NATIONAL MILK PRODUCERS FEDERATION

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November 30, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD, 20852

Re. Collecting On-Farm Antimicrobial Use and Resistance Data (Docket No. FDA-2015-N-2768)

To Whom It May Concern:

The National Milk Producers Federation is pleased to provide the Food and Drug Administration (FDA) comments on Collecting ON-Farm Antimicrobial Use and Resistance Data (Docket No. FDA-2015-N-2768). The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

Among the measures available to treat and prevent the outbreak and spread of animal diseases among the nation's dairy cattle, the judicious and responsible use of antimicrobial drugs has a positive impact on animal health and well-being while maintaining a safe milk supply for the public.

For more than 25 years, the U.S. dairy industry has focused educational efforts on the judicious and responsible use of antimicrobial drugs through the annual publication of a Best Practices Manual. The 2016 edition of the National Dairy FARM Program: Farmers Assuring Responsible Management™ *Milk and Dairy Beef Drug Residue Prevention Manual*[i] (published October 2015) developed by NMPF is the primary educational tool for dairy farm managers throughout the country on the judicious and responsible use of antibiotics including avoidance of drug residues in milk and meat.

Additionally, the 2016 edition of the Residue Prevention Manual provides dairy farm managers guidance about the implementation of the Food and Drug Administration Guidance for Industry (GFI) #209[ii] and #213[iii] and the revised Veterinary Feed Directive (VFD) Rule.[iv]

Antimicrobial Data Collection Goals

NMPF supports the efforts of the FDA, the U.S. Department of Agriculture (USDA), and Centers for Disease Control and Prevention (CDC) to engage stakeholders for feedback on the best approaches for data collection about antimicrobial use and potential resistance in food-producing animals. We have previously commented on our support for the FDA's GFI #209 & #213 and VFD rule which collectively limit the use of medically important antimicrobials to therapeutic purposes in livestock. Therapeutic uses include disease treatment, control, and prevention.

We agree that assessing the impact of GFI #209 & #213 and the VFD rule will be difficult due to external drivers of bacterial resistance, the inherent unpredictability of bacterial mutation, and the length of time needed to assess change. As such, NMPF urges caution that data collection cannot be used to evaluate whether the GFIs and the VFD rule are having the "desired effect" on antibiotic use practices and antimicrobial resistance.[v] Without careful definition, "desired effect" could easily be viewed as simply decreasing antimicrobial use in livestock without any discernible impact on resistance. A goal of merely decreasing antimicrobial use would be not only medically unreasonable, but also dangerous for animal health and wellbeing, as it cannot be guaranteed that rates of resistance will drop.

The relationship between antibiotic use and resistance is highly complex with multiple factors extending beyond antibiotic use in food-producing animals, and associated data has strong potential to be misinterpreted to portray responsible husbandry practices as harmful, especially if bacterial resistance were not to decrease. Compounding this challenge is the reality that collecting meaningful representative data would be highly resource intensive. These factors contribute to our concern that collecting on-farm antimicrobial use data without first outlining science-based goals and objectives may lead to less robust, useful results.

NAHMS Data Collection

We agree that on-farm resistance data has value, as do data from other settings such as healthcare facilities, to monitor the landscape of antimicrobial resistance in these environments. Such data provides important information to help protect current and future populations in farm or healthcare settings. Monitoring of antimicrobial resistance on farms has been explored in the past through the National Animal Health Monitoring System (NAHMS), and we remain supportive of this voluntary and confidential sampling method. We also agree that data on animal demographics and health is needed; NAHMS additionally surveys data on existing animal diseases, while academic researchers and the World Organization for Animal Health (OIE) provide excellent monitoring of both existing and emerging diseases. NMPF looks forward to continuing to communicate with USDA on how to best evaluate antimicrobial stewardship

through initiatives proposed in the Antimicrobial Resistance Action Plan, and how the NAHM S program may aid in these goals.[vi]

