MINISTERIO
DE AGRICULTURA, PESCA Y
ALIMENTACIÓN

SECRETARÍA GENERAL DE AGRICULTURA Y ALIMENTACIÓN

DIRECCIÓN GENERAL DE SANIDAD DE LA PRODUCCIÓN AGRARIA

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IMPORT OF BIOLOGICAL MATERIAL (INFECTIOUS MATERIAL AND OTHER BY-PRODUCTS OF ANIMAL ORIGIN) INTENDED SOLELY FOR RESEARCH PURPOSES COMING FROM NON EUROPEAN UNION COUNTRIES OTHER THAN NORWAY SWITZERLAND ICELAND OR NORTH IRELAND [1]

This document describes the authorization procedures for the introduction of biological material intended for research which is by Delegation of the DG for Agricultural Production Health, in the field of Animal Health the responsibility of the Subdirectorate-General for Health Agreements and Border Control (SGASCF).

If the research project focuses on the competences of the Ministry of Health such as diagnosis or research in human beings, in the field of pharmaceuticals, cosmetics or medical devices (human use/consumption) or food safety, you must submit the request to the Ministry of Health. More information at: Ministerio de Sanidad - Profesionales - Importación y exportación de muestras biológicas

ATTENTION:

This procedure applies only to biological materials of animal origin from third countries other than Norway, Switzerland, Iceland or Northern Ireland and which are listed in the Annex to Implementing Regulation (EU) 2021/632. In the event that the product is not checked at the Border Control Post (e.g. non pathogenic cultures or cell lines, antibodies, DNA or non-pathogenic viruses or bacteria in animals) it is not necessary to process any permits as these products can be introduced without the need for veterinary border checks.

Only import applications for shipments managed through authorised transport companies will be accepted[2].

Application for approval

For the introduction of biological material (infectious material or other by-products of animal origin) into the national territory, **exclusively for research purposes**, there are two different procedures:

1. **STANDARD PROCEDURE**
2. **EXCLUSIVE PROCEDURE FOR THE IMPORT OF BLOOD SAMPLES FOR THE RABIES SEROLOGY TEST**

[1] For imports of these biological materials coming from EU countries or Norway, Switzerland, Iceland or Northern Ireland, the competent autohority is the Subdirectorate-General for Animal Health and Hygiene and Traceability (contact by email in: sganimal@mapa.es).

[2] Entries of biological material may be accepted directly by passengers in certain cases and only for imported blood samples for the rabies serology test.

1. STANDARD PROCEDURE

Application for authorisation

1. For the introduction of biological material (infectious material or other by-products of animal origin) into the national territory, exclusively for research purposes, a prior application must be submitted by Delegation of the Directorate-General for Agricultural Health, to the Subdirectorate-General for Health Agreements and Border Control (SGASCF).

2. The applicant shall send the application in accordance with **Annex** for the Standard procedure to the Subdirectorate-General for Health Agreements and Border Control (SGASCF). The application must be completed in full and signed by the person responsible for the research project. It shall be completed with the Spanish format. The **Annex** in English shall be used solely in case of entry the biological material by a Border Control Post placed in other Member State.

The Application should be accompanied by a **letter** of the person responsible of the research, **describing the purpose of the research**, the main features of the material to be imported in order to be able to assess the risk associated. This letter shall include in any case:

1. Scope of research: (description of the project and specification in the field within animal health or animal nutrition).
2. Treatment of decontamination of samples, or indication that no such treatment has been carried out.
3. Relevant information concerning the animals of provenance of samples where appropriate (health status, controls, surveillance, treatments...).
4. Include, where appropriate and relevant in the animal health risk assessment, an express reference to the commitment of the staff working with the samples to follow the biosecurity protocols when leaving the laboratory and, where appropriate, that they shall not go to holdings of susceptible/concerned species until at least 7 days after the last contact with the samples.
5. A statement including that users handling samples for diagnosis and investigation shall take all necessary measures to prevent the spread of communicable diseases to humans or animals during the handling of materials under their control, in particular through the application of good laboratory practice.

The application must be sent in advance of receipt of the goods at the airport. Otherwise, it may be retained until the completion of the procedure.

Applications will be submitted through the electronic platform of the Ministry of Agriculture, Fisheries and Food:

Ficha Procedimiento - Sede Electrónica MAPA

Processing and resolution: authorisation for the introduction and transport of the material.

This procedure has two parts:

Part one: Review and, when appropriate, authorisation and signature by the Subdirectorate-General for Health Agreements and Border Control. If necessary, additional information could be requested by the competent authority.
Part two: Review by the Animal Health Service of the airport/port of entry into Spain. This service will carry out the mandatory official identity check and after carrying out the appropriate verifications, if the check is satisfactory, the inspector shall sign the corresponding part of the application for the import of biological material, this document being sufficient for customs clearance.

Import applications shall be assessed taking into account the type of material, the animal species of provenance, its susceptibility to the various diseases, the animal health status of the country of origin and the biosecurity conditions of the facility for which they are intended.

Although this administrative procedure has a fixed resolution period of three months, in general they are processed within a few working days.

This import permit is valid for 60 calendar days from its issuance from the date of signature by the Subdirectorate.

2. EXCLUSIVE PROCEDURE FOR THE IMPORT OF BLOOD SAMPLES FOR THE RABIES SEROLOGY TEST

This procedure is reserved for Spanish laboratories accredited and designated to carry out serological tests for the detection of rabies antibodies. For individuals you can consult more information, as well as the list of laboratories authorised for this test under the **heading 4. Return to Spain after visiting a non-EU country- Rabies-Serology test**: Travelling with dogs, cats and ferrets (mapa.gob.es).

You can also contact the chosen laboratory directly to perform the test. In Spain it has two entities:

Laboratorio Central de Sanidad Animal Santa Fe
Camino del Jau s/n 18320 - Santa Fe (Granada)

Telf.: 958 440400

CLVgr@mapa.es

Instituto Valenciano de Microbiología (IVAMI)
Masía el Romeral; Ctra. Bétera a San Antonio de Benagéber, km 0.3
46117 - Bétera (Valencia)
ivami@ivami.com / Telf.: 96 169 17 02

(www.ivami.com)

3. BIOLOGICAL MATERIAL IMPORTED BY ANOTHER COUNTRY OF THE EUROPEAN UNION:

Biological materials destined for Spain that, coming from a third country, are introduced through another Member State of the European Union must present the import permit signed by this Sub-directorate and pass the identity control at the corresponding border control post of said country. In these cases, they must also process the CHEDP through TRACES, entering all the necessary data about the item and present Annex for the Standard procedure in English by electronic office, accessing the IMPORT website IMPORTACION (mapa.gob.es) to view the content in English and Download the Annex also in English. It is important to **indicate in said Annex the airport of entry** into the country of the European Union