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Committee on Sanitary and Phytosanitary Measures

EUROPEAN UNION REVIEW OF LEGISLATION ON VETERINARY MEDICINAL PRODUCTS - SPECIFIC TRADE CONCERN 446

SUBMISSION BY THE UNITED STATES OF AMERICA

The following submission, received on 27 March 2023, is the statement made by the United States of America at the 22-24 March 2023 WTO SPS Committee, and is being circulated at the request of the Delegation of the <u>United States of America</u>.

- 1. The United States again raises our concerns with the European Union regarding the implementation of Article 118 of EU regulation 2019/6.
- 2. The United States again stresses that animal species, specific pathogen-causing diseases, health management practices, antimicrobial access, availability of alternative treatments, and antimicrobial susceptibility profiles vary by region, country, and even regions within particular countries. The European Union should allow flexibility to trading partners to use official controls and techniques deemed necessary to achieve the same public health objectives, in a manner that is appropriate for farmers and producers within the exporting countries' own domestic context.
- 3. Further, following the recently notified delegated act, the United States again requests the European Union to share its scientific evidence used to determine the human health risk posed by veterinary use of antimicrobial drugs not identified as medically important for humans, when such drugs are used for animals' growth promotion or to increase yield.
- 4. We also continue to seek clarification on the EU's process for amending and updating its list of antimicrobials reserved for human use and on the scientific justification and risk assessments for the EU's restrictions on the use of antimicrobial drugs that are not medically important for humans, including those used for growth promotion in animals.
- 5. The United States further requests clarification around how the European Union will consider equivalent regulatory systems that achieve the same public health objectives.
- 6. We thank the EU Commission for recently hosting a virtual meeting for third countries to better understand Article 118 and the draft Delegate Regulation and encourage the EU Commission to continue offering these meetings to further clarify how compliance with this regulation will be verified and enforced.
- 7. Finally, the United States reiterates its request that the Commission provide a new timeline for the pragmatic implementation of these measures that considers the lifespan of different animal species and the shelf and storage life of products already in the supply chain. Building on our previous experience renegotiating certificates for animals and animal products, we would request that entry requirements are limited to what is reasonable and necessary to achieve the EU's appropriate level of protection.
- 8. Instead of taking unilateral actions to address global challenges like antimicrobial resistance, we request the European Union to work with its trading partners to develop mutually agreed-upon measures that are science-based and based on established international standards, and to be

mindful of the impacts of its SPS measures on global animal health, food security, international trade, and agricultural sustainability.

9. The United States appreciates the EU's dedication to combatting antimicrobial resistance and the international collaboration on this issue. We look forward to continued collaboration and discussion on how to best reduce antimicrobial resistance around the world.