) in Thanatopraxy, established in the sole annex to Royal Decree 1535/2011 of 31 October 2011, which establishes a professional certificate in the professional field of Health, included in the National Catalogue of Professional Certificates or its corresponding qualification, may apply the biocidal treatment PT 22.

Article 17. *Functions and minimum training requirements for the technical manager of biocidal services.*

1. Biocidal services performing biocidal treatments for third parties on a corporate basis or in fixed installations for product types 2, 3, 4, 5, 8, 11, 14, 15, 16, 17, 18, 19 and 20 shall have at least one technical manager on their staff. In this case, holders of any of the following qualifications or certificates will be considered accredited to act as technical manager.

a) Professional Certificate in Service Management for the Control of Harmful Organisms (Level 3) (Royal Decree 624/2013 of 2 August 2013 establishing eight professional certificates in the Safety and Environment group included in the National Catalogue of Professional Certificates and updating the professional certificates established as Annex I to Royal Decree 1377/2009 of 28 August 2009 and as Annexes I and II to Royal Decree 1536/2011 of 31 October 2011) or its corresponding qualification.

b) Advanced Vocational Training Qualification in Chemistry and Environmental Health (Royal Decree 283/2019 of 22 April 2019 establishing the qualification of Senior Technician in Chemistry and Environmental Health and laying down the basic aspects of the curriculum).

c) University degree certifying the acquisition of appropriate skills and knowledge for the management of harmful organism control processes, related to environmental health or sanitary engineering.

2. The technical manager responsible for biocidal treatments shall assume the following functions.

a) Responsibility for carrying out the situation diagnosis before initiating any physical-chemical, chemical or biological treatment, justifying it where such diagnosis does not apply.

b) Responsibility for planning and evaluating treatments.

c) Responsibility for conducting risk assessments, supervising risk management and defining the necessary personal and environmental protection measures related to human and animal health and the environment. Responsibility for the communication of the risks inherent to the treatment.

d) Responsibility for complying with the technical obligations contained in the decision to enter the products in question into the Official Register of Biocidal Products or in the Official Register of Non-Agricultural Pesticides.

e) Responsibility for serving as the point of contact with the competent authorities in matters of a technical nature, without prejudice to the legal representation of the company, or delegating to another technical officer, if applicable.

f) Responsibility for ensuring that the application technicians have the required training, without prejudice to the responsibility of the owner of the biocidal treatment company.

g) In their actions, the technical manager for treatments with biocidal products shall take into account Integrated Control of Harmful Organisms strategies to ensure that the minimum necessary doses of biocidal products are used to achieve the desired effect, ensuring the protection of public health, non-target organisms, property and the environment and minimising the health impacts of harmful organisms and unwanted effects arising from the use of biocidal products.

3. The biocidal services referred to in paragraph (1) shall have a sufficient number of technical managers to ensure that the functions referred to in paragraph (2) are fulfilled in all biocidal treatments.

## CHAPTER V

## **Surveillance and control actions**

Article 18. *Exchange of information and alerts.*

The Ministry of Health shall provide the relevant ministerial departments and the competent authorities of the autonomous communities with guidelines, information or any other material at its disposal so that they may properly perform their functions in relation to the manufacture, import, making available on the market, storage and misuse of biocidal products.

The Ministry of Health and the competent authorities of the autonomous communities may exchange information through the National Network for the Monitoring, Inspection and Control of Chemical Products and the Rapid Information Exchange System on Chemical Products (SIRIPQ)

of the Directorate-General for Public Health and Health Equity of the Ministry of Health and the Regional Ministries of Health of the autonomous communities, as well as the EU's Information and Communication System for Market Surveillance (ICSMS).

Article 19. *Official Controls.*

1. The Ministry of Health will coordinate with the Ministry for the Ecological Transition and Demographic Challenge and the Ministry of Agriculture, Fisheries and Food, as well as with the relevant authorities of the autonomous communities, to ensure the proper exercise of their functions within the scope of their respective powers.

