Draft Royal Decree No xxx/2026 laying down health requirements for the import and export of biological material

I

In accordance with Article 149(1)(16) of the Spanish Constitution, international health matters fall within the exclusive competence of the State. In exercise of this competence, Article 38 of General Health Law 14/1986 of 25 April 1986 establishes that all activities relating to the monitoring and control of potential health risks arising from the import, export or transit of goods, as well as from international passenger traffic, shall be regarded as external health activities. In this regard, Royal Decree 1418/1986 of 13 June 1986, on the functions of the Ministry of Health and Consumer Affairs in the field of international health, assigns to the current Ministry of Health the responsibility for carrying out health and hygiene control and surveillance activities in relation to the international movement of goods that may pose a risk to public health or the physical safety of individuals.

To date, the control of the public health risks associated with the import and export of biological material intended for diagnosis or research in humans has been carried out in accordance with the provisions of Royal Decree 65/2006 of 30 January 2006 laying down requirements for the import and export of biological samples. However, the experience gained since its implementation, the adoption of new national and European regulations, and the significant increase in international trade in biological material for diagnostic or research purposes—driven by advances in biomedical research and clinical diagnosis—make it necessary to update the current procedure, adapting it to the current situation and to the level of health risk associated with each type of material.

II

The purpose of this Royal Decree is to streamline the health control and authorisation procedures relating to the import and export of biological material, including in vitro diagnostic reagents, intended for biomedical research, diagnosis in humans or quality control, whilst ensuring the protection of public health through the application of requirements proportionate to the health risk posed by each type of material, without hindering international trade.

To this end, the regulation establishes a classification of biological material according to the risk it may pose to public health, defining specific and proportionate requirements for each category. Experience and scientific evidence identify transport safety and adequate biosecurity of the facilities involved as essential elements of

health control. Consequently, in order to authorise import or export operations, it will be necessary to verify that the transport complies with the international standards applicable to infectious substances and that the facilities of origin or destination meet appropriate biosafety standards.

In the case of biological agents in groups 2, 3 and 4, as defined in Royal Decree 664/1997 of 12 May 1997 on the protection of workers from risks related to exposure to biological agents at work, authorisations shall require that the premises be duly designated by the competent authorities and comply with the applicable health and safety regulations.

Verification of biosafety conditions at the facilities involved in the handling of hazardous biological agents requires cooperation between the national health authority and the competent public health or occupational health authorities of the General State Administration and of the autonomous communities and cities. The Royal Decree therefore provides for mechanisms for cooperation and the exchange of information between these authorities, with a view to ensuring that appropriate health and safety standards are met in the authorisation procedures.

Furthermore, the regulation establishes a national information system that will enable the electronic submission and processing of applications for the import and export of regulated biological material, and which will also be used to manage applications relating to certain human substances falling within the scope of Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on quality and safety standards for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC. Such substances include, amongst others, human cells and tissues, reproductive cells, gut microbiota, blood and blood components and products derived therefrom, and breast milk.

Consequently, this Royal Decree replaces Royal Decree 65/2006 of 30 January 2006, bringing its content into line with national and European Union legislation adopted subsequently, and consolidating into a single provision the regulatory framework governing health controls and the authorisation of imports and exports of biological material intended for biomedical research, diagnosis in humans or quality control. At the same time, it streamlines the administrative procedures and enhances the effectiveness of control measures, ensuring the protection of public health without hindering the international trade in such materials.

III

This regulation is also in line with the principles of sound regulation set out in Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations.

Specifically, in accordance with the principles of necessity and effectiveness, the initiative serves the public interest by improving the regulatory framework governing the requirements for the import and export of biological material, including in vitro diagnostic reagents, intended for biomedical research, diagnosis in humans or quality control, whilst ensuring the protection of public health. Furthermore, in accordance with the principle of proportionality, the regulations set out herein are strictly necessary to achieve the aforementioned public interest, as they simplify the authorisation procedures for the import or export of the material, thereby contributing to greater administrative efficiency and a reduction in both administrative and economic burdens and costs.

