Message 001

Communication from the Commission - TRIS/(2026) 1396

Directive (EU) 2015/1535

Notification: 2026/0255/ES

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx il-perijodi ta’ dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20261396.EN

1. MSG 001 IND 2026 0255 ES EN 22-05-2026 ES NOTIF

2. Spain

3A. Ministerio de Asuntos Exteriores, Unión Europea y Cooperación
Dirección General de Coordinación del Mercado Interior y Otras Políticas Comunitarias
Subdirección General de Asuntos Industriales, Energéticos, de Transportes y Comunicaciones, y de Medio Ambiente
Plaza Marqués de Salamanca 8, 28006 Madrid

3B. Subdirección General de Sanidad Exterior
D.G. de Salud Pública y Equidad en Salud
Ministerio de Sanidad
Paseo del Prado, 18-20, 28071 – Madrid
saniext@sanidad.gob.es
+34915962040

4. 2026/0255/ES - X00M - GOODS AND MISCELLANEOUS PRODUCTS

5. Draft Royal Decree establishing health requirements for the import and export of biological material

6. Human, animal or synthetic biological material for research, human diagnosis or quality control; haematopoietic progenitor cells for analytical purposes; and environmental samples suspected of containing pathogenic agents for analysis or research.

7.

8. The aim of the draft 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, human diagnosis 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.

The regulation also creates a nationwide information system enabling the electronic submission and processing of applications for the import and export of regulated biological material, as well as human substances intended for application in humans.

The draft brings its provisions into line with national and European Union regulations, 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, human diagnosis or quality control. At the same time, it aims to streamline administrative procedures and enhance the effectiveness of control measures, ensuring the protection of public health without hindering the international trade in this type of material.

9. Update the current regulations laying down the health requirements for the import and export of biological material intended for diagnosis or research in humans, including in vitro diagnostic reagents (Royal Decree 65/2006 of 30 January 2006, establishing requirements for the import and export of biological samples).

Simplify and streamline the administrative procedures for applying for and obtaining import, export or transit permits for the aforementioned biological material, ensuring the protection of public health by applying requirements proportionate to the health risk posed by each material, without hindering international trade.

Regulate the nationwide information system for the electronic submission and processing of applications for health authorisation for the import, export or transit of biological material intended for diagnosis or research in humans, as well as substances of human origin intended for application in humans

9a. The notified measure aims to address the risks to the protection of public health associated with the import and export of biological material intended for diagnosis or research in humans, or quality control in those areas not covered by harmonised European Union legislation.

This matter was already partially regulated by Royal Decree 65/2006 of 30 January 2006. However, the experience gained from its application and the regulatory, technical and operational developments occurred since its approval have revealed the advisability of updating and systematising the regulatory framework, in order to adapt it to the current reality of international flows of biological material and to the changes

introduced in European Union legislation, particularly in the field of official controls and health risk management.

The absence of clear and up-to-date regulations may lead to disparities in the application of health controls, difficulties in traceability and the predictability of administrative procedures, as well as non-uniform treatment of operators. These elements pose a risk to the adequate protection of public health and to the consistency of administrative action.

The draft royal decree contributes to the achievement of the public interest objective by establishing a clear and up-to-date regulatory framework that organises and systematises a previously regulated area, specifying the health requirements, administrative procedures and obligations of operators and the Administration—including those relating to eGovernment—without affecting market access conditions or intra-Community trade.

The objective of protecting public health is also pursued in a coherent and systematic manner, insofar as the regulation is integrated into the general framework of national and European Union health legislation, applies only in the absence of harmonised rules, and maintains a risk-based, proportionate and non-discriminatory approach.

9b. The draft royal decree does not introduce any substantive restrictions on the internal market, nor does it create barriers to trade or the cross-border provision of services. The measure is strictly health-related and procedural in nature, and is limited to regulating the requirements and control mechanisms applicable to the import of biological material from third countries or territories and the export of such material outside EU territory, exclusively in cases not regulated at a harmonised level.

The impact on the internal market is minimal, as the measure does not establish prohibitions, technical requirements relating to products, or conditions affecting their marketing. The measure is applied with complete commercial neutrality, without introducing any distinctions based on the origin of the goods and without affecting the free movement of goods within the European Union. On the contrary, the clarification of the administrative procedures and applicable requirements contributes to greater legal certainty and predictability for economic operators.

Existing general or sector-specific regulations are insufficient on their own to achieve the desired objective, as they do not provide specific and uniform rules governing the health checks applicable to this type of biological material. In particular, the previous regulation contained in Royal Decree 65/2006 has a limited scope and does not fully reflect the regulatory, technical and operational developments that have taken place in recent years, nor the increasing diversification of international flows of biological material.

The proposed measure constitutes the least restrictive option possible, given that it does not introduce a substantially new regime, but updates, organises and systematises an existing framework, applying only when there is no harmonised legislation and avoiding regulatory duplication. Alternatives such as the maintenance of the existing framework or the use of non-binding guidelines were considered but discarded as they did not ensure a uniform application of health controls and the necessary legal certainty.

Consequently, the adoption of this royal decree is considered necessary, as it makes it possible to achieve

the objective of protecting public health with a minimum impact on the internal market.

9c. The measures provided for in the draft royal decree respond to an essential public interest objective, consisting in the protection of public health and biosecurity, in a context of increasing international circulation of biological material and risks associated with emerging infectious agents.

The measure does not introduce any substantive restrictions, but is limited to regulating the procedural and organisational aspects necessary for the proper health management of these movements.

The requirements arising from the draft strike a balance between the potential seriousness of the health risk and the need to ensure that the competent authority applies the controls in a uniform and consistent manner. These are requirements of limited scope, based on a preventive and proportionate approach, which do not affect the characteristics of the products or impose additional technical conditions on their manufacture, composition or use.

The protection of the public interest pursued has been assessed by the competent authorities in relation to the potential extent of interference with the functioning of the internal market, and it has been concluded that such interference is either non-existent or strictly residual. The draft does not impose any conditions on market access, does not discriminate on the basis of the origin of goods, nor does it affect the free movement of goods or services within the European Union. On the contrary, the clarification and systematisation of administrative procedures contributes to greater legal certainty, transparency and predictability, reducing possible indirect burdens on operators.

Finally, it should be noted that the harm resulting from any failure to control the import or export of biological material—including the potential spread of infectious diseases or the introduction of pathogenic agents—would be significantly greater than the impact that the proposed measures might have on economic operators. Consequently, the balance struck between the protection of the public interest and the potential impact on the internal market is considered to be appropriate and consistent with the principle of proportionality.

10. References to the basic texts:

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

****

European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu