

**Voluntary Report** – Voluntary - Public Distribution

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**Report Name:** Delegated Act Published for Article 118 of the EU Veterinary Medicinal Products Regulation

**Country:** European Union

**Post:** Brussels USEU

**Report Category:** SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports

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**Report Highlights:**

The European Commission published Delegated Act 2023/905 in the Official Journal on May 4, 2023. This Act addresses the rules under Article 118 of the EU Veterinary Medicinal Products Regulation 2019/6 for the use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries to the European Union. Additional Implementing Acts will follow enforcing the third country list and certification. Once published, the Implementing Acts are expected to enter into force 24 months later.

## **Executive Summary:**

On May 4, 2023, the European Commission published Delegated Act 2023/905 in the Official Journal. This Act outlines the rules under Article 118 of the EU Veterinary Medicinal Products Regulation 2019/6 for the use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the European Union. Two Implementing Acts will follow the Act to enforce third country compliance. The Implementing Acts will contain 1) a list of approved third countries to assure that only consignments in alignment with the prohibitions detailed in Regulation 2019/6 will be exported to the EU, and 2) the requirement of an official certificate. Once published in the Official Journal, the Implementing Acts are expected to enter into force 24 months later.

## **Background:**

On January 28, 2022, the EU's Veterinary Medicinal Products Regulation (EU) 2019/6 entered into force imposing restrictions on the use of antimicrobials in veterinary medicine as part of the EU's effort to address antimicrobial resistance (AMR). The EU's veterinary drug legislation restricts a list of antimicrobials to human medical use only. The legislation also prohibits producers within EU Member States and producers in countries exporting to the EU from using certain antimicrobial drugs for growth promotion, irrespective of whether the antimicrobials are medically important. Article 118 of the Regulation applies these requirements to producers in third countries exporting to the EU. The Delegated Act for Article 118 missed the January 28, 2022 implementing deadline of the Veterinary Medicinal Products Regulation.

In December 2022, the European Commission shared a draft of the Delegated Act for public comment and also notified it to the WTO. On February 27, 2023, the Commission adopted the Delegated Act implementing the rules for a ban on the use of certain antimicrobials in animals and products of animal origin to imports into the Union. [Commission Delegated Regulation \(EU\) 2023/905](#) was published in the Official Journal on May 4, 2023. It formally extends the EU ban on the use of certain antimicrobials reserved for human medicine in animal farming as listed in Commission Implementing Regulation (EU) 2022/1255 to animals and animal products imported into the EU. The Act applies to live food-producing animals (Combined Nomenclature (CN) codes laid down in Part 2, Chapter 1 of Annex I to Regulation (EEC) 2658/87) and products of animal origin intended for human consumption (CN codes laid down in Part 2, Chapters 2-5, 15, 16 of Annex I to Regulation (EEC) 2658/87). This new Act will not apply to transshipments and further exempts insects, wild animals, composite products, and other highly refined products, including gelatin, collagen, and their products.

The implementation of Article 118 and Delegated Act 2023/905 will be enforced through:

1. A list of approved third countries to assure that only consignments in alignment with the prohibitions detailed in Regulation 2019/6 will be exported to the EU (pre-amble 12).
2. The requirement of an official certificate (pre-amble 13).

Both the list of third countries and the specific requirements of the official certificates have not been published yet and will be issued through additional Implementing Acts. The conditions for consignments of animals or products will enter into force 24 months after both Implementing Acts have been published.

	Status	Publication	Relevant FAS GAIN Report
<b>Veterinary Medicinal Products Regulation 2019/6</b>	Adopted December 2018 with application as of January 28, 2022	<a href="https://eur-lex.europa.eu/eli/reg/2019/6/oj">https://eur-lex.europa.eu/eli/reg/2019/6/oj</a>	
<b>Delegated Act 2021/1760 for the Criteria of the List of Antimicrobials</b>	Adopted May 2021 with application as of January 28, 2022	<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1760&amp;qid=1685725324574">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1760&amp;qid=1685725324574</a>	
<b>Implementing Act 2022/1255 with the List of Antimicrobials</b>	Adopted July 2022 with application as of February 9, 2023	<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R1255&amp;qid=1685724101671">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R1255&amp;qid=1685724101671</a>	<a href="https://fas.usda.gov/data/european-union-european-commission-opens-feedback-period-list-antimicrobials-reserved-human">https://fas.usda.gov/data/european-union-european-commission-opens-feedback-period-list-antimicrobials-reserved-human</a>
<b>Delegated Act 2023/905 for Article 118</b>	Adopted February 2023 with application 24 months after date of application of Implementing Acts	<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R0905&amp;qid=1684331329732">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R0905&amp;qid=1684331329732</a>	<a href="https://www.fas.usda.gov/data/european-union-draft-commission-delegated-regulation-implementing-article-118-eu-veterinary">https://www.fas.usda.gov/data/european-union-draft-commission-delegated-regulation-implementing-article-118-eu-veterinary</a>
<b>Implementing Act for Third Country List</b>	Not yet adopted		
<b>Implementing Act for Third Country Certification</b>	Not yet adopted		

### Post Outlook:

The European Commission held a meeting with third countries in January 2023 to discuss the Delegated Act and another meeting will take place in June 2023 to discuss the Implementing Acts. The Commission also requested third countries to complete a document demonstrating their guarantee for compliance for the development of the third country list. This document is due to the Commission by November 2023.

These overall measures could impact up to \$1.5 billion per year in exports of U.S. animal products to the EU depending on when and how requirements for compliance and implementation timelines are enforced. The United States exported \$1.5 billion in animal products to the European Union in 2022, including seafood exports making up \$1.1 billion, followed by beef at \$246 million, dairy \$147 million, poultry and egg products at \$64 million, pork at \$7.3 million with \$2.2 million directly from natural swine casings, other meat products at \$2.9 million, and honey at \$23,000.

### Attachments:

No Attachments.