

23 July 2021

Original: English

(21-5804) Page: 1/2

## **Committee on Sanitary and Phytosanitary Measures**

## THE EUROPEAN UNION'S (EU) VETERINARY LEGISLATION THAT WOULD RESTRICT THE USE OF ANTIMICROBIALS BY PRODUCERS IN THIRD COUNTRIES – SPECIFIC TRADE CONCERN 446

## SUBMISSION BY THE UNITED STATES OF AMERICA

The following submission, received on 20 July 2021, is the statement made by the United States of America at the 14-16 July 2021 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 would like to again call attention to our previous statements made at the July 2018, November 2018, March 2019, June 2020, and March 2021 meetings of this Committee and documented in the summary reports that lay out our concerns regarding the implementation of Article 118 of EU Regulation 2019/6.
- 2. Since the March 2021 Committee meeting, the European Commission notified two proposals associated with the prohibition of certain uses of antimicrobials. However, we continue to have concerns that the European Commission has not yet published the implementing acts on the list and rules for imports that we understand must be adopted no later than 28 January 2022.
- 3. The European Commission notified G/SPS/N/EU/464 that adds to Article 118 of EU Regulation 2019/6 and amends Regulation 2017/625 regarding official controls on animals and products of animal origin exported from third countries into the European Union. The legislation, however, does not explain how the European Union plans to verify compliance of imported products with Article 118. As such, the implications of this legislation on trade to the European Union remain unclear. In particular, there has been no clarification on how risk assessments will be used to inform import policies, nor has the European Union appeared to consider the challenges foreign producers will face to comply with the legislation when it enters into force in a few months.
- 4. The European Commission also notified G/SPS/N/EU/478 of the delegated regulation to establish the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans and adopted the criteria on 26 May 2021. However, we remain concerned that the European Union has not provided details on how the criteria will be used to inform its list of antimicrobials reserved for human use and how or whether the list will be updated. We note that this information is necessary to ensure a fair, transparent, and science-based risk assessment.
- 5. We understand that, through the criteria it developed, the European Commission is attempting to enhance its One Health approach to addressing AMR. As Members of this Committee are aware, a One Health approach recognizes the interconnectedness of people, animals, plants, and their shared environment.
- 6. Animal species, pathogens causing diseases, health management practices, antimicrobial access, availability of alternative treatments, and antimicrobial susceptibility profiles vary by country, and the United States is concerned that the European Union is not adequately or appropriately considering the health of animals within this new policy, especially in cases where alternative treatments are not available in an exporting country.

- 7. Specifically, through its actions, we fear that the European Union may unnecessarily limit access to the medicines needed to address common livestock diseases associated with modern husbandry. Risk management actions such as restricting use of antimicrobial drugs without scientific justification may result in unintended negative animal health consequences through disease spread and ultimately damage the livelihoods of livestock producers in the European Union and beyond its borders. This, in turn, may affect countries' abilities to achieve goals related to food security and sustainable development.
- 8. We are also concerned that the European Union will not allow a sufficient transition period between the finalization of its list of antimicrobials reserved for human use and the application of SPS measures to imported products. We would note that, to limit unnecessary disruptions in production and trade, an appropriate transition period for justified SPS measures should be based on the lifespan of livestock under production and would also consider the shelf and storage life of products already in the supply chain. Cattle, poultry, and pigs, for example, have different life cycles and the transition periods for use of antimicrobial treatments would likely need to reflect those differences.
- 9. Further, we understand that the EU legislation includes restrictions around specific uses of antimicrobial drugs that are not medically important for humans, and we are concerned that these provisions will divert countries' attention and resources away from more meaningful interventions with direct human health impacts. Therefore, we ask the European Union to maintain the use of antimicrobials for growth promotion that are not medically important for humans. This would allow countries to focus efforts and resources on areas of public health concern while promoting safe and effective animal husbandry practices that support agriculture sustainability and food security.
- 10. AMR is a health issue, and should not be used as an unjustified barrier to trade. For instance, the United States has avoided trade restrictions while successfully implementing national programs to address the development and spread of AMR. We urge the European Union to avoid trade disruption, base its regulations on science and risk, and to consider the impact of its SPS measures on global animal health, food security, and agriculture sustainability.
- 11. Through this intervention, we reiterate our request that the European Commission issue relevant implementing regulations in a timely manner and allow sufficient time for careful review and comments by Members and foreign stakeholders such that the input may be considered. Further, as the European Union moves forward with this process, we request that the European Union both recognize and respect the level of protection provided by national regulatory systems and afford national competent authorities the flexibility they need to implement their own effective SPS systems.