



PROCEDURE FOR THE AUTHORISATION OF THE ENTRY, EXIT OR TRANSIT OF BIOLOGICAL MATERIAL OF HUMAN OR ANIMAL OR SYNTHETIC OR OF ENVIRONMENTAL BIOLOGICAL AGENTS INTENDED FOR BIOLOGICAL RESEARCH, HUMAN DIAGNOSTIC RESEARCH, QUALITY CONTROL OR EVALUATION OF THE OPERATION OF DIAGNOSTIC REAGENTS, FROM OR FOR GIBRALTAR

This procedure shall apply to the entry, transit or exit from Spain of the following materials, coming from or destined for Gibraltar, intended for biomedical research, human diagnosis, quality control or evaluation of the functioning of diagnostic reagents:

- Biological material of human or synthetic origin and of biological agents isolated from the environment;
- Biological material of animal origin not 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) and not subject to official controls referred to in Article 47(1) of Regulation (EU) 2017/625 at the border control post of first arrival in the Union.

1. BIOLOGICAL MATERIAL FOR GIBRALTAR DESTINATION

1.1. Material from the United Kingdom or other third countries or territories

For the entry of material from the United Kingdom or other third countries or territories to Gibraltar, the interested party must submit an application for authorization through the existing form in the electronic headquarters of the Ministry of Health (<https://sede.mscbs.gob.es/registroElectronico/formularios.htm>), together with the following documentation:

- Proof of representation, where the importer or exporter was a legal person, or where the application was signed by a representative of the importer or exporter.
- Responsible declaration of the recipient signed electronically, indicating the type of material and its purpose, and the responsibility for its correct use and destruction and in which he declares to know and comply with the sanitary requirements for transit and departure from our country. It must also be stated that, according to the information available, the consignment meets all the requirements and that the corresponding supporting documentation is available.
- Part I of the dispatch document ([doc_despacho_muestrasbiologicas_Gibraltar.pdf](#)), for the import of biological material, completed and signed electronically by the operator.

Once the application has been reviewed and all the necessary documentation has been provided, the Directorate-General for Public Health and Health Equity will authorise or, where appropriate, refuse the introduction, transit and subsequent export to Gibraltar by completing Part II of the dispatch model mentioned above, notifying the interested party through the electronic headquarters of the Ministry of Health.

Authorisation decisions shall be valid for one month from the date of making them available at the electronic headquarters of the Ministry of Health, being sufficient time to be able to plan the logistical aspects of the consignment and ensure that all relevant administrative permits are in place upon arrival.



The material can only be entered through the authorized border points included in Order SAS/3166/2009 (Barcelona, Bilbao, La Farga de Moles, Madrid, Malaga, Palma de Mallorca, Seville, Tenerife, Valencia and Vitoria).

Once the entry is authorized, the goods in transit must leave the national territory through the Designated Customs Post or DCP of La Línea de la Concepción, where the corresponding customs procedures of exit must be carried out.

1.2. Biological material from Spain or other Member States

No specific authorisation will be required from the Ministry of Health, unless requested by the Gibraltar health authorities. However, such operations shall be subject to the customs formalities resulting from their application.

In any case, the physical departure of the goods must take place by the DPE located in La Línea de la Concepción or Algeciras.

2. BIOLOGICAL MATERIAL FROM GIBRALTAR

2.1. Material destined for Spain

For the entry of material from Gibraltar to Spain, the interested party must submit an application for authorization through the existing form in the electronic headquarters of the Ministry of Health (<https://sede.mscbs.gob.es/registrationElectronico/forms.htm>), together with the following documentation:

- Proof of representation, where the importer or exporter was a legal person or where the application was signed by a representative of the importer or exporter.
- Annex II duly signed and stamped by the laboratory or establishment of origin (M_B_Annex II.doc), identifying the consignment, its characteristics and the possible health risk if any.
- Written declaration describing, briefly, the purpose of the use of the samples, the responsibility for their correct use and destruction and the specification that they are not samples with commercial value, for which the invoice will be attached.
- Document proving the importer's activity and complying with the occupational safety regulations applicable to these products.
- Part I of the dispatch document for the import of biological material ([doc_despacho_imp_muestrasbiologicas.pdf](#)), completed and signed electronically by the operator.

Once the application has been reviewed and it has been verified that all the necessary documentation has been provided, the Directorate-General for Public Health and Health Equity will authorise or, where appropriate, refuse importation by completing part II of the dispatch model mentioned above, notifying the interested party through the electronic headquarters of the Ministry of Health.

Authorisation decisions shall be valid for one month from the date of making them available on the website of the Ministry of Health.

The material can only be introduced through the DPE of La Línea de la Concepción, where the corresponding customs procedures of entry must be carried out.



2.2. Material destined for the United Kingdom or other third countries or territories or other EU Member States

For the entry of material from Gibraltar to the United Kingdom or other countries, the interested party must submit an application for authorization through the existing form in the electronic headquarters of the Ministry of Health (<https://sede.mscbs.gob.es/registrationElectronico/forms.htm>), together with the following documentation:

- Proof of representation, where the importer or exporter was a legal person or where the application was signed by a representative of the importer or exporter.
- Declaration responsible for the establishment of origin, signed electronically, indicating the type of material and its purpose, as well as the responsibility for its correct use and destruction and declares to know and comply with the applicable health requirements for the transit and departure of the material from our country. It must also be stated that, according to the information available, the consignment meets all the requirements and that the corresponding supporting documentation is available.
- Part I of the dispatch document ([doc_despacho_imp_samplestrasbiologicas.pdf](#)), for the import of biological material, completed and signed electronically by the operator.

Once the application has been reviewed and all the necessary documentation has been provided, the Directorate-General for Public Health and Health Equity will authorize or, where appropriate, refuse the introduction and subsequent exit of the material, by completing part II of the dispatch model mentioned above, notifying the interested party through the electronic headquarters of the Ministry of Health.

Authorisation decisions shall be valid for one month from the date of making them available on the website of the Ministry of Health.

The material can only be introduced through the DPE of La Línea de la Concepción, where the corresponding customs procedures of entry must be carried out.