



ABBREVIATED REPORT ON THE REGULATORY IMPACT ANALYSIS

Royal Decree amending Royal Decree 429/2022, of 7 June, laying down regulations for the marketing of reproductive products of livestock species at a national level and regulating measures for the application of the European legislation applicable to movements within the European Union of reproductive products of livestock species

Justification for the abbreviated report:

In accordance with Article 3 of Royal Decree 931/2017, of 27 October, regulating the regulatory impact analysis report, this abbreviated report on the proposed regulation has been prepared for the proposed regulation, as no appreciable impacts arise in the areas described in that Royal Decree.

This draft legislation has no significant impact, as it consists of specific amendments to Royal Decree 429/2022, of 7 June, which establishes regulations for the marketing of reproductive products of livestock species at the national level and regulates measures for the application of European regulations applicable to the movement of reproductive products of livestock species within the European Union, aimed at ensuring the proper effectiveness of commercial transactions involving reproductive products of livestock species, eliminating unnecessary obstacles, without compromising the traceability of the material, and improving its wording to avoid inconsistencies in its application. These amendments do not alter the framework provided for in the amended regulation, either from a jurisdictional authority perspective or with regard to the other parameters subject to analysis.

Furthermore, the draft has no effect on market competition and does not have any general economic effects. Nor does it give rise to an increase in public expenditure.

Legal basis and rank of the draft:

The regulation is based on the fifth final provision of Law 8/2003, of 24 April, on animal health, which empowers the Government to adopt any provisions necessary for its specific application and implementation.

Regarding the rank, in this case the circumstances exist that justify the rank of the draft (basic regulation) as a Royal Decree. Thus, the case-law of the Constitutional Court, since STC (Constitutional Court ruling) 69/1988, of 19 April, Legal basis 5, has consistently held that the review of basic legislation requires the review of two dimensions: a material dimension and a formal dimension. The former responds to the need to prevent regional jurisdictional authority from being rendered meaningless or unconstitutionally curtailed. The latter aims to ensure that the closure of the system is not left in a permanent state of ambiguity that would arise from recognising that the State has power to suddenly impose on the Autonomous Regions, as a basic regulation, any kind of legal or regulatory precept, regardless of its rank or structure. The formal perspective of the basic regulation is based on the principle of formal law "...as only through this regulatory instrument can



there be... a clear and certain identification of the areas of organisation of matters pertaining to and articulating basic state and regional regulatory jurisdictional authorities.” It also states that “... as an exception to said principle of formal law... the Government may use its regulatory power to regulate by Decree any of the basic provisions of a matter when, due to its jurisdiction, these are a necessary supplement to safeguard the objective of the power on the basic texts, such that the basic texts should not be formulated through regulatory instruments whose legal rank is lower than that of the Law and the Royal Decree, in which they are ordinarily enshrined”. Therefore, the regulatory rule is a necessary supplement to safeguard the objective of the basic texts. And this basic character of the regulation, according to the Court, may be inferred from the content and structure of the regulatory rule that has that basic purpose (SSTC (Constitutional Court rulings) 197/1996, Legal bases 5 and 24, and 118/1998, Legal basis 16)), factors that are present in this case, in which the essential aspects are provided for in Law 8/2003, of 24 April, on animal health, and the draft sets out aspects that are eminently technical and procedural.

In any case, since these are amendments to a regulation in force, the regulatory rule must have the same rank as the regulation being amended.

Timeliness and contents:

Animal genetic resources, and native breeds in particular, provide an essential basis of biodiversity, resilience and adaptability in the face of threats such as climate change, emerging diseases, production conditions and market and societal demands. They are, therefore, essential instruments for the sustainable development of the livestock sector, thus guaranteeing food security.

The recognition of all the benefits they provide has led to the need to prioritise the characterisation, conservation and improvement of animal genetic resources, not only at national level, but also internationally.