2. Official control programmes shall be established by the competent authorities of the autonomous communities in order to ensure compliance with the provisions of the Biocidal Products Regulation and this Royal Decree. The Directorate-General for Public Health and Health Equity shall coordinate the projects arising from the ECHA Forum Subgroup for the Biocidal Products Regulation.

3. The Public Health Committee of the Interterritorial Council of the National Health System shall establish the appropriate priorities with regard to the inspection, monitoring and control of biocidal products.

4. The competent authorities in non-health areas involved in the control of activities related to the application of the Biocidal Products Regulation shall coordinate with the health authorities to ensure compliance with the provisions of the legislation in force. The competent regional ministries for environmental issues in the autonomous communities must adequately monitor compliance with this Royal Decree in relation to persistent, bioaccumulative and toxic substances in order to avoid high risks to the environment, such as cases of secondary poisoning, due to the improper use of rodenticides, and shall coordinate with the Ministry for the Ecological Transition and the Demographic Challenge in the exercise of their respective powers.

5. The competent authorities shall adopt the necessary measures for the correct implementation of the recommendations contained in the final inspection reports resulting from the controls of the European Commission.

## CHAPTER VI

## **Penalty regime**

Article 20. *Parties responsible for infringements.*

1. Natural or legal persons who are found to be responsible for the administrative infringements regulated in this chapter may be sanctioned in accordance with the provisions of this Royal Decree.

2. Where compliance with the provisions of both the Biocidal Products Regulation and this Royal Decree falls to several natural or legal persons jointly, they shall be jointly and severally liable for the infringements and the penalties imposed, in accordance with the provisions of Law 40/2015 of 1 October 2015 on the Legal Regime for the Public Sector.

Article 21. *Infringements.*

1. Without prejudice to any other regulations that may apply, infringements committed against the provisions of the Biocidal Products Regulation and this Royal Decree shall be considered administrative infringements of health regulations, in accordance with the provisions of Chapter VI of Title I of Law 14/1986 of 25 April 1986, the General Health Law, and the other applicable provisions.

2. Actions and omissions that contravene the provisions of this article, as well as those that, where applicable, are established by the regional legislation implementing this Royal Decree, shall constitute infringements.

3. The infringements described in this Royal Decree are classified as very serious, serious and minor.

4. In any case, for the purposes of this Royal Decree, the following shall be considered to be very serious infringements.

a) The making available on the market and use of biocidal products without the authorisation granted in accordance with the Biocidal Products Regulation, or non-compliance with the conditions laid down in this Royal Decree for the biocidal products referred to in Article 89(2) of that Regulation, as provided for in Article 35(c)(1) of the General Health Law.

b) The manufacture and making available on the market of active substances that do not meet the requirements laid down in the Biocidal Products Regulation, unless it can be justified that they are intended exclusively for export to countries outside the European Union, as provided for in Article 35(C)(1) of the General Health Law.

c) The making available on the market and use of biocidal products without respecting the conditions of authorisation, including those relating to the composition and purity requirements of the active substances, as well as the labelling and packaging requirements, as provided for in Article 35(C)(1) of the General Health Law.

d) The making available on the national market of treated articles containing biocidal active substances that contravene the provisions of the Biocidal Products Regulation, as provided for in Article 35(C)(1) of the General Health Law.

e) The falsification of information necessary to comply with the obligations of the Biocidal Products Regulation, as well as its intentional concealment or alteration, as provided for in Article 35(C)(1) of the General Health Law.

f) The making available on the market of biocidal products prohibited or limited for a specific use other than that authorised, as provided for in Article 35(C)(1), as well as those ordered to be withdrawn from the market because they constitute an unacceptable risk to human or animal health or the environment, as provided for in Article 35(C)(2) of the General Health Law.

g) The use of biocidal products in applications, conditions or application techniques other than those authorised, as provided for in Article 35(C)(1) of the General Health Law.

h) Failure to comply with the measures adopted in application of the safeguard clause provided for in Article 88 of the Biocidal Products Regulation, as provided for in Article 35(C)(1) of the General Health Law.

i) Repeat commission of three infringements classified as serious within a period of five years, in accordance with Article 35(C)(8) of the General Health Law.

