

Richard A. Carnevale, VMD
Vice President, Regulatory, Scientific & International Affairs

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

Re: Docket No. FDA-2011-N-0471; 2011 Scientific Meeting of the National Antimicrobial Resistance Monitoring System; Public Meeting; Request for Comments

The Animal Health Institute (AHI) submits these comments to Docket No. FDA-2011-N-0471; 2011 Scientific Meeting of the National Antimicrobial Resistance Monitoring System; Public Meeting. AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

During the course of the NARMS meeting on July 20, 2011, new information was shared that, upon further reflection, may provide additional direction to NARMS leadership as the on-farm and retail meat sampling strategies are revised.

AHI envisions a core program of NARMS whose sole purpose is to obtain isolates from a statistically-based, nationally representative scheme on-farm, perhaps at slaughter and at retail. The collection of isolates, identification and susceptibility testing would comprise the basic operational aspect of NARMS. The goal would be to monitor trends of resistance in key foodborne bacteria through the pre-harvest and post-harvest processing environments, and at retail, with yearly reports.

Additional research, e.g., on molecular characterization of isolates, or specific on-farm studies, would be done separately. These studies might provide additional insight into aspects of epidemiology, clonal relationships, or information that could help guide farm-level antibiotic use practices or husbandry techniques. Regarding research programs associated with NARMS, we encourage NARMS leaders to continue to communicate research findings that put legitimate animal antimicrobial uses into proper context, in addition to related concerns. For example, multi-drug resistant *Salmonella* serotypes may be clonally spread and may persist in some species regardless of selection pressure from antimicrobial use.

The presentation by Dr. Esteban of FSIS featured an overview of the new sampling strategy for HACCP verification. As the samples are obtained “at slaughter” using existing processes, the strategy is risk-based wherein larger plants are sampled more than smaller plants, with a volume adjustment made, includes carcasses of cattle, swine, chickens and turkeys, and has sufficient sample numbers available, this presents an attractive opportunity for further exploration as a source of isolates for NARMS.

We believe it is important that the labels “cattle, swine, turkey, chicken” for those isolates obtained from slaughter facilities should from now on be changed to reflect their source, i.e., swine or bovine carcass, ground beef, ground turkey, chicken carcass rinsates. The labels “cattle, swine, turkey, chicken” imply that the isolates were taken from live animals, when in fact they are not. The species-only labels are subject to misinterpretation in that regard, and we see evidence of this in publications and presentation of the data.

The retail meat sampling strategy was reviewed by Dr. Tong. Improvements might be considered by further exploration of the CIPARS and EFSA program approaches which have developed statistical rationale to limit sample sizes and adjust for population representativeness. It was noteworthy that CIPARS used a simulation software program to assist in the design; a possibility that was of interest to two of the panel members. Regarding additional bacteria of interest, it may be feasible to consider a special project approach that would add a particular pathogen for a limited time. Pilot studies with other meat products, for example, fish or other aquaculture products, might be considered, however the specific bacteria to be cultured remains unclear.

National on-farm prevalence could be obtained by USDA ARS working with APHIS and NAHMS. Although there is a 5+ year interval between food animal species reports, this might prove to be the most expedient and cost-effective means to obtain such data. Alternatively, implementing the NAHMS sampling model into the present reporting frequency may also be a plausible option in order to maintain timely updates.

Prior to augmenting the current on-farm sampling strategy, it may be necessary to further define where on-farm samples are collected in relation to the time of slaughter. Defining the segment of the production chain (e.g. ranch or feedlot; farrowing barn or finishing barn) that best represents pre-harvest prevalence of antimicrobial resistance is necessary in order to develop proper sampling methods that reduce the presence of bias, minimize variation, and ensure the validity of the culture results.

The essential research work done on-farm by USDA ARS under the direction of Dr. Paula Fedorka-Cray needs to be continued and a secure source of funding identified, ideally outside of NARMS, so that there is independence from NARMS governance assured for her work. Certainly interactions are encouraged, but the operational, analytical and reporting would remain under her oversight.

AHI is interested in achieving public health and food safety goals while maintaining access to antibiotics that contribute to animal health and welfare. AHI supports the efforts of NARMS leadership to revise the program to achieve the FDA Science Board recommendations.

Thank you in advance for your consideration of these comments. Should you have any questions, please do not hesitate to contact AHI at (202) 637-2440.

Sincerely,



Richard A. Carnevale, VMD