As regards the principles of legal certainty, transparency and efficiency, the regulation also complies with those principles, since it is consistent with the rest of the legal system and stakeholder participation has been encouraged, while avoiding unnecessary or ancillary administrative burdens.

In producing this Royal Decree, the mandatory procedures for prior public consultation and public information have been carried out. Furthermore, the Autonomous Communities and the cities of Ceuta and Melilla have been consulted.

This provision has been subject to the procedure laid down 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 to the provisions of Royal Decree 1337/1999 of 31 July 1999 regulating the provision of information in the field of technical standards and regulations and of regulations on Information Society services.

This Royal Decree is adopted pursuant to Article 149(1)(16) of the Spanish Constitution, which confers exclusive competence on the State in matters of external health, and Article 38 of General Health Law 14/1986 of 25 April 1986.

Accordingly, on the proposal of the Minister for Health, with the prior approval of the Minister for Digital Transformation and the Civil Service, in agreement with the Council of State, and following deliberation by the Council of Ministers, at its meeting on xx xx 2026,

THE FOLLOWING IS DECREED:

CHAPTER I

General provisions

Article 1. *Purpose.*

The purpose of this Royal Decree is to:

a) Regulate the health requirements and procedures for the import and export of the biological material referred to in Article 2(1).
b) Regulate the nationwide information system for the electronic submission and processing of applications for health authorisation for the import, export or transit, and for health certification for the export, of the following types of biological material:

   i. the material referred to in Article 2(1);
   ii. the following substances falling within the scope of Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC:
      a. human tissues and cells or products obtained or derived therefrom intended for application in humans;
      b. reproductive cells for assisted human reproduction;
      c. human blood and blood components and derivatives;
      d. the gut microbiota;
      e. breast milk; and
      f. any other substance of human origin that can be applied in humans.

Article 2. *Scope of application.*

1. The scope of application of this Royal Decree includes the import, export and international transit of the following material:

   a) biological material of human or synthetic origin intended for biomedical research, diagnosis in humans, quality control or performance evaluation of in vitro diagnostic reagents;
   b) biological material of animal origin, including in vitro diagnostic reagents, intended for biomedical research,

diagnosis in humans or quality control, provided that all of the following conditions are met:

1. That it has been obtained from any of the following animals:

   i. animals showing signs of a serious disease transmissible to humans, including laboratory animals;
   ii. wild animals that may carry biological agents capable of causing serious illness in humans; and
   iii. animals that have been in contact with other infected animals or humans, or that show signs of a serious disease transmissible to humans, unless the relevant quarantine period has been completed or the incubation period has elapsed without the disease having developed.

2. That it is not subject, at the border control post of first entry into the Union, to the official controls referred to in Article 47(1) of Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, and rules on animal health and welfare, plant health and plant protection products, and amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009, and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC, and Council Decision 92/438/EEC (Official Controls Regulation);

3. That it does not fall within the scope of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal By-Products Regulation);

c) Haematopoietic progenitor cells, used by the National Transplant Organisation for analytical purposes in the search for unrelated donors.
d) Samples of air, water (including wastewater), soil or earth, where there is reasonable cause to suspect that they may contain biological agents capable of causing serious illness in humans, and which are intended for analysis, diagnosis or research.

2. The following material is excluded from the scope of this Royal Decree:

a) Raw materials, active pharmaceutical ingredients and their precursors, and intermediate products intended for the manufacture of medicinal products, medical devices, cosmetics, biocidal products and personal care products, which are regulated within the scope of Royal Legislative Decree 1/2015 of 24 July, approving the consolidated text of the law on guarantees and the rational use of medicines and medical devices.
b) Organs or parts of organs, where their intended use is within the human body to perform the same function as the whole organ, are regulated by Law 30/1979 of 27 October 1979 on the removal and transplantation of organs.
c) Corpses, anatomical parts and other cadaveric remains, regulated by Decree 2263/1974 of 20 July 1974 approving the Mortuary Health Police Regulation.
d) Biological material of animal origin for diagnostic and research purposes in the field of veterinary medicine.
e) Animal by-products and derived products not intended for human consumption falling within the scope of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products regulation).

f) Substances of human origin falling within the scope of Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.
However, applications for authorisation to import, export or transit such material shall be processed via the computerised system referred to in point (j) of Article 3(2), and its entry into and exit from the territory may only take place through the designated points referred to in Article 9.