5. For the purposes of this Royal Decree, the following shall be considered serious infringements.

a) The making available on the market of biocidal products whose authorisation has expired, as provided for in Article 35(B)(4) of the General Health Law, unless a provisional authorisation has been granted in accordance with Articles 55 and 71 of the Biocidal Products Regulation.

b) Failure to comply with the obligations relating to the classification, packaging and labelling of biocidal products in accordance with Article 69 of the Biocidal Products Regulation, as provided for in Article 35(B)(1) of the General Health Law.

c) Failure to comply with the labelling requirements for treated articles that contravene the provisions of Article 58 of the Biocidal Products Regulation, as provided for in Article 35(B)(1) of the General Health Law.

d) The introduction onto the market of any product belonging to a family of biocidal products without prior notification at least 30 days in advance to the competent authorities that have granted authorisation for that family of biocidal products, as provided for in Article 35(B)(1) of the General Health Law.

e) The introduction of a biocidal product, authorised under the simplified authorisation procedure, onto the national market without prior notification from the authorisation holder to the competent authority, as provided for in Article 35(B)(1) of the General Health Law.

f) The failure to notify or unjustified delay in the notification by the authorisation holder to the competent authority in the case of an authorisation of any information relating to the authorised biocidal product or the active substances contained therein, which may affect the authorisation, where it is not appropriate to classify it as a very serious failure, as provided for in Article 35(B)(5) of the General Health Law.

g) The making available on the market and use of existing stocks of biocidal products outside the transition period established for their disposal, making available on the market and use as provided for in Article 35(B)(1) of the General Health Law.

h) The making available on the market and use of a biocidal product without obtaining the corresponding parallel trade permit, where appropriate, as provided for in Article 35(B)(1) of the General Health Law.

i) Failure by the holders to retain the information on the registers of biocidal products placed on the market for the period established in Article 68 of the Biocidal Products Regulation, as provided for in Article 35(B)(5) of the General Health Law.

j) Failure by manufacturers of biocidal products made available on the market to retain documentation, in paper or electronic format, relevant to the quality and safety of the biocidal product, in accordance with Article 65(2) of the Biocidal Products Regulation, as provided for in Article 35(B)(2) of the General Health Law.

k) The advertising of biocidal products that does not comply with the provisions of Article 72 of the Biocidal Products Regulation, as provided for in Article 35(B)(4) of the General Health Law.

l) The modification of the conditions of authorisation of the biocidal product without prior approval by the competent authority, or where applicable notification in accordance with Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal

products authorised in accordance with the Biocidal Products Regulation, as provided for in Article 35(B)(1) of the General Health Law.

m) Conducting experiments involving release into the environment without the notification required under Article 56 of the Biocidal Products Regulation, or without complying with the conditions set out in the opinion issued by the competent authority, as provided for in Article 35(B)(2) of the General Health Law.

n) Carrying out tests on vertebrates that contravene the provisions of the Biocidal Products Regulation, as provided for in Article 35(B)(1) of the General Health Law.

o) The making available on the market of biocidal products which, due to the characteristics of their packaging, are likely to be confused with foodstuffs or feed, or are attractive to children within the meaning of Article 69 of the Biocidal Products Regulation, as provided for in Article 35(B)(4) of the General Health Law.

p) The manufacture, packaging, storage, making available on the market or use of biocidal products in biocidal establishments or services that are not registered or that do not comply with the provisions of the ROESB, without prejudice to the exceptions provided for in this Royal Decree and its implementing legislation, provided that they represent a danger to public health, as provided for in Article 35(B)(2) of the General Health Law.

q) The use of biocidal products without the training requirements established by current legislation, as provided for in Article (35)(B)(2) of the General Health Law.

r) Repeat commission of minor infringements in the last three months, as set forth in Article 35(B)(7) of the General Health Law.

s) Failure to collaborate with the relevant Public Administration, in the work of inspection, control and monitoring, as provided for in Article 35(B)(5) of the General Health Law.

