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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 – <u>SPECIFIC TRADE CONCERN 446</u>

SUBMISSION BY THE UNITED STATES

The following submission, received on 30 March 2021, is being circulated at the request of the Delegation of the <u>United States</u>.

1.1. The United States would like to call attention to our previous statements made at the July 2018, November 2018, March 2019, and June 2020 Committee meetings that lay out our concerns regarding the implementation by the EU of Article 118 of EU 2019/6.

1.2. We will not reiterate the details of our previous interventions, as they are documented in the Committee's summary reports.

1.3. We appreciate our bilateral engagement with the EU, as well as the EU's willingness to meet with concerned third countries, most recently in December 2020.

1.4. However, we are concerned that the European Commission has not yet published the delegated act of the criteria to designate antimicrobials to be reserved for human treatment for comment and review, which we understand will be adopted no later than 27 September 2021. The EU has also not yet published the implementing acts on the list and rules for imports that, again, we understand must be adopted no later than 27 January 2022. Recognizing these still remaining steps in the EC legislative process, we urge the EC to issue relevant documents in a timely manner allowing sufficient time for careful review and comments by stakeholders.

1.5. Further, the EU has yet to provide details regarding the scientific justification and risk assessments that will inform its list of antimicrobials reserved for human use. The EU has also not clarified how risk assessment will be used to inform its import policies, including whether data from third countries will be considered in assessments, nor has the EU explained how producers will be able to meet the requirements when the legislation is expected to go into force in less than one year.

1.6. Third countries cannot begin to make changes to their production practices until they know which antimicrobials may be reserved for human use or what type of control systems the European Commission may require for imports.

1.7. In addition to concerns around the extraterritorial implications of the EU's proposed measures, we are concerned that the EU 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. From our perspective, an appropriate transition period for justified SPS measures would 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 producers, for example, may need at least five years to adopt changes in the use of antimicrobial treatments.

1.8. Through its actions, we fear that the EU may end up limiting access by veterinarians to the medicines they need to address common livestock diseases associated with modern husbandry,

while at the same time undermining the competence of national veterinary authorities, and we remind the EU that equivalence is a key provision of the SPS Agreement.

1.9. While we support innovation and the search for alternative approaches, data and information on safe and effective alternative approaches simply do not currently exist in some cases. Unnecessarily limiting access to safe veterinary medical products and practices will likely result in unintended negative animal health consequences and damage the livelihoods of livestock producers in the EU and beyond its borders. This, in turn, will affect Members' ability to achieve goals related to food security and sustainable development.

1.10. Therefore, we ask the EU to limit phasing out the use of antimicrobials for growth promotion to those products that are medically important, rather than all antimicrobials. This would allow countries to focus efforts and resources on areas of public health concern while supporting safe and effective animal husbandry practices.

1.11. The United States has avoided trade restrictions while successfully implementing national programs to address the development and spread of antimicrobial resistance. Beyond simply considering possible human health outcomes, we urge the EU to consider the needs of agricultural producers and both recognize and respect the level of protection provided by national regulatory systems as it works to implement its own system.

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