Article 3. *Definitions.*

For the purpose of this Royal Decree, the following definitions are used:

a) 'Biological agents': microorganisms, including genetically modified organisms, cell cultures and human endoparasites, capable of causing any form of infection, allergy or toxicity.

b) 'Documentary control': Verification of the application, certificates, declarations or other documents that must accompany applications for import or export of the biological material.

c) 'Identity check': Visual inspection of closed or sealed containers and/or packaging, to verify that they are intact and correctly labelled, and to verify that the information printed on the containers or packaging corresponds with the information contained in the application and the documents accompanying the biological material.

d) Self-declaration: A document signed by the importer, exporter, recipient of the biological material or their legal representative, in which they declare, on their own responsibility, that they comply with the requirements established for importing, exporting or handling the biological material, that they possess the documentation proving this, and that they will make it available to the authorities upon request.

e) 'Recipient': A natural or legal person responsible for the biological material at the destination facility for the samples and who is named as the person responsible for

the declarations and other documents relating to the destination facility for the biological material.

f) ‘Importer’: Natural or legal person established in the national territory that introduces biological material from a third country into Spain, and who appears as such in certificates, declarations and other documents, including documents of a commercial nature issued in the country or territory of origin.

g) ‘Biological material’: Any substance of human, animal or synthetic origin, which may contain biological information, including viable biological agents, their parts or products, toxins, antigens, nucleic acids and viral vectors (replicative or not), as well as microbial strains and preserved materials.

h) ‘Human embryonic biological material’: cells or tissues derived from a human embryo.

i) ‘Consignor’: In the case of imports, the natural or legal person who takes charge of the biological material upon its arrival in the European Union and submits the necessary declarations to the Directorate-General for Public Health and Health Equity, either as the importer or on behalf of the importer. In the case of exports, the natural or legal person responsible for sending the samples to the third country or territory and for submitting the necessary declarations to the Directorate-General for Public Health and Health Equity, either as the consignor or on behalf of the consignor.

j) ‘Transit operator’: the natural or legal person responsible for ensuring the proper management, custody and transport of biological material from the point of entry to its destination within the national territory or to the point of exit.

k) ‘Information system for the import, export or transit of biological material (hereinafter referred to as MuBi)’: An application that enables the electronic submission, management and processing of applications for the import, export or transit of consignments of biological material falling within the scope of this Royal Decree, as well as the import, export or transit of human cells and tissues and products derived therefrom, reproductive cells for assisted human reproduction, blood and human blood

components and derivatives, breast milk and any other human substance intended for use in humans.

Article 4. *Competent authorities.*

1. The Directorate-General for Public Health and Equity in Health shall be responsible for authorising the import, export or international transit of the biological material referred to in Article 2(1) and for managing and maintaining the MuBi information system.

2. The Directorate-General for Public Health and Health Equity, through the Sub-Directorate-General for International Health, and the international health services of the Health and Social Policy Departments and Units responsible for the points of entry or exit, shall be responsible for carrying out the inspections referred to in Article 11.

3. The health or labour authorities of the General State Administration, of the Autonomous Communities or cities of Ceuta and Melilla shall be responsible for checking compliance with the biosecurity requirements of their laboratories or diagnostic or research centres, as well as for authorising or designating the centres or laboratories that may import, export or handle biological agents in groups 2, 3 or 4 referred to in Article 5 and points (b) to (d) of Article 3(1) of Royal Decree 664/1997 of 12 May 1997 on the protection of workers from risks related to exposure to biological agents at work.

Article 5. *Classification of biological material.*

For the purposes of this Royal Decree, biological material is classified into the following categories:

1. Category I: Samples that do not contain, or are highly unlikely to contain, biological agents capable of causing disease in humans, and those that contain or may contain biological agents that do not pose a risk to public health, with a low likelihood of spreading to the community and for which effective prophylaxis or treatment is generally available.