Data Collection Should Have a Public Health Focus

The above-listed objectives are supported by NMPF because they point to meaningful health outcomes for both animals and humans; however, we must reiterate that we are not supportive of collecting data on antibiotic sales or distribution.[vii] It has been acknowledged that antibiotic sales and distribution data does not yield information on how or why the antimicrobials have been used.[viii] Collecting aggregated species-specific sales and collection data does not alleviate this problem; rather it fosters an inaccurate perception of animal production agriculture without accounting for a host of factors contributing to treatment. Such factors are varied and can include age, sex, and production method for the given animal; weather; geographic location; and disease events. Many of these factors are outside of both the farmers' and the companies' control. This has led to erroneous comparisons and misuse of the information as to the actual amounts and kinds of antibiotics used for people versus animals. While FDA has attempted to caution about using data for these comparisons to make critical judgements on antibiotic use, misinformation and exaggerated claims are still reported in both print and social media.

One-Health Goal

Upon reviewing the proposed antimicrobial data collection activities, and the corresponding proposal of a Summary Report encompassing solely antibiotic drug use and resistance in animal agriculture, NMPF has a number of concerns. While this report is intended to be integrated in nature – collecting data on animal health, demographics, drug sales, resistance, and on-farm data – we are disappointed to learn that this report would not include data on antibiotic drug use and resistance in human medicine. The continued reporting of antibiotic use and resistance separately for humans versus animals propagates the view of antimicrobial resistance as a problem brought on by agriculture, and does not support a true One-Health perspective. Such reporting does not provide the opportunity to observe the joint objectives of animal and human health organizations to practice judicious and responsible use of antibiotics, nor does it allow context to explain the complexities of antimicrobial resistance and whether that resistance is posing a threat to human health.

Given that this report is intended to be an inter-agency effort, NMPF believes it is not logical or accurate to present only data collected from food-producing animals and omit human-use data. Furthermore, such reporting also omits companion and specialty animal antibiotic use. If we are to achieve "action by public health, health care, and veterinary partners in a common effort"[ix], antimicrobial resistance cannot be strictly viewed strictly as just an animal-use or human-use caused issue. Rather this is a collective challenge that must be addressed by all sectors together.

Conclusions

The U.S. dairy industry is committed to the judicious and responsible use of antimicrobials and supports both transparency and good data on use and resistance for both animal and human use. FDA and its federal partners should present a comprehensive plan for antibiotic use data collection complete with justifications and goals rather than incomplete, ad-hoc approaches that only confuse the issue. We believe that working with USDA to gather on-farm use data under the NAHMS program combined with defined goals is vital. Additionally, human use and resistance data needs to be effectively gathered and analyzed to understand the entire antimicrobial resistance picture to assure One Health solutions.

Please contact me if you have any questions about these comments.

Sincerely,

Jamie Jonker
Vice President, Sustainability & Scientific Affairs

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[i] National Dairy FARM Program: Farmers Assuring Responsible Management™ Milk and Dairy Beef Drug Residue Prevention Manual 2016 http://nationaldairyfarm.com/sites/default/files/2016-Residue-Manual.pdf

[ii] FDA Guidance for Industry #209
http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf

[iii] FDA Guidance for Industry #213
http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf

[iv] FDA Veterinary Feed Directive http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf

[v] FDA. Flynn, William. "Goals and Objectives for Data Collection". Data Collection Public Meeting. 13 (September 30, 2015).
http://www.fda.gov/downloads/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/UCM464318.pdf

[vi] USDA APHIS Veterinary Services. Info Sheet: "Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan". April, 2015. https://www.aphis.usda.gov/animal_health/nahms/amr/downloads/ProposedInitiatives.pdf

[vii] National Milk Producers Federation. Public Comment: "Re: Docket No. FDA-2012-N-0447, Proposed Rule: Antimicrobial Animal Sales and Distribution Reporting". August 18, 2015. http://www.nmpf.org/files/NMPF%20Comments%20FDA%202012-N-0447.pdf

[viii] As stated in the 2013 Summary Report, data submitted is "not indicative of how these antimicrobial drugs were actually used in animals". 2013 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. 2015. Food and Drug Administration-Department of Health and Human Services.
http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM440584.pdf

[ix] The White House. "National Action Plan for Combating Antibiotic-Resistant Bacteria". (March, 2015).
https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf