

Friday, November 13, 2020

United States Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

[docket number: FDA-2020-N-1764]

Dear Sir or Madam:

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the National Antimicrobial Resistance Monitoring System (NARMS) Strategic Plan 2021-2025 which was announced by the U.S. Food and Drug Administration (FDA) in cooperation with the U.S. Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) on August 18, 2020.

Established in 1958, PFI is the trade association and the voice of U.S. cat and dog food manufacturers. Our 25 members account for the vast majority of the dog and cat food made in the United States, with more than \$35 billion in domestic annual dog and cat food sales and annual exports of around \$1.6 billion. PFI membership also includes companies that supply ingredients, equipment and services to dog and cat food makers. We are proud of our strategic alliance with the National Grain and Feed Association, as well as our coordination with the American Feed Industry Association and the North American Renderers Association on a range of issues.

PFI members and their products are subject to regulatory oversight by both the FDA and state departments of agriculture or health. We share the FDA's commitment to pet food safety and we're proud of the strong safety record of pet food.

The NARMS Strategic Plan for 2021-2025 which was released on August 18, 2020, outlines the program's goals and objectives for the coming years. Specifically, we'd like to comment on objective 1.3, which directs the NARMS program to initiate an antimicrobial resistance testing program for animal feed and pet food, including their ingredients, and share data in an integrated database and in NARMS reports.

Pet food makers support the overall goals of NARMS, particularly with respect to developing a better understanding of the evolution and spread of antimicrobial resistance among foodborne pathogens. For the reasons stated below, we urge the program to reconsider its proposed sampling and surveillance of pet food products, specifically processed dog and cat foods that

employ a pathogen mitigation step. We believe that the inclusion of pet food and its ingredients in the NARMS sampling plan will not lead to a greater understanding of antimicrobial resistance and instead suggest the program utilize a more fact- and science-based approach in this regard.

First, the vast majority of commercial dog and cat foods in the United States employ a validated thermal process, which includes specific time/temperature and pressure requirements, to eliminate foodborne pathogens that may be present, including pathogens of concern to human and animal health. Second, commercial dog and cat foods represent the end of the food chain upon consumption by the target animal. Evidence of antibiotic resistance is both highly unlikely to be found in processed dog or cat food and must be addressed further up the food chain, since our ingredients are largely the by-products of human food production. Finally, antibiotics are prohibited (by FDA regulation) in the formula for any commercial dog or cat food produced in the United States.

For these three reasons we believe strongly that commercial dog and cat food products contribute very little, if at all, to antimicrobial resistance overall. A risk-based approach to conducting sampling and surveillance of foods does not support including dog and cat foods that undergo a validated pathogen mitigation step as part of their processing, nor would such sampling and surveying contribute appreciably to the understanding of antimicrobial resistance.

During the NARMS Public Meeting held October 13-14, 2020, it was announced that the sampling handbook has not yet been completed. Based on our contention that the determination of the scope of sampling and surveying of foods must factor in the contribution to the understanding of antimicrobial resistance, PFI members urge the agency to remove from its sampling handbook any reference to dog and cat food products that have undergone a validated pathogen mitigation step.

PFI reiterates our support for the NARMS program generally and the plan laid out in the 2021-2025 Strategic Plan. We must note, however, the lack of stakeholder engagement during the development of the Strategic Plan. Stakeholders met for the first time in October 2020 with the FDA officials who drafted the NARMS Strategic Plan. Those officials acknowledged during this initial meeting that neither sharing this document with affected stakeholders or soliciting any stakeholder input was undertaken prior to publishing the plan. We believe the Strategic Plan could have benefited greatly from earlier and more thoughtful stakeholder engagement as the Strategic Plan was conceived and developed. We urge FDA to consult in a more meaningful way with stakeholders as the Strategic Plan is further developed and finalized.

Finally, our review of the Strategic Plan, as well as comments from both interested stakeholders and FDA during the public meeting, prompt concern that the plan draws no distinction between general surveillance and testing on one hand and any resulting regulatory action on the other. We raise this concern because sampling and testing, of foods for example, may yield information related to antimicrobial resistance that may have no bearing on product safety. FDA must share in the Strategic Plan what it will do with the information gathered and ensure stakeholders and the public that findings related to antimicrobial resistance, but with no impact on product safety or constituting violations of applicable regulations, will be disclosed in a manner appropriate to the risk, mindful of the commercial impacts such disclosure may have.

PFI thanks FDA for the opportunity to comment on the NARMS Strategic Plan. We support efforts to identify and address the challenges associated with antibiotic resistance and trust our comments are considered in the manner intended, that is, to encourage FDA to employ a risk- and science-based approach to all facets of the Strategic Plan.

Sincerely,



Dana Brooks
President & CEO
Pet Food Institute