National Pork Producers Council Comments on European Union’s Proposal for a Regulation on Veterinary Medical Products

The National Pork Producers Council (NPPC) submits the following comments in response to a Regulation (EU) 2019/6 of the European Parliament and the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

NPPC is a national association representing a federation of 42 state producer organizations. It represents the federal and global interests of 60,000 U.S. pork operations. The U.S. pork industry is a major value-added enterprise in the agricultural economy, and a significant contributor to the overall U.S. economy.

NPPC has significant concerns on the precedent Regulation 2019/6 would have on the global trade of meat and meat products. There is a long history of global and national efforts to address potential food safety concerns from the use of animal health products in food animal production. While the United States Food and Drug Administration (FDA) has a robust approval process that addresses safety from both veterinary drug residues and antimicrobial resistance, the international standard setting has been led by the Codex Alimentarius, in coordination with the World Health Organization (WHO) and the World Animal Health Organization (OIE).

Codex Alimentarius develops robust, science-based, consensus standards in the area of veterinary drug residues through its Joint FAO/WHO Expert Committee on Food Additives (JECFA), working in coordination with the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) and its Task Force on Antimicrobial Resistance (TFAMR). During the process of setting these standards, input is provided from the other United Nations Organizations (FAO and WHO), in addition to the OIE. The United States plays an active role in the leadership of the CCRVDF, as well as in TFAMR. CCRVDF sets Maximum Residue Levels (MRLs) based on human toxicology data to set safe levels of residues in food. This process considers the effect of average daily intakes to set those safe levels.

The WTO's Sanitary and Phytosanitary Agreement states that “to harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations.” The Agreement names the joint FAO/WHO Codex Alimentarius as the relevant standard-setting organization for food safety.

**Regulation (EU) 2019/6 threatens to undermine the scientific process of the Codex Alimentarius**

While the U.S. pork sector does not have robust trade with European Union countries, there is significant concern that other countries could impose precautionary, non-science-based requirements on U.S. pork products based on this precedent. It is essential that the U.S. Department of Agriculture (USDA) advocates to the European Parliament and the Council to consider international standards set by the CODEX Alimentarius Commission.
The U.S. FDA has addressed public health concerns from the use of antimicrobials to promote growth. It carefully considered the classes of antimicrobials that could potentially select for resistance to antimicrobials used in human medicine and restricted their uses to only therapeutic purposes. This process is sufficient to assure our trading partners that U.S. regulation provides for the safety of meat and meat products produced in the United States. The NPPC urges USDA’s Foreign Agricultural Service to utilize the certainty of the robust FDA process in the argument on the unnecessary restrictions posed by Regulation 2019/6.

Regulation 2019/6 requires the development of a list of antimicrobial agents that will be restricted for human use only. The U.S. FDA has a similar list that was developed based on the importance of antimicrobials in human medicine, however, there is a great deal of uncertainty about what criteria and how it will be applied to the development of an EU list. An overly restrictive list has the potential to negatively impact animal health, welfare and even food safety, since we know that carcasses of animals that have been sick have a higher likelihood to be contaminated with foodborne pathogens. Additionally, while the U.S. has a list of antimicrobials restricted from use in food animals, the country follows MRLs on its imported food products. NPPC urges the EU to adhere to that same principle.

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