Royal Decree 429/2022, of 7 June, which establishes regulations for the marketing of reproductive products of livestock species at national level and regulates measures for the application of European regulations applicable to the movement of reproductive products of livestock species within the European Union, aims to ensure the rational and safe use of reproductive products at national level, for which it is necessary to guarantee their zootechnical and sanitary quality. To that end, it lays down specific regulations for the authorisation or commencement of operation of establishments that collect, produce, process, store or distribute these products, as well as the requirements applicable to donor animals and to the reproductive products themselves.

All of the above should be subject to a traceability system that includes registers of establishments by administrations, registers of movements of reproductive products in each establishment involved in their marketing, and regulations on the labelling of reproductive products and for the documents accompanying their consignments. That document is a requirement laid down in Article 50 of Law 8/2003, of 24 April, on animal health.



After detecting that certain traceability requirements, provided for in the aforementioned Royal Decree 429/2022, of 7 June, make it difficult to market these products, without providing additional guarantees, these requirements are amended in order to guarantee the purpose of the control system established. Similarly, the wording of some sections has been reviewed to improve clarity in the application of this regulation. And all this in order to guarantee the productive efficiency of many of our livestock sectors.

As regards its content, the draft royal decree consists of a preamble, a sole article with three paragraphs and a final provision, referring to the entry into force.

For the sake of completeness, the amendments to Royal Decree 429/2022, of 7 June, are as follows:

- **Section 1** provides a **new wording for Article 9, Paragraph 3**, which establishes additional traceability requirements for national trade, including the possibility that the document that must accompany the marketed products can be issued, signed and kept in digital format, resulting in an improvement in the management of their traceability.
- **Section 2** amends **Article 12, Paragraph 2**, which regulates the zootechnical and traceability requirements for distributors. Its wording has been improved to facilitate its application by expressly including registered establishments, and not only authorised ones, for the production of material that can be marketed.
- **Section 3** amends **Annex I, Paragraph 5**, to include more specific information that must be included in the document accompanying reproductive products during their transport.

Processing of the draft

The processing of this provision has been carried out within the framework of the Royal Decree establishing the regulatory basic texts for grants aimed at promoting Spanish native breeds, in accordance with Article 26 of Law 50/1997, of 27 November.

The prior public consultation referred to in Article 26, Paragraph 2, of Law 50/1997, of 27 November, was carried out between 12 February and 26 February 2025 without any allegations being received.

The public hearing and information session provided for in Article 26, Paragraph 6, of Law 50/1997, of 27 November, has been held, and direct consultation with the Autonomous Regions and the sector took place between 30 July 2025 and 26 August 2025. The observations received, as well as their analysis, have been collected in Annex I.

Furthermore, the draft has been approved by the Technical General Secretariat of the Department in its report dated 29 July 2025 (Article 26, Paragraph 5, Subparagraph 4, of Law 50/1997, of 27 November), without comments.

Likewise, the report from the Ministry of Territorial Policy dated 5 August on the draft's compliance with the constitutional distribution of jurisdictional authority (Article 26, Paragraph 5, Subparagraph 6, of Law 50/1997, of 27 November), has been obtained, and its considerations have been taken into account in the text.



The report on regulatory quality from the Ministry of the Presidency, Relations with the Courts and Democratic Memory (Article 26, Paragraph 9, of Law 50/1997, of 27 November) was requested on 29 July 2025 (without being issued within the deadline), and so the proceedings continue.

Once the previous actions were completed, the then second final provision has been separated from said draft since it required two additional procedures, which continue their course as an autonomous draft.

By virtue thereof, as of December – with the initial draft already published as Royal Decree 1133/2025, of 10 December, establishing the regulatory basic texts for subsidies aimed at promoting native Spanish breeds – the following actions will be carried out:

In accordance with Articles 5 and 6 of 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, the draft has been notified to the European Commission.

