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August 19, 2011

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

Re: Comments of Keep Antibiotics Working on animal and retail sampling methods for the National Antimicrobial Resistance Monitoring System, Docket No. FDA-2011-N-0471

Introduction

Keep Antibiotics Working (KAW) appreciates this opportunity to submit comments on ways to improve animal and retail sampling methods for the National Antimicrobial Resistance Monitoring System (NARMS). [Keep Antibiotics Working](#) is a coalition of health, consumer, agricultural, environmental, humane and other advocacy groups with more than eleven million supporters dedicated to eliminating a major cause of antibiotic resistance: the inappropriate use of antibiotics in farm animals.

KAW recognizes NARMS as a vital public health monitoring program that provides the necessary data for the surveillance of resistant bacteria in the food supply. Information from NARMS is absolutely necessary to understand the role of antimicrobial use in food animals in the spread of resistant bacteria in food and to manage the risk associated with this spread. Despite the vital and unique nature of this program, it has been chronically underfunded and has never had sampling strategies that would provide data needed to meet its goal of comprehensive national surveillance.

While KAW appreciates this opportunity to comment, we feel that to a great extent they are unneeded as the [Science Board](#) to the FDA has already made adequate [recommendations](#) on ways to improve the program that have never been implemented. KAW's first and most important recommendation to the FDA on NARMS is to implement the recommendations the Science Board made in 2007. The Science Board's first and, we believe, most important recommendation is that NARMS needs "an improved, statistically valid, and rigorous sampling strategy." The Science Board went on to describe serious limitations in the sampling of isolates from animals. Because of this problem, the focus of our comments will be on improving sampling in animal isolates.

Sampling of animal isolates

KAW strongly recommends that animal isolates continue to be collected at slaughter, but that they not be collected as a convenience sample of USDA in-plant Hazardous Analysis and Critical Control Point (HACCP) monitoring system isolates. The HACCP monitoring isolates are widely recognized as being inadequate for the needs of NARMS. Instead the USDA should collect samples as part of ongoing baseline surveillance of pathogens at slaughter as recommended by the Science Board to the FDA. Ideally the sampling should be designed to get at prevalence levels of resistant organisms in slaughtered animals and not just level of resistance. This would require sampling to be based upon the volume of slaughter at plants.

This is important because the risk is a combination of both the level of resistance (proportion of isolates resistant) and the prevalence of the pathogen in the animals. Understanding prevalence is particularly important for *Salmonella* where resistance is highly linked to serotype. Understanding changes in overall resistance requires understanding changes in the individual serotypes. Under the current sampling methodology there have been large changes in the number of isolates collected between years. For example, *Salmonella* isolates from chicken have varied from a low of 551 in 2009 to a high of 1500 in 2002. It is unclear to what extent this change is based on sampling methodology or actual prevalence of *Salmonella* in chickens.

In addition, baseline sampling creates the potential for culturing for organisms not captured in the HACCP monitoring. While there is significant evidence that cattle are a source of *Campylobacter* infection in humans, NARMS provides almost no information on resistance in *Campylobacter* for cattle. The USDA does not currently collect *Campylobacter* at cattle slaughter plants and *Campylobacter* is not often found in ground beef sampled in the NARMS retail meat arm. Slaughter samples collected specifically for NARMS could be cultured for *Campylobacter* spp., *Escherichia coli* and *Enterococcus* spp. as well as *Salmonella enterica*.

KAW does not have a specific recommendation on the exact type of samples to take, but recommends that samples be taken early in the processing stage or even in lairage. USDA should determine which types of sample (eg. cecal, fecal, lymph nodes), at what point in slaughter the samples should be collected, and appropriate methods of culturing and selection of isolates that will provide the best data with the aim of understanding resistance coming into the slaughter facility. KAW understands that USDA has the relevant expertise to design a comprehensive nationally representative and statistically valid sampling strategy if the agency chooses to do so.

KAW acknowledges that collecting samples specifically for NARMS has a different cost than using HACCP monitoring isolates, but we do not see the cost as prohibitive. While there has been a consistent lack of transparency on funding for NARMS, information provided in a meeting of the Interagency Task Force on Antimicrobial Resistance in 2005 showed that the funding for the animal arm of NARMS exceeded the funding for the retail meat arm. With current funding, the retail meat arm collects 5,000 samples annually and requires travel to grocery stores and the purchase of meat. Therefore KAW

believes that it would not cost more to collect and culture 5,000 samples from slaughter facilities where it would not be necessary to travel or purchase meat. 5000 slaughter samples would likely yield at least as many isolates as the current sampling effort.

In addition to sampling at slaughter, KAW supports sampling on farm if this is part of a comprehensive program that includes antimicrobial drug use data collection and includes farms with different levels of antimicrobial drug use. KAW supports the USDA's Collaboration on Animal Health and Food Safety Epidemiology.

What additional information should NARMS collect and report?

While KAW believes improving sampling of animal isolates is the most important change needed in NARMS, we feel there are some other areas of needed change:

- 1) Information on antimicrobial drug use should be included in the NARMS reports.
- 2) Information on outbreaks should be included in NARMS reports and there should be analysis of the links between outbreaks and the other monitoring data.
- 3) Monitoring of feed and feed ingredients for their role in the spread of resistance and/or at the least publication of the results of monitoring of feed carried out so far.
- 4) Monitoring of imported foods.
- 5) Monitoring of pathogens that may have a food animal source such as *Staphylococcus aureus*, *Clostridium difficile*, and *Klebsiella* spp.
- 6) Specific studies are needed:
 - a) Sampling of shell egg breakers or *Salmonella Enteritidis* control program monitoring isolates to determine if shell eggs are a source of nalidixic resistant *Salmonella Enteritidis* in humans in the U.S.;
 - b) Genotypic comparison human and animal cephalosporin resistant *Salmonella* Newport isolates to determine if related;
 - c) Investigate presence of extended-spectrum betalactamase producing *E. coli* in food animals in the U.S. to determine prevalence and risk factors;
 - d) Compare food animal and retail meat isolates to human pathogenic *E. coli* genotypically including plasmid typing.

Conclusion

The NARMS program is a critical public health surveillance program that provides information needed to understand the role of food animal production in the spread of antimicrobial resistance. KAW hopes that our recommendations and the recommendations of the FDA Science Board are followed to ensure that NARMS can fulfill its mission.

Sincerely,



Richard R. Wood
Steering Committee Chair, Keep Antibiotics Working