

Royal Decree amending Royal Decree 429/2022, of 7 June, which establishes rules 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 within the European Union of reproductive products of livestock species.

Royal Decree 429/2022, of 7 June, which establishes rules 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 within the European Union of reproductive products of livestock species, aims to guarantee a rational and safe use of reproductive products at the national level, for which purpose it is necessary to guarantee their zootechnical and health quality. To this end, it establishes specific rules for the authorisation or operation of establishments that collect, produce, process, store or distribute these products, as well as the requirements applicable to donor animals and the reproductive products themselves.

All of the above must be subject to a traceability system that includes records of establishments maintained by the relevant authorities, records of the movements of reproductive products in each establishment that is involved in their marketing, and rules on the labelling of these products and the documents that accompany their shipments. This document is a requirement stipulated in Article 50 of Law 8/2003, of 24 April, on animal health.

After it was determined that certain traceability requirements, established in the aforementioned Royal Decree 429/2022, of 7 June, hinder the marketing of these products without providing additional guarantees, these requirements are being amended to ensure the end purpose of the established control system. Similarly, the wording of some sections has been revised to improve clarity in the application of this regulation. All of this is aimed at guaranteeing the productive efficiency of our livestock sectors.

The autonomous communities as well as the representative entities of the sector, have been consulted during the drafting of this Royal Decree. The notification procedure to the European Commission, as stipulated in Articles 5 and 6 of Directive (EU) 2015/1535 of the European Parliament and of the Council, of 9 September, laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services has also been fulfilled.

The content of this Royal Decree complies with the principles set forth in Article 129 of Law 39/2015, of 1 October, on the Common Administrative Procedures in Public Administration. Thus, in accordance with the principles of necessity and effectiveness, this regulation is justified by the need to adapt our legislation to that of the European Union, and it is the most appropriate instrument to ensure its uniform application throughout the national territory, thereby guaranteeing the public interest. It has also been adapted to the principle of proportionality, since there is no alternative that is less restrictive of rights or that imposes fewer obligations on the recipients. With regard to the principles of legal certainty, transparency and efficiency, this regulation adheres to them, as it is consistent with the rest of the legal system and efforts have been made to ensure the participation of interested parties, thus avoiding unnecessary administrative burdens.

This Royal Decree is issued by virtue of the authorisation contained in the fifth final provision of Law 8/2003, of 24 April, on animal health and pursuant to the provisions of rules 13 and 16 of Article 149(1) of the Spanish Constitution, which respectively grants the State exclusive competence regarding the basic principles and coordination of general economic planning and the general coordination of health.

Therefore, at the proposal of the Minister of Agriculture, Fisheries and Food, in accordance with the Council of State, and after deliberation by the Council of Ministers at its meeting on xxxxxxxx, xxxx,

I HEREBY ORDER:

Sole article. Amendment of Royal Decree 429/2022, of 7 June, which establishes rules 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 within the European Union of reproductive products of livestock species.

Royal Decree 429/2022, of 7 June, which establishes rules 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 within the European Union of reproductive products of livestock species, is amended as follows:

One. Section 3 of Article 9 is worded as follows:

'3. The marketed reproductive products must be accompanied by a document containing the data specified in Annex I, issued by the veterinarian of the authorised centre or team or by the veterinarian responsible for the registered establishment. This document may be issued, signed and stored in digital format, with full legal validity and evidentiary effectiveness, in accordance with the provisions of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, Regulation (EU) 910/2014 of the European Parliament and of the Council, of 23 July, on electronic identification and trust services in electronic transactions in the internal market and repealing Directive 1999/93/EC, as well as Law 6/2020, of 11 November, regulating certain aspects of electronic trust services or other applicable regulations.'

Two. Section 2 of Article 12 is worded as follows:

'2. They may only market material obtained from establishments registered or authorised under national or European legislation and whose recipients are end-users.'

Three. Section 5 of Annex I is worded as follows:

'5. Where applicable, the name of the added antibiotic(s) and their concentration, or the trade name of the semen extender containing antibiotics.'

Sole final provision. *Entry into force.*

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