   This category is further subdivided into:
   a) Group 0: includes biological material with low probability of presence of biological agents, including diagnostic

specimens not related to infectious diseases. This group also includes any microbiological entity unable to reproduce or transfer genetic material.

b) Group 1: comprises biological material containing, or suspected of containing, Group 1 biological agents referred to in point (a) of Article 3(1) of Royal Decree 664/1997 of 12 May 1997.
c) Group 2: includes biological material containing, or suspected of containing, Group 2 biological agents referred to in point (b) of Article 3(1) of Royal Decree 664/1997 of 12 May 1997.

2. Category II: Samples containing biological agents or their toxins that may cause serious disease in humans, with a risk of spreading to the community.

   This category in turn includes:

   a) Group 3: includes biological material that contains, or is suspected of containing, Group 3 biological agents as referred to in point (c) of Article 3(1) of Royal Decree 664/1997 of 12 May 1997.
   b) Group 4: includes biological material that contains, or is suspected of containing, Group 4 biological agents as referred to in Article 3(1)(d) of Royal Decree 664/1997 of 12 May 1997.

CHAPTER II
Obligations of operators, establishments, authorities and official control agents

Article 6. *Obligations of importers, exporters, transit operators, laboratories or recipient centres, certifying authorities and official control agents.*

1. The obligations and responsibilities of the importer or exporter shall be as follows:

a) be registered in the MuBi IT application. Registration of the importing or exporting company may be requested directly through the application in one of the following ways:
   i. as a user with a certificate representing a legal entity, acting on behalf of the company represented;
   ii. as a user with a natural person certificate, acting either on their own behalf or as a user authorised by the importing or exporting company, as applicable;
b) communicate to the Ministry of Health, through the Directorate-General for Public Health and Health Equity, any changes in its activity, facilities, processes, administrative authorisations or in any of the relevant data recorded in MuBi.
c) in relation to biological material that is intended to be introduced, imported or exported, it must know and comply with the health, documentary, procedural or other requirements required by Spanish regulations, those of the European Union and, where appropriate, those established by the country of destination;
d) be familiar with the procedures established by the Ministry of Health for obtaining authorisation for entry or exit, or for obtaining an export health certificate;
e) comply with the packaging, transport, labelling and documentation requirements laid down in national and international regulations, in accordance with the UN classification of dangerous goods and the provisions of the WHO Guidance on Regulations for the Transport of Infectious Substances, the International Civil Aviation Organisation's (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air, the International Air Transport Association (IATA) Regulations, the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the International Maritime Dangerous Goods Code (IMDG) and the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)
f) accept liability, whether financial or otherwise, that may be claimed by any party who considers themselves to have suffered harm, including the competent authorities, should the information provided or the documents submitted to the Sub-Directorate-General for External Health / external health service prove to be inaccurate, incomplete or false, or should this be subsequently established; all of which is without prejudice to the application,

where appropriate, of the relevant precautionary measures or penalty regime.

2. The obligations of the transit operator shall be as follows:

   a) ensure the correct receipt, registration and custody of biological material from its origin until its delivery or until its exit from the national territory;
   b) monitor and certify that the equipment used for transport is within specifications and suitable for the sample type;
   c) Document the movements, as well as the parties responsible involved and, where appropriate, any handling carried out.
   d) Ensure compliance with biosafety standards by implementing safe handling practices.
   e) Ensure the correct storage, conservation and transport of biological material, including temperature conditions, packaging, authorised transport and delivery times.
   f) Notify the competent health authority of any situation that may affect the safety or quality of the biological material.

3. The obligations and responsibilities of laboratories and centres of origin and destination of biological material located within the national territory shall be as follows:

   a) be aware of and comply with the health and biosecurity requirements required by Spanish or European Union regulations;
   b) hold the accreditation required according to their activity and comply with the applicable occupational safety regulations;
   c) Apply to the competent health or labour authority, as appropriate, for the designation to be able to import, export or handle Group 2, 3 or 4 biological agents set out in Article 5.