Finally, an opinion shall be sought from the Council of State, in accordance with Article 22, Paragraph 3, of Organic Law 3/1980, of 22 April, on the Council of State.

Identification of the prevailing jurisdictional authority:

This regulation is issued pursuant to Article 149, Paragraph 1, Subparagraphs 13 and 16, of the Spanish Constitution, which respectively assign the State jurisdictional authority regarding the basic texts and coordination of the general planning of economic activity and the basic texts and general coordination of health.

The draft respects the doctrine of the Constitutional Court. Thus, with regard to Rule 13, in Ruling 58/2015, of 18 March, Legal basis 2, it is clarified that: 'In general, as has been recognised by constitutional doctrine, the State's jurisdictional authority in the basic texts and coordination of economic planning is projected onto the livestock subsector, given the recognised and express relationship it has with general economic policy (SSTC (Constitutional Court rulings) 145/1989, Legal basis 5; 158/2011, of 19 October, Legal basis 8 and 207/2011, of 20 December, Legal basis 7)). Thus, the Court has held that it is for the State, pursuant to its responsibility for general organisation of the economy, to establish the overall guidelines for the organisation and regulation of the national agricultural market, leaving it to the Autonomous Region to adopt, within the framework of those general guidelines, any measures which are not contrary to them but complementary, concurrent or neutral, in such a way that, if they are aimed at improving the structures of its own agriculture and livestock farming, they do not interfere negatively or distort the general organisation established by the State, instead either aiding it or being innocuous to state organisation. In addition, the Court has recognised the powers of the Autonomous Region to adopt the necessary provisions in addition to European law and to implement and apply community legislation within their territorial scope provided that, *ratione materiae*, the Autonomous Regions



have such jurisdictional authority and do not exceed the boundary established by community and basic national or coordinating legislation (STC (Constitutional Court Ruling) 104/2013 of 25 April 2013, Legal basis 5).

Constitutional doctrine has also demonstrated the role of the jurisdictional authority contained in Article 149, Paragraph 1.16 EC in the livestock subsector (among others SSTC (Constitutional Court Rulings) 32/1983, of 28 April, Legal basis 3, and 158/2011, of 19 October, Legal basis 10)). This Court recognised this by stating that epizootic diseases affecting livestock fall jurisdictionally under health matters (Constitutional Court Ruling 32/1983, of 28 April, Legal basis 3, and 192/1990, of 29 November, Legal basis 2)), a jurisdiction that also includes measures for the prevention and control of animal diseases, as stated in Constitutional Court Ruling 158/2011, of 19 October, Legal basis 10. State jurisdictional authority for health include the establishment of the basic texts and coordination.

List of regulations that are repealed:

This draft royal decree does not repeal any previous regulation.

Ex-post evaluation

Pursuant to the provisions of Article 28, Paragraph 2, of the Government Law, Articles 2, Paragraphs 5 and 3, of Royal Decree 286/2017, of 24 March, regulating the Annual Regulatory Plan and the Annual Report on Regulatory Evaluation of the General State Administration and establishing the Regulatory Planning and Evaluation Board and Article 2, Paragraph 1(j), of Royal Decree 931/2017, of 27 October, this regulation is not considered to be subject to evaluation since none of the legal assumptions provided render this evaluation compulsory.

Economic and budgetary impact:

The purpose of this draft is to make specific amendments to the aforementioned Royal Decree 429/2022, of 7 June. Given its content and scope, it is clear that these amendments do not represent an increase in public expenditure.

Personnel expenses, supplies or remuneration, expenses on digital administration media or services or any other expenses at the service of the Public Sector are zero, as they are the usual ones in the management and control process.

This regulation does not affect access to economic activities under market conditions and their exercise by operators legally established anywhere in the national territory, and therefore does not fall within the scope of Law 20/2013, of 9 December, on guaranteeing market unity.

Impact based on gender:

This draft has no impact on gender, within the meaning of Article 26, Paragraph 3(f), of Law 50/1997, of 27 November, on the Government.



Impact based on climate change:

This draft has no impact in terms of climate change mitigation and adaptation, within the meaning of Article 26, Paragraph 3(h), of Law 50/1997, of 27 November, on the Government, introduced by the fifth final provision of Law 7/2021, of 20 May, on climate change and energy transition.

Impact on children and adolescents:

In accordance with the fifth provision of Article 22 of Organic Law 1/1996, of 15 January, on the Legal Protection of Minors, partially amending the Civil Code and the Civil Procedure Act, as amended by Law 26/2015, of 28 July, amending the system for the protection of children and adolescents, the draft order has no impact on children or adolescents.

Impact on the family:

In accordance with the tenth additional provision of Law 40/2003, of 18 November, on the protection of large families, introduced by the fifth final provision of Law 26/2015, of 28 July, amending the system of protection for children and adolescents, the draft order has no impact on the family.

Other impacts:

There are no impacts in regard to the environment, equal opportunities, non-discrimination or universal access for persons with disabilities.

Since this draft royal decree deals with specific amendments to Royal Decree 429/2022, of 7 June, it also does not represent an impact on citizens and on the digital administration in its application.



ANNEX I

Comments received during the public hearing and information procedure on the draft royal decree amending Royal Decree 429/2022, of 7 June

ENTITY	NUMBER	Comment and Justification	Proposal	Assessment (to be completed by the Administration)	Resolution (to be completed by the Administration)
AUTONOMOUS REGION OF GALICIA	Second final provision. One. Article 12, Paragraph 2, shall read as follows: '2. They may only place on the market material obtained from establishments approved by national or European legislation and whose recipients are the end-users.'	They can also market material from third countries.	'2. They may only place on the market material obtained from establishments approved by national, European Union or third-country legislation and whose recipients are the end-users.'	Centres in third countries that could supply equipment to distributors must be approved and entered on the Commission's lists, and in order to do so they must comply with European legislation. It is thus not appropriate to include "or from third countries" because in no case could the marketing of material from a centre in a third country that does not comply with European	NOT ACCEPTED.



				legislation be accepted. The mention of third countries is therefore redundant.	
ANPS (Spanish National Association of Breeders of Select Swine) and RFEAGAS (Royal Spanish Federation of Associations of Selected Livestock)	Article 6. Point 5 of Royal Decree 429/2022	1. Official laboratories Consideration should be given to the possibility of carrying out the official analyses in an official laboratory of another Autonomous Region, even if there is a laboratory in the Autonomous Region where the farm is located. The rationale is twofold: <input type="checkbox"/> Overload of work in some regional laboratories delays the delivery of results. <input type="checkbox"/> Need for speed in obtaining diagnoses in order to apply immediate health measures. Article 24, Section 3, Chapter 1, Part III, of Delegated Regulation (EU) 2020/686 establishes that the tests must be carried out in official laboratories, but at no point does it restrict this to the same Autonomous Region. This flexibility is necessary, since in many cases the regional laboratories do not have adequate resources or deliver the results several days late.		Neither Regulation (EU) 2020/686 nor Royal Decree 429/2022 in its current wording hinders the choice of laboratory, as long as they are official laboratories. Therefore, the amendment of the regulation is not appropriate.	NOT ACCEPTED
ANPS (Spanish National Association of Breeders of Select Swine) and RFEAGAS	PRRS	It is essential to define the procedure to follow in the event of a positive PRRS result, whether it comes from an official laboratory or from a private laboratory with accredited certification . The reason is that not all the Autonomous Regions have the technology to perform these tests in their official laboratories.		The possibility of using certified private laboratories for these tests is not being considered. In 2022 the CNZ	NOT ACCEPTED



