

National Pork Producers Council
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Dockets Management Staff
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

FDA-2022-N-0824: FDA Seeks Public Comment on Possible Framework for Collecting and Analyzing Data on Antimicrobial Use in Food-Producing Animals

To Whom it May Concern,

The National Pork Producers Council (NPPC) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) *Possible Framework for Collecting and Analyzing Data on Antimicrobial Use in Food-Producing Animals*. NPPC is the global voice for the U.S. pork industry and consists of 43 affiliated state organizations representing America's 66,000 pork producers who supply a demonstrably safe, wholesome, and nutritious product that is appreciated on American and international tables.

The pork industry recognizes the importance of antimicrobial stewardship in maintaining animal health and welfare and producing a safe protein product. Thus, producers and veterinarians collect antimicrobial use data to make informed decisions on appropriate interventions and treatments. However, this type of data cannot establish causality for antimicrobial resistance (AMR) in human illness. For example, there are multiple contributions to human enteric illness that make it largely impossible to singularly tie an illness back to antimicrobial use on the farm. Although antimicrobial stewardship is important, the pork industry is concerned with data privacy, data collection, and data reporting methods proposed in this framework. NPPC appreciates the efforts to facilitate conversations between stakeholders to foster antimicrobial stewardship in food-producing animals, while understanding concerns for utilizing this data for decision-making, as this type of data cannot establish causality for AMR in human illnesses.

Results from Public Meeting and Roundtable

NPPC strongly encourages the FDA to consider the feedback from multiple stakeholders who also expressed the same concerns NPPC outlined in previous comments submitted on phase one. Those involved in the roundtable and public meeting expressed concern that antimicrobial sales and distribution data and antimicrobial use data are not the same and should not be treated as such. Also, the consideration of context, such as the animal number, size, and species, and indication for product use, is essential to understand antimicrobial use in food-producing animals. There are also challenges

to collecting standardized data across species and routes of administration, as well as comparing data from different species. Lastly, there is major concern over privacy: clear data access and privacy protection are essential to build and maintain mutual trust among public and private partners. Data should be protected and unidentifiable, and raw data should be maintained by the external data partners.

Data Collection and Privacy

Privacy of data is the utmost priority to ensure stakeholders are participating in this public-private partnership (PPP). Raw data must remain with the primary access level and restricted to those directly collecting the data. NPPC does not support the Tertiary-Level Access that would grant others access to the raw data. This level of access will not foster a trusting environment and will deter participation in the PPP. Raw data will include confidential business information, ensuring stakeholders will not participate if others can access this data.

The Data Quality and Verification Processes is concerning, as it would frequently give external tertiary level access to raw data. We urge the FDA to establish another avenue to ensure quality control, as what is proposed in this document would compromise data privacy and the ability to have buy-in from stakeholders.

The pork External Data Partner (EDP) will be responsible for collecting and housing raw data. This EDP must not be subject to the Freedom of Information Act (FOIA). If this data is housed in a place that is subject to FOIA requests, stakeholders will not participate.

Data Elements

In the numerator data elements section, the table lists “duration of use” (e.g., treatment length), and indicates it is a “maybe” when accessing this information in swine. This information is always recorded to calculate withdrawal information for the animal(s) being treated. Under the data elements section, the denomination lists: “animal weights at time of treatment” (e.g., average weight at treatment, slaughter weights, carcass weights, static weights, and changing weights) and that access is only “age at time of treatment but not animal weight.” Although treating most swine also means treating a population, producers will know average weights according to the ages when pigs are treated. Also, breeding animals, such as sows, boars, and gilts, will be treated based off average weight. Both the numerator and denominator each list five data elements, but there could be additional data elements added. This variation of data will not allow for standardization. Lack of standardization will prevent comparison, and, therefore, any trends or results discussed will be insignificant.

Data Reporting

The draft purpose and intended outcomes of the PPP are to “monitor antimicrobial use in food-producing animals to lead to an understanding of public health trends across each species, regions, and time to foster optimal antimicrobial stewardship.” The draft framework will collect data without appropriate context. For example, data collected at a nursery may show the number animals treated in that barn, but it does not provide explanation for why the animals were treated. Antimicrobial use is

dependent on multiple factors. Each decision is intentional and unique and will be impossible to compare, even within the same species.

There is also concern that the data collected will be used to establish performance standards. The generalized notion presented in the PPP of fostering optimal antimicrobial stewardship only lends itself to establish a level for antimicrobial use. Optimum antimicrobial use will differ between species, among producers, and animal production time. NPPC does not support antimicrobial performance standards, as they could negatively impact animal health and welfare.

Conclusion

NPPC appreciates the opportunity to comment on the *Possible Framework for Collecting and Analyzing Data on Antimicrobial Use in Food-Producing Animals* and looks forward to continuing to work with the FDA and other stakeholders to support antimicrobial stewardship. Although this type of data cannot establish causality for AMR in human illnesses, it has value for producers and veterinarians to make informed decisions that affect antimicrobial stewardship. NPPC urges the FDA to strongly consider the feedback from the roundtable and continue holding similar meetings with stakeholders to help shape this framework. NPPC urges the FDA to ensure that the correct data is collected; data privacy is upheld; and data reporting does not hinder animal health and welfare. The pork industry is committed to supporting antimicrobial stewardship and producing a safe and wholesome protein product for consumers in the United States and globally.

Sincerely,



Dr. Ashley Johnson
Director of Food Policy
National Pork Producers Council