4. The obligations and responsibilities of the certifying authorities and official control officers of the Autonomous Communities, the cities of Ceuta and Melilla and of the General State Administration, apart from being authorised, are the following:

   a) possess satisfactory knowledge of the health and biosecurity regulations applicable to the biological material to be introduced, imported or exported, as well as the procedures or examinations that they must carry out before issuing the entry or exit authorisation or the export certification.

b) carry out the necessary control actions to issue the corresponding authorisations or certifications.
c) monitor shipments of Group 3 and 4 biological material set out in Article 5, as well as any type of biological material whose entry or exit has been refused on health grounds.
d) comply with current regulations on personal data protection.

CHAPTER III
Requirements for the introduction, import or export, and points of entry and exit

Article 7. *Requirements for the introduction or importation of biological material*

The entry or importation of biological material shall be subject to compliance with the following requirements:

a) in the case of biological material that contains or may contain biological agents of groups 2, 3 or 4, the recipient facility must be duly designated in accordance with the provisions of Article 12.
b) the recipient centre must comply with the applicable occupational health and safety regulations relevant to its activities, including Law 31/1995 of 8 November 1995 on the Prevention of Occupational Risks and, where applicable, Royal Decree 664/1997 of 12 May 1997 on the protection of workers against risks related to exposure to biological agents at work.
c) the entry of the material shall only be made through the control posts referred to in Article 9;
d) the only destination of the material is that declared and for which the introduction or import is authorised;
e) once the introduction or import is authorised, the material shall be moved directly to the premises of the importer or recipient;
f) shipments shall comply with the packaging, transport, labelling and documentation requirements laid down by national and international regulations, in accordance with the UN classification of dangerous goods and in line with the WHO Guidance on Regulation of the Transport of Infectious Substances, the International Civil Aviation Organisation's (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air, the International Air Transport Association (IATA) Regulations, the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the International Maritime Dangerous Goods

Code (IMDG) and the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID);

g) once the diagnosis or study has been completed, any remaining biological material must be safely destroyed in accordance with current legislation or stored in an authorised biobank or collection, in accordance with Royal Decree 1716/2011 of 18 November 2011, which establishes the basic requirements for the authorisation and operation of biobanks for the purposes of biomedical research and the handling of biological samples of human origin, and regulates the operation and organisation of the National Register of Biobanks for biomedical research under the relevant transfer agreement, ensuring traceability and data protection.

Article 8. *Requirements for the export of biological material.*

The export of the biological material is subject to compliance with the following requirements:

a) In the case of biological material that contains or may contain Group 2, 3 or 4 biological agents, the centre of origin must be duly designated in accordance with the provisions of Article 12.
b) The centre of origin must comply with the applicable health and safety regulations relating to its activities, including Law 31/1995 of 8 November 1995 on the Prevention of Occupational Risks and, where applicable, Royal Decree 664/1997 of 12 May 1997 on the protection of workers from risks related to exposure to biological agents at work.
c) it is only necessary to apply for exit authorisation or the issue of a certificate for export in the following cases:
    i. in the case of biological material containing Group 3 or 4 biological agents; or
    ii. if the health authorities of the third country or territory of destination require that biological material, of any category, be accompanied by an export authorisation or a certificate issued by the competent Spanish health authorities authorising the export.
d) the dispatch of the material referred to in point (a) shall only be made through the control posts referred to in Article 9.

Article 9. *Designated points for the entry and exit of biological material*

A list of authorised points for the entry and exit of biological material, as referred to in Article 2(1) and point (f) of Article 3(2), will be published on the Ministry of Health's website.

CHAPTER IV

Application for entry or exit certificate or authorisation

Article 10. *Application for an entry or exit certificate or authorisation*.

1. In order to apply for an entry or exit authorisation, or for the issuance of an export certificate, importers, exporters or recipients shall first be required to register in the MuBi application, as detailed in point (a) of Article 6(1).

2. The application procedure shall be initiated when the importing or exporting company established in the national territory or its representative, as appropriate, submits the corresponding application addressed to the Directorate-General for Public Health and Equity in Health. All applications must be submitted electronically via the MuBi computer system, in accordance with the provisions of Article 14(3) of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations, taking into account the professional activity of importers and exporters.

3. As a general rule, the General Directorate of Public Health and Health Equity will issue the authorisation decision or the export health certificate within a maximum of three working days of the application being correctly completed.