<p>(Royal Spanish Federation of Associations of Selected Livestock)</p>		<p>In addition, a clear criterion should be laid down for the results of private laboratories to be taken into account in the decision-making affecting a farm, including its immobilisation.</p>		<p>(Spanish National Commission of Animal Husbandry) agreed on a procedure for dealing with these cases, which is published in ARCA (Spanish National Breed Information System): https://www.mapa.gob.es/dam/mapa/contenido/ganaderia/temas/zootecnia/arca/razas/publicaciones-de-interes/libros/procedimientopositivotestserologicopr18_10_22web.pdf</p>	
<p>ANPS (Spanish National Association of Breeders)</p>	<p>Article 6. Point 7</p>	<p>7. Transport of reproductive products There is some ambiguity regarding the obligation to seal the transport containers, since Regulation (EU) 2020/686 states in Recital 27 that the containers must be</p>		<p>In order to ensure the traceability of movements of reproductive</p>	<p>NOT ACCEPTED.</p>



<p>of Select Swine) and RFEAGAS (Royal Spanish Federation of Associations of Selected Livestock)</p>		<p>sealed when transporting reproductive products:</p> <ul style="list-style-type: none">• <input type="checkbox"/> From authorised establishments towards other Member States.• <input type="checkbox"/> At the national level, from authorised establishments to processing establishments or storage centres for reproductive products. <p>At no point is it mentioned that the transport of processed product directly to the end user should be subject to this obligation.</p> <p>Likewise, in Section 5, Chapter 1, Part III, of the same Regulation, neither is the requirement for sealing in these cases expressly established.</p> <p>It is therefore necessary to clarify this point in the wording of the article, clearly differentiating the situations in which sealing is mandatory and those in which it is not.</p> <p>Furthermore, we reiterate the need to move forward with the standardisation of the sealing system for transport containers, through the definition of basic standards that include the type of seal material, shape and system of closure, and minimum identification and traceability requirements.</p> <p>This standardisation would provide legal certainty, homogeneity of criteria between</p>		<p>products, the sealing of the transport containers must continue to be required. This also provides a guarantee against tampering with the material.</p> <p>Regarding the request for standardisation, defining it in a regulation would place an additional burden on operators of all species, since different types of seals may exist depending on the type of reproductive product container. The current wording is maintained in this regard so that each</p>	
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		Autonomous Regions and a higher guarantee of animal health in the transport of reproductive products.		operator can find the most efficient way to seal the containers.	
ANPS (Spanish National Association of Breeders of Select Swine) and RFEAGAS (Royal Spanish Federation of Associations of Selected Livestock)	Article 9. "3. Reproductive products placed on the market must be accompanied by a document containing the particulars specified in Annex I, issued by the veterinarian of the approved site or team or the veterinarian responsible for the registered establishment."		3. Reproductive products placed on the market must be accompanied by a document containing the particulars specified in Annex I, issued by the veterinarian of the approved site or team or the veterinarian responsible for the registered establishment. <i>This document may be issued, signed and stored in digital format, with full legal validity and probative value, in accordance with the provisions of Law 39/2015, of 1 October, on the Common Administrative</i>	The proposal is included with an amendment, to provide greater clarity, so that the wording of Article 9, Paragraph 3, would be: <i>Reproductive products placed on the market must be accompanied by a document containing the particulars specified in Annex I, issued by the veterinarian of the approved site or team or the veterinarian responsible for the registered establishment. This document may be issued,</i>	ACCEPTED



			<p>Procedure of Public Administrations, and Law 6/2020, of 11 November, regulating certain aspects of trusted electronic services.”</p>	<p><i>signed and kept in digital format, with full legal validity and evidentiary effect, in accordance with the provisions of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, Regulation (EU) No 910/2014 of the European Parliament and of the Council, of 23 July 2014, on electronic identification and trust services in electronic transactions in the internal market and repealing Directive 1999/93/EC, and Law 6/2020, of 11 November,</i></p>	
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				<i>regulating certain aspects of electronic trust services or other applicable legislation.</i>	
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