6. The commission of any of the serious or very serious infringements shall be considered minor infringements when, due to their minor nature or significance, they do not warrant such classification, as well as any other breaches of the Biocidal Products Regulation that have not been classified as serious or very serious infringements in the previous paragraphs, in accordance with Article 35(A)(1), (2) and (3) of the General Health Law.

Article 22. *Penalties.*

With regard to the penalties and penalty procedure, these shall be governed by the provisions of Law 39/2015 of 1 October 2015, Law 40/2015 of 1 October 2015, and Articles 32 to 37 of Law 14/1986 of 25 April 1986.

Article 23. *Provisional measures.*

Once the sanctioning procedure has been initiated, the competent body, acting on its own initiative or at the proposal of the investigating officer, may at any time adopt, by means of a reasoned decision, any provisional measures it deems necessary to ensure the effectiveness of the decision that may be taken and to prevent the continuation of risks or damage to human and animal health and the environment. Such measures must be proportionate to the nature and seriousness of the alleged infringements.

Article 24. *Reparation of damage and compensation.*

1. Without prejudice to the penalty imposed, if the penalised conduct has caused damage or loss, the decision concluding the proceedings may require the offender to restore the situation altered by the infringement to its original state, as well as to pay compensation for the damage caused.

2. In cases of environmental damage, the offender shall be obliged to repair the damage in accordance with the terms of Law 26/2007 of 23 October 2007 on Environmental Liability.

First additional provision. *The cities of Ceuta and Melilla*.

References to the autonomous communities shall also be understood as references to the cities of Ceuta and Melilla, within the scope provided for in their respective Statutes of Autonomy and Royal Decrees on the transfer of functions and services.

Second additional provision. *Protection of personal data.*

All processing of personal data derived from the application of this Royal Decree shall be carried out in strict compliance with the provisions of Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, and with Organic Law 3/2018 of 5 December 2018 on the protection of personal data and the guarantee of digital rights, thereby ensuring the fundamental right of those affected to the protection of their personal data. Personal data collected as a result of the provisions of this Royal Decree shall not be processed for purposes other than the registration and conditions of authorisation, manufacture, making available on the market and use of biocidal products.

Third additional provision. *Use of the terms 'Hygienising' or 'Sanitising'*.

The terms 'hygienising' and 'sanitising' shall be considered biocidal claims.

Fourth additional provision. *References to the Official Register of Biocidal Products*.

In general, all references made in this Royal Decree to the Official Register of Biocidal Products are also understood to refer to the Official Register of Non-Agricultural Pesticides of the Directorate-General for Public Health and Health Equity, including those that have been transferred from the Register of the Directorate-General for Agri-Food Production and Animal Welfare and from the Register of the Spanish Agency for Medicines and Medical Devices once the active biocidal substances have been approved.

Fifth additional provision. *Powers of the Ministry of Defence*.

When the provisions of this Royal Decree concern the units, centres or agencies belonging to the Ministry of Defence and its public bodies, they shall be applied by the General Defence Health Inspectorate as the health authority of the Department, which shall coordinate any necessary actions with the other health authorities.

Sixth additional provision. *Waste legislation.*

The provisions of this Royal Decree are without prejudice to compliance with the obligations that producers and packagers of biocidal products must fulfil under Royal Decree 1055/2022 of 27 December 2022 on packaging and packaging waste, in particular as regards labelling obligations,

extended producer responsibility and registration in the packaging section of the Register of Product Producers, with a view to ensuring proper environmental management of the packaging used.

First transitional provision. *Registers provided for 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*.

1. Pesticides for environmental use and those for use in the food industry, those for use in personal hygiene, disinfectants for clinical and pharmaceutical equipment and for clinical and surgical environments, and those for use in livestock farming falling within the registers provided for in Royal Decree 3349/1983 of 30 November 1983 shall continue to be registered in their respective registers of the Directorate-General for Public Health and Health Equity, the Spanish Agency for Medicines and Medical Devices of the Ministry of Health, and the Directorate-General for Agri-Food Production and Animal Welfare of the Ministry of Agriculture, Fisheries and Food, as established in Article 89(2) of the Biocidal Products Regulation.

2. For the purposes of application in the field of non-agricultural pesticides, Articles 1, 2, 4, 7 and 13 of Royal Decree 3349/1983 of 30 November 1983 shall apply until the 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.

3. For that purpose, communications between the Directorate-General for Public Health and Health Equity shall be made, without prejudice to the provisions of Law 39/2015 of 1 October 2015, through the official electronic portal of the Ministry of Health.

4. The time limits laid down in Article 89 of the Biocidal Products Regulation shall apply to the making available on the market and use of biocidal products during the transitional period referred to in that article, unless a reasoned decision provides otherwise.

5. Once a decision has been taken at EU level as to whether or not to approve the active substances on the list referred to in Article 9(2) of the aforementioned Regulation, the provisions of Articles 89(2) and 89(3) shall apply to those biocidal products respectively.

6. By the date of approval of the active substances, the holders of the registrations must have submitted an application for authorisation of a biocidal product that corresponds in all respects to that registered under national legislation using one of the procedures provided for in the Biocidal Products Regulation or the regulations implementing it, in order to be able to continue making it available on the market.

Second transitional provision. *Notification of the making available on the market of biocidal products*.

1. The notification of making available on the market provided for in the second transitional provision of Royal Decree 1054/2002 of 11 October 2002 shall apply to biocidal products not subject to registration under Royal Decree 3349/1983 of 30 November 1983, as established in Article 89(2) of the Biocidal Products Regulation.

2. The notification of making available on the market shall continue to apply, in compliance with Article 89 of the Biocidal Products Regulation, until the 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 date of approval of the active substances, notifiers of the biocidal products referred to in the first paragraph must have submitted an application for authorisation of a biocidal product identical to the one notified, using one of the procedures established in the Biocidal Products Regulation or its implementing regulations. Biocidal products that were not notified on the date of approval of the active substance may not be made available on the market until the application under the EU procedure has been approved.

Third transitional provision. *Register of biocidal product transactions.*

A period of six months from the entry into force of this Royal Decree is established for the application of the provisions of Article 13(2) on the traceability system for biocidal product transactions; during this transitional period, the provisions of Article 28 of Royal Decree 1054/2002 of 11 October 2002 shall apply. During this transitional period, economic operators shall adapt their systems and procedures to comply with the newly established registration requirements.

Fourth transitional provision. *Obtaining new professional qualifications*.

Application technicians who currently perform treatments with biocidal products will need the training or certificates mentioned in Article 16 within six years of the date of entry into force of this Royal Decree, unless the applicable sectoral regulations establish different requirements. Those who already have the training or the professional certificates SEAG0110 and SEAG0212 referring to qualifications SEA028 and SEA492, respectively, are exempt from this rule, as these certificates shall be considered equivalent to the new certificates derived from the qualification of Technician in Applied Environmental Health. Professional experience shall be recognised through the procedure for accrediting professional skills acquired through work experience and other formal or informal channels, as set out in Royal Decree 659/2023 of 18 July 2023 establishing the framework for the Vocational Education and Training System.