4. Along with the application submitted electronically, the operator must submit the following documents via MuBi:

   a) Evidence of representation, where the importer or exporter was a legal person or the application was signed by a representative of the importer or exporter. However, if that representation is already listed in MuBi, there is no need to include it again.

   b) In all cases, a self-declaration from the importer, exporter or recipient, in accordance with the template established by the Directorate-General for Public Health and Health Equity, for the purposes set out in Article 69.1 of Law 39/2015 of 1 October 2015, specifying the type of sample to be brought in, imported or exported and its purpose, in which they declare that they are aware of and comply with the health requirements for entry into or exit from our country or for importation into the country of destination, stating that, according to the information in their possession, the consignment meets all the required conditions, they have the documentation to prove this, and that they will make it available to the authorities when requested.

c) In the case of biological material referred to in Article 35(1) of Law 14/2007 of 3 July 2007 on biomedical research, the mandatory report of the Commission on Guarantees for the Donation and Use of Human Cells and Tissues and the Register of Research Projects must be provided in accordance with the provisions of Article 6(2) of Royal Decree 1527/2010 of 15 November 2010 regulating the Commission on Guarantees for the Donation and Use of Human Cells and Tissues and the Register of Research Projects. Notwithstanding the provisions of this paragraph, research projects involving human pluripotent cells obtained through cell reprogramming, as set out in Article 35(3) of Law 14/2007 of 3 July 2007 on Biomedical Research, shall not require a prior report from the Commission, it being sufficient to provide the favourable prior report on the biomedical research project for which the biological material is intended, issued by the Commission for Guarantees on the Donation and Use of Human Cells and Tissues.

d) In the case of exports, where the exporter has documentation issued by the country of destination justifying the need to provide an export authorisation or certificate, such documentation must be submitted with a Spanish translation, unless an official Spanish version already exists.

5. In exceptional cases, where a technical fault has prevented the submission or processing of an application via MuBi, the time limits for processing the application shall be extended by the duration of the technical fault, in accordance with Article 32(4) of Law 39/2015 of 1 October 2015; both the technical fault that has occurred and the specific extension of the time limit that has not yet expired must be published on the official website.

6. For the purposes of calculating the time limits for issuing entry or exit authorisations or export certificates, the application shall not be considered completed until all the information and documentation necessary to issue the corresponding authorisation or certification has been provided. If the required documentation is not provided in full or is incorrect, the Directorate-General for Public Health and Health Equity will require the applicant to complete or rectify it within a maximum of ten working days, in accordance with Article 68 of Law 39/2015 of 1 October 2015. The requirement shall be made through the MuBi application. If the deadline has passed without the documentation having been completed or fully rectified, it shall be deemed that the applicant has withdrawn their application, subject to a decision to be issued in accordance with the provisions of Article 21 of Law 39/2015 of 1 October 2015, and the procedure shall be deemed to have been

concluded. If the applicant is still interested in the operation, the exporter will have to re-submit a new application.

7. The importer, exporter or recipient may consult the status of their file in MuBi, as well as the additional information required where appropriate.

8. The entry or exit authorisation or export health certificate, as applicable, shall be issued in electronic form, shall be available for download through the MuBi application and shall, where necessary, accompany the consignment upon entry to or exit from the national territory.

9. Every application received will be recorded in MuBi, together with the accompanying documentation and any additional documents submitted by the importer, exporter, recipient or their representative, and by the control or certification agents

CHAPTER V

Inspections and the designation of centres and laboratories

Article 11. *Inspections and the duty to cooperate.*

1. The Directorate-General for Public Health and Equity in Health, through the Subdirectorate-General for External Health and the external health service corresponding to the point of entry or exit, may carry out identity inspections of consignments subject to entry or exit authorisation or export certification in accordance with the frequencies established by the Subdirectorate-General for External Health based on risk, and depending on the type of material, purpose, origin or destination.

2. If non-compliances are detected as a result of the inspections, the control frequencies may be reviewed. Depending on the severity or frequency of the breaches identified, a specific, more frequent monitoring regime may be established for a particular operator or a specific type of sample. Furthermore, the adoption of interim measures in accordance with current legislation may be proposed, or the relevant disciplinary proceedings may be initiated.

3. Within the scope of this Royal Decree, any natural or legal person is subject to the duty of collaboration with the Subdirectorate-General for External Health and the external health services, in compliance with Article 18 of Law 39/2015 of 1 October 2015. It is also obliged to provide, at the request of the control officers, the data and information at its disposal that may be necessary for the purpose and conduct of the inspection.

4. The deadline for providing the information referred to in the previous paragraph shall be ten working days from the day following the date on which the request is notified, unless, given the nature of the request and the circumstances of the case, the Ministry of Health sets a different deadline, giving reasons for doing so.

5. In exceptional cases, where a technical fault has prevented the submission or processing of an application via MuBI, the time limits for processing the application will be extended by the duration of the technical fault, in accordance with Article 32(4) of Law 39/2015 of 1 October 2015.

Article 12. *Designation of approved centres or laboratories*.

1. Laboratories or centres of origin or recipient laboratories or centres located within the national territory that are to receive, or from which biological material containing, or liable to contain, the biological agents referred to in Article 3(1)(b), (c) and (d) of Royal Decree 664/1997 of 12 May 1997, classified in Groups 2, 3 or 4, is to be dispatched, shall be duly designated by the competent authorities to carry out such activities and shall comply with the applicable health requirements and occupational health and safety legislation.
2. The competent authority responsible for the designation referred to in paragraph 1 shall be the corresponding body of the Autonomous Community or city of Ceuta or Melilla where the diagnostic or research laboratory or centre is located. Within the Ministry of Defence, the authority to make such appointments shall lie with the Defence Health Inspectorate. The diagnostic or research laboratory or centre shall address its application for designation to the relevant competent authority.

CHAPTER VI

Cooperation between authorities, processing of personal data and regime of infringements and penalties.

Article 13. *Cooperation with the Spanish customs authorities.*

Within the framework of the mandatory cooperation between the authorities responsible for the control of goods, as provided for in Article 47(1) of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013, establishing the Union Customs Code, notifications from interested parties and notifications regarding the timing of controls may be made via a single customs window system. To this end, the necessary

cooperation arrangements will be established between the Ministry of Health and the National Agency for Tax Administration.

Article 14. *Cooperation with the regional authorities and competent authorities of the General State Administration*

1. The autonomous communities, the cities of Ceuta and Melilla, and the other competent authorities shall submit to the Sub-Directorate-General for International Health, on a quarterly basis and whenever any changes occur, a list of the laboratories or centres that meet the necessary biosafety requirements to import, export and handle biological agents in groups 2, 3 or 4, and shall notify any suspensions or withdrawals of designation for health or biosafety reasons.
2. In the case of consignments of Category II biological material whose entry into or exit from the country has been authorised, or of biological material of any category whose entry into or exit from the country has been refused, the Ministry of Health shall, through MuBi, notify the competent authority responsible for the place of destination or the originating centre, as applicable in the case of imports or exports, of all details relating to the consignment.

Article 15. *Processing of personal data*

1. The Ministry of Health, through the Directorate-General for Public Health and Health Equity, via the Sub-Directorate-General for International Health, shall act as the data controller for personal data processed by the MuBi app, in compliance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of 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 Organic Law 3/2018 of 5 December 2018 on the Protection of Personal Data and the Guarantee of Digital Rights.

   In any event, and in accordance with the principle of data minimisation, only the data that is strictly necessary will be processed.

   Furthermore, with regard to the processing of contact details of sole traders and self-employed professionals, the provisions of Article 19 of Organic Law 3/2018 of 5 December 2018 on the Protection of Personal Data and the Guarantee of Digital Rights shall apply

2. The processing of personal data referred to in Article 1(b)(ii) of this Royal Decree, relating to substances covered by Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024, on quality and safety standards for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC through the exchange of information on the EU SoHO Platform, shall be conducted in accordance with the provisions of that Regulation and Commission Implementing Regulation (EU) 2025/1467 of 18 July 2025, laying down implementing rules for Regulation (EU) 2024/1938 of the European Parliament and of the Council as regards the technical specifications of the EU SoHO Platform for the exchange of information on substances of human origin intended for human application, and any implementing provisions adopted thereunder. Such processing shall also be governed by Royal Decree-Law 9/2014 of 4 July 2014, establishing standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human cells and tissues, and approving the coordination and operating rules for their use in humans.

   The categories of personal data to be processed and the retention period are set out in Annex II to Implementing Regulation (EU) 2025/1467.

   Where applicable, Royal Decree 1088/2005 of 16 September 2005 laying down the technical requirements and minimum conditions for blood donation and transfusion centres and services shall apply.

3. The processing of personal data referred to in Article 2(1) of this Royal Decree is limited to the contact details of individual entrepreneurs and liberal professionals, in their capacity as exporters or importers, or their representatives.

Article 16. Infringements and penalties

In the event of non-compliance with the provisions of this Royal Decree, the regime of infringements and sanctions applicable under Law 14/1986 of 25 April 1986, the General Health Law, and Law 33/2011 of 4 October 2011, the General Public Health Law, shall apply, without prejudice to any civil, criminal or other liabilities that may also arise.

Sole additional provision. Powers of the Ministry of Defence.

1. Within the Ministry of Defence, the General Inspectorate of Defence Health, as the department’s health authority, will take

the necessary measures to ensure compliance with this Royal Decree, following the guidelines issued by the Ministry of Health for the development and adaptation, where appropriate, of the specific procedures required to align compliance with the regulation with the needs of national defence.

2. The Ministry of Defence shall communicate quarterly by electronic means to the Ministry of Health the information obtained in the exercise of its powers provided for in the previous paragraph.

First transitional provision. Import authorisation for importers listed in the voluntary register of importers and exporters of biological samples.

During a transitional period ending three months after the date of entry into force of this Royal Decree, natural or legal persons who are registered in the voluntary register of importers and exporters of biological samples, as provided for in Article 6 of Royal Decree 65/2006 of 30 January 2006, laying down requirements for the import and export of biological samples, may continue to import or export such biological material using the documents established prior to the date of entry into force of this provision.

Second transitional provision. Applications submitted before the date of entry into force of this Royal Decree.

Import or export applications submitted to the competent authorities prior to the date of entry into force of this Royal Decree shall be processed and decided in accordance with the provisions of Royal Decree 65/2006, using the standard forms that were in force until the entry into force of this provision.

Third transitional provision. Designation of approved centres or laboratories.

During a transitional period ending twelve months after the date of entry into force of this Royal Decree, centres or laboratories of origin or destination for samples located within the national territory which are not designated by the competent authority in accordance with the provisions of Article 13 may continue to import or export biological material, provided they demonstrate compliance with the applicable health requirements and occupational health and safety legislation by means of the documents established prior to the date of entry into force of this provision.

Single repealing provision. Repeal of regulations.
Royal Decree 65/2006 of 30 January 2006, laying down requirements for the import and export of biological samples, is hereby repealed.

First final provision. Jurisdictional competence.
This Royal Decree is issued pursuant to the provisions of Article 149(1) (16) of the Spanish Constitution, which grants the State exclusive competence over external health.

Second final provision. Regulatory authorisation and power of amendment.
The head of the Ministry of Health is empowered to issue, within the scope of its powers, the necessary provisions for the implementation of the provisions of this Royal Decree and, jointly with the head of the Ministry of Finance, issue the necessary provisions to give effect to the cooperation system provided for in Article 13.

Third final provision. Authorisation to agree on the application of an accelerated procedure in emergency situations.

1. The Head of the Directorate-General for Public Health and Health Equity is authorised, within the scope of their powers, to decide to apply an expedited procedure in cases where there is a declaration, by the Director-General of the World Health Organisation of a Public Health Emergency of International Concern or a Pandemic Emergency, or the declaration by the Minister of Health of a Public Health Emergency of National Concern, where such situations require immediate action.

2. The emergency fast-track procedure shall apply exclusively to types of biological material directly related to the emergency situation that led to its adoption, and only for as long as that situation persists.

Fourth final provision. Entry into force.

This Royal Decree shall enter into force on the day after its publication in the 'Official State Gazette'.