

Department of Health and Human Services  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
The National Antimicrobial Resistance Monitoring System Strategic Plan 2011-2015  
Re: Docket No. FDA-2010-N-0620 [www.regulations.gov](http://www.regulations.gov)

**Comments submitted by the Alliance for the Prudent Use of Antibiotics on March 24, 2011**

APUA applauds the advances that NARMS has made in monitoring antimicrobial resistance in humans (enteric bacteria) and in food-producing animals to safeguard public health and promote interventions that mitigate resistance in food-borne pathogens. We appreciate the refinements of the program and planned focused research studies to examine risk factors and the genetic transfer of resistance. Particularly of note are NARMS' publications to disseminate its data and research findings to the scientific community, its international research collaborations and enhanced laboratory capacity-building activities in surveillance of food-borne illness and outbreak detection. Given the increasing threat of antibiotic resistant organisms we suggest that this program receive expanded funding as a vital component in a comprehensive interagency surveillance plan to track antibiotic resistance and use in both human medicine and food production. Below are other APUA's suggestions to improve the NARMS Strategic Goals, as outlined in the Strategic Plan 2011 – 2015.

**Develop, implement and optimize a shared database, with advanced data acquisition, analysis and reporting tools**

- In 2001 APUA convened a panel of multidisciplinary experts on antibiotic resistance and produced a report of the Facts about Antibiotics in Animals and the Impact on Resistance (FAAIR) Project published in Clinical Infectious Disease in June of 2002. This panel identified a serious gap in surveillance data on antimicrobial use in animals and recommended that such data be made “publicly available to improve risk assessment and better inform policy decisions on antimicrobial use in animals” (FAAIR Scientific Advisory Panel, 2002). The plan should have as a goal the collection of or linking to data on use of medically important antimicrobials in food animal production. The FDA does have some data on antibiotic sales and distribution which should be made publically available and enhanced. The agency should require NARMS to collect and employ necessary supplementary species -specific use data to allow better cross analyses with the resistance data.
- In 2006 APUA published a situation analysis to consider adequacy and potential methodologies to collect antibiotic use data in food animals to assist in development of more responsible public health policies. A major finding of that study was that :“Despite the improvement and expansion of antimicrobial resistance monitoring, the United States still lacks a mechanism for collecting antimicrobial usage data” (Jennifer Nunnery, Frederick J. Angulo, Linda Tollefson, “Public health and policy” Preventive Veterinary Medicine 73 (2006) 191-195). The agency has yet to advance adequately towards this goal.

- APUA recommends that the US adopt the model of the European Union on harmonizing systems of monitoring antimicrobial use and antimicrobial consumptions in humans, animals (both agricultural and companion animals) with monitoring of antimicrobial collection and analyses for antimicrobial use and antimicrobial consumption across both agencies (EMA, ECDC, EFSA) and member states for human medicine and food and companion animals. Integrated systems will aid in data analysis for risk profiling and risk assessment regarding antimicrobial resistance with specific policy implications for the health of humans, animals and the environment.
- The goal of US antibiotic resistance surveillance should be to generate better understanding of resistance to allow for better management of use of antibiotics in both human health and food production. Without data collection on antibiotic use, creative cross-analyses are wanting; notably absent is the tracking of “genotypically-confirmed distinctive phenotypes that represent and track cross-species outbreaks (Thomas F. O’Brien, MD, APUA Vice President)

#### **Make sampling more representative and more applicable to trend analysis**

- We recommend on-farm sampling: Focus on use of antibiotics & assess the impact on not only animal feed, but also environmental impact of antimicrobial use: Air, soil, water, sewage, sludge etc (ecological reservoirs of resistant bacteria as a result of antibiotic usage); Identify broad categories of antibiotic use that are unnecessary (p.224 Prev. Vet. Med. Vol. 73, issues 2-3, February 24, 2006).

#### **Strengthen collaborative research projects and international food safety activities**

- Collaborate with EU through the Trans Atlantic Task Force on Antimicrobial Resistance to develop a common database and language to understand antibiotic use and resistance.

Since antibiotic use is considered a major driver of resistance, it is vitally important that the resistance data be paired with relevant antibiotic use data. A weakness in the US government’s efforts thus far is the willingness to collect and utilize robust antibiotic use data to explore links and inform policy and practice interventions. It is APUA’s long standing position, based scientific research and expert opinion of many distinguished advisory committees, that use of medically important antimicrobials in food animals should be limited to therapy for the animals and only with veterinary consultation. Without these protections and without the antibiotic use data, the agency is operating in the dark and at a major disadvantage in carrying out the purpose of the NARMS program and ensuring public health, food safety and homeland security.

Submitted by Carol Cogliani and Kathleen Young on behalf of APUA See [www.apua.org](http://www.apua.org)  
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