Sole repealing provision. *Regulatory repeal.*

Any provisions of a similar or lesser scope that oppose the provisions of this Royal Decree are hereby repealed, and in particular:

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

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 that regulation, which shall continue to apply as regards non-agricultural pesticides, in compliance with Article 89 of the Biocidal Products Regulation, until the 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 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 and third transitional provisions of this Royal Decree;

e) Royal Decree 830/2010 of 25 June 2010 establishing the regulations governing the training required to perform treatments with biocidal products, except for the fourth final provision for as long as Order SCO/3269/2006 of 13 October 2006 establishing the bases for the registration and operation of the ROESB remains in force;

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

g) the Order of 24 February 1993 laying down the rules governing the Official Register for the Movement of Hazardous Pesticides, as regards non-agricultural pesticides;

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

First final provision. *Attribution of powers*.

This Royal Decree is issued under Article 149(1)(16) and (23) of the Spanish Constitution, which confer on the State powers in matters relating to the basic framework and general coordination of healthcare, and basic legislation on environmental protection, respectively, without prejudice to the autonomous communities' power to establish additional rules of protection.

Second final provision. *Implementation authority*.

The Minister for Health, the Minister for Agriculture, Fisheries and Food and the Minister for the Ecological Transition and the Demographic Challenge shall be authorised, within the scope of their powers, to implement the provisions of this Royal Decree and to lay down the rules necessary for the coordination of the requirements for entry in the registers of the autonomous communities.

Third final provision. *Entry into force*.

This Royal Decree shall enter into force on 2 January of the year following its publication in the Official State Gazette. However, the provisions laid down in paragraph (h) of the sole repealing provision shall take effect on the day following that of their publication in the Official State Gazette.

Madrid, dd of month yyyy,-The Minister for ministry, First name and surname

ANNEX I

**Declaration of responsibility template for the acquisition of biocidal products for professional or specialised professional use**

Mr/Ms/company:

NIF/NIE (National ID No):

Email:

| Trade name of biocidal product | Official Register of Biocidal Products (ROB) No / Official Register of Pesticides (ROP) No | Net quantity | Date of the Safety Data Sheet (SDS) |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

You are provided with the safety data sheet(s) (SDS) for the biocidal product(s):

☐at the establishment.

☐Email.

Name of the establishment making the product available:

ROESB No:

☐ The above-mentioned natural/legal person declares that they are acquiring the biocidal product for professional use for use in the workplace.

☐ The above-mentioned natural/legal person declares that they possess the training established in Article 17 required to acquire biocidal products for specialised professional use due to their involvement in biocidal treatments.

In_____, on ___ of _____of ____

Signed: Product purchaser

ANNEX II

## Certificate template for biocidal service performed

**Details of the applicant for the Biocidal Service**

Name:

Address:

NIF (National ID No):

Phone:

Fax (optional):

Email:

**Details of the biocidal service company(ies) or of the corporate biocidal service**

Name:

ROESB No:

Address:

NIF (National ID No):

Phone:

Fax (optional):

Email:

**Details of the application technician(s) performing the biocidal treatment**

Name:

DNI (Personal ID No):

Accreditation of the training of each application technician:

**Signature of the technical manager of the biocidal treatment**

Name:

DNI (Personal ID No):

Accreditation of training:

* This template will not apply where there is specific legislation in place.

**Situation diagnosis and justification of the biocidal treatment**
**Data relating to the biocidal treatment**

Target harmful organism to be controlled:

Type of treatment, according to product type (PT):

Pre-treatment status of the facility/scenario:

Cleaning has been carried out prior to biocidal treatment: ☐ YES ☐ NO.

Biocidal treatment carried out, description (application technique, quantity/dose applied, area treated and affected by the treatment):

Biocidal products used under trade name and registration no:

Indicate other chemical substances or mixtures used (if any):

Date and time of commencement and completion of the biocidal treatment:

Safety period and other precautionary and safety measures taken (if applicable):

Date of issue of certified biocidal service:

Signature of the application technician(s)/person(s) performing the biocidal treatment:

Signature of the technical manager for the biocidal treatment:

Signature of the client or contracting party:

Place and date:

* This template will not apply where there is specific legislation in place.