

Rules on prohibited antimicrobials in imported animal products

Published by AGRINFO on 23 May 2023; Revised 04 Apr 2024

Information still required from many non-EU countries to meet new rules on antimicrobials in animal products

Commission Delegated Regulation (EU) <u>2023/905</u> of 27 February 2023 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Update

The European Commission has indicated that many non-EU countries still need to submit information related to compliance with rules on antimicrobial medicinal products to ensure that they can continue to export animal products in September 2026. Regulation 2023/905 established stricter requirements to ensure that live animals and certain animal products exported to the EU are not produced using certain prohibited antimicrobials.

In order to export such products, countries will have to be included in an official list of authorised exporting countries (confirming they are compliant with the new antimicrobial rules), and must use the updated official certificates that have an attestation of compliance signed by their competent authorities. The deadline to be included in the first version of the EU's list of authorised exporting countries was the end of November 2023. Any non-EU countries that have not submitted information by this date **should send the required written declaration guaranteeing compliance** as soon as possible. The declaration must include **every** type of animal product exported to the EU to avoid potential disruptions to trade.

On 6 March 2024, the European Commission indicated that 21 countries (out of 98) had not replied at all, and some countries had not provided the declaration for all the commodities they currently export. Providing this information rapidly will be crucial when exporting animal products from 2026 onwards.

Impacted products

Livestock and animal products for human consumption.

Exceptions are:





- gelatine, collagen, highly refined products, composite products, wild animals, insects, frogs, snails, and reptiles
- animals and food in transit not placed on the EU market
- animals or animal products not intended for human consumption
- samples for product analysis and quality testing not placed on the market.

What is changing?

Under Regulation <u>2022/1255</u>, certain antimicrobials are prohibited from being used in food-producing animals, and Regulation <u>2019/6</u> (Art. 107) bans the use of antimicrobials for growth promotion in the EU. Non-EU countries (<u>2019/6</u>, Art. 118) must:

- show evidence of compliance with the prohibition on antimicrobials; compliant countries will be placed on the list of authorised exporting countries
- confirm compliance by signing a new specific attestation for each consignment, which must be added to the official certificates already required for animal product exports.

This Regulation establishes the basic principles. It is complemented by the revised <u>Model health</u> <u>certificates</u> and the list of authorised countries.

Non-EU countries received a letter in May 2023, requesting them to produce a written declaration providing guarantees of conformity with Article 3 of Regulation 2023/905 before the end of November 2023. The EU Commission will assess the guarantees, and draft an Implementing Act with the list of non-EU countries that have provided guarantees.

The new rules will not apply to products in transit in the EU, or to gelatine, collagen, highly refined products, composite products, wild animals, insects, frogs, snails, or reptiles.

Why?

Antimicrobial resistance is viewed as a major threat to global health. The EU seeks to ensure prudent and responsible use of antimicrobials in animals. It prohibits the use in animals of certain antimicrobials that are used to treat humans, to ensure their continued effectiveness. Antimicrobials cannot be used either as growth promoters or to increase yield.

Timeline

Date of publication: 4 May 2023.





Date of application: **3 September 2026** (24 months after the entry into application of Regulation 2024/399 laying down the revised Model health certificates).

What are the major implications for exporting countries?

Non-EU countries exporting livestock and animal products to the EU will have to put in place a system guaranteeing that prohibited antimicrobials are not used in goods exported to the EU market during the whole lifetime of the animals. This will be a condition for inclusion on the dedicated list of authorised exporting countries.

If non-EU countries do not provide the declaration guaranteeing compliance with rules on antimicrobials for **every** animal product they export to the EU, they risk not being included in the list. In that case, they will no longer be able to export the animal products that are missing from the declaration.

When Regulation <u>2023/905</u> enters into application, non-EU country authorities will need to certify each consignment of animal products exported to the EU.

Recommended Actions

Competent authorities in exporting countries must verify that they have submitted the declaration requested by the Commission, including all relevant export products. On 6 March the Commission indicated that 21 countries had not yet submitted a declaration (European Commission 2024). They also indicated that "some countries have not provided guarantees for all commodities they are authorised to export under the residue list: countries will only be listed for the commodities for which they have submitted guarantees" (European Commission 2024; see Third country lists for public health — explained). Competent authorities must ensure that a declaration has been made for all relevant products including, for example, for honey, casings, and aquatic animals. Although the November 2023 deadline has passed, to prevent any disruption of trade in 2026, it is recommended to provide all information as soon as possible to SANTE-VETERINARY-MEDICINES@ec.europa.eu.

Particular attention must be paid to products that have a long cycle of production (beef, casings, processed products, etc.). To be able to export such products to the EU from 3 September 2026, the guarantees must be in place **from the birth** of the food-producing animals, which may mean, for example, a period of 2 years or more prior to export.

In each country, competent authorities will have to assess what steps are required to comply with Regulation 2023/905. Coordination with representatives of the livestock and animal products sector will be needed, and potentially the adoption of national legislation or adaptation of control systems.





A forthcoming draft Implementing Regulation listing authorised non-EU countries will be notified to the World Trade Organization. In the meantime, any questions can be emailed to agrinfo@colead.link.

Background

To fight antimicrobial resistance and combat its global spread, Regulation <u>2019/6</u>, Art. 118(1) established that the following provisions are also to be applied to operators from non-EU countries exporting animals and certain animal products for human consumption to the European Union:

- the prohibition of using antimicrobials to promote growth and increase yield
- the prohibition of using antimicrobials reserved for the treatment of specific infections in humans, as listed in the Annex of Implementing Regulation 2022/1255 (see List of antimicrobials reserved for treatment of certain infections in humans); the criteria for which antimicrobials are reserved for human use are established in Regulation (EU) 2021/1760.

The list of non-EU countries, and the adaptation of the official certificates, will be based on the Official Controls Regulation 2017/625 (Arts. 126 and 127).

Resources

European Commission (2024) <u>State of play concerning the implementation of Commission</u> <u>Delegated Regulation (EU) 2023/905</u>. Powerpoint presentation, 6 March.

European Commission: Regulation (EU) 2019/6 – Delegated Acts: "Detailed rules regarding animals or products of animal origin imported into the Union (Article 118 (2))"

Regulation <u>2024/399</u> as regards model certificates for the entry into the Union of consignments of certain products of animal origin and certain categories of animals

Regulation (EU) <u>2022/1255</u> designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans

Regulation (EU) <u>2021/1760</u> establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans

Regulation <u>2019/6</u> on veterinary medicinal products





Sources

Regulation <u>2023/905</u> as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

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