ANIMAL HEALTH INSTITUTE
Representing manufacturers of animal health products

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Water Docket
Environmental Protection Agency
Mailcode: 28221T
1200 Pennsylvania Ave. N.W.
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2011-0188, National Pollutant Discharge Elimination System (NPDES) Concentrated Animal Feeding Operation (CAFO) Reporting Rule

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to Docket ID No. EPA-HQ-OW-2011-0188, National Pollutant Discharge Elimination System (NPDES) Concentrated Animal Feeding Operation (CAFO) Reporting Rule. AHI is the national trade association representing manufacturers of animal health products -- the pharmaceuticals, biological products and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. AHI member companies represent the majority of companies producing antibiotics and hormones used in animal production and thus have an interest in the way the use of those products have been characterized in the proposed rule.

AHI would like to offer the following comments:

1. EPA mischaracterizes the uses of antibiotics in animal agriculture.

   The Food and Drug Administration's Center for Veterinary Medicine (CVM) reviews and approves antibiotics using four discrete label claims: disease treatment, disease prevention, disease control and growth promotion, as measured by increased daily weight gain or increased feed efficiency. The treatment, control and prevention claims are all considered "therapeutic" claims by the FDA and others. Thus, the regulated uses of antibiotics cannot be summarized by EPA's statement "to promote growth and to control the spread of disease."

   The statement "other pharmaceutical agents are often added to feed rations or water" is unclear. If there are specific, FDA-approved pharmaceuticals that may be of concern to water quality, EPA should specify them. The term "often" is subjective; in fact, producers use these products sparingly, trying to maximize efficiency by using these agents only when necessary.

2. EPA's claim that there has been a significant increase in antibiotic use has no basis in fact.

   EPA cites the FDA report of antibiotics sold for use in animals which reported 13.3 million kilograms were sold for use in animals in 2009. EPA claims this was a significant increase

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from the 8.8 million pounds reported in 1995 and cited an Office of Technology Assessment (OTA) report. There are several errors in this conclusion.

The OTA study published in 1995 actually cites a 1985 report by the Institute of Medicine (IOM). So the estimate is actually for 1985, not 1995.

The IOM estimate is actually cited as "Correspondence from R.H. Gustafson (American Cyanamid Company) to E. Eastman (Subcommittee on Investigations and Oversight, House Committee on Science and Technology)". FDA's 2009 report is based on data reported by companies; the 1985 estimate is based on one individual's estimate. These vastly different methodologies cannot be compared.

EPA refers to the estimate of use, whereas the discussion in the IOM report clearly refers to sales. Sales and use are not the same.

Much has changed between 1985 and 2009, including production practices, the type and number of antibiotic products available, and the number of animals in the U.S. These changes, along with the non-comparability of the data sets cited, leaves no basis for making assertions about the relative level of antibiotic use in the past 25 years.

3. EPA adds to the speculation and confusion about antibiotic resistance.

The statement "The dosing of livestock animals with antimicrobial agents for growth promotion and prophylaxis may promote antimicrobial resistance in pathogens…" is both inaccurate and commonly found in the literature of interest groups, not scientific literature. In fact, all uses, those in animals and humans and those for treatment or growth promotion, may promote antimicrobial resistant pathogens. In the context of animal use, it is well established that the use of these products often results in antimicrobial pathogens in animals. What is not clear is the extent to which these pathogens find their way into humans via food or other pathways. FDA focuses on the food pathway as the most direct source of potential transfer. A great deal of scientific effort has been expended to document examples of transfer of resistant bacteria via food resulting in human illness, with little success. We suggest regulatory actions based on risk – hazards that do happen – rather than upon what may happen.

4. EPA ignores the regulatory precautions taken in the FDA review process.

All antibiotics used in animal agriculture are, like human drugs, approved under the Federal Food, Drug and Cosmetic Act, and must be proven to be safe and effective. Included in the rigorous process for animal antibiotics is the requirement of an environmental assessment, whereby sponsors must conduct studies on the potential for the drugs to impact the environment. Mitigation steps, including the setting of withdrawal times, are implemented by the agency to address this potential.

We suggest EPA consult the FDA to learn more about how these products are regulated and what is known about potential environmental impacts.

Finally, we draw to EPA's attention the baseline water survey conducted by the U.S. Geological Survey as reported in Environmental Science and Technology, 2002, 36, 1202-1211. Given that sampling focused on water most likely to contain contaminants, it is notable that many of the veterinary pharmaceuticals were not detected at any of the sampling sites. Of those veterinary products detected, the frequency of detection was low and the concentrations of detections were very low.

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,

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