

## PolicyPennings by Daryll E. Ray & Harwood D. Schaffer Government agencies are collecting comments on implementation of antibiotic- use restrictions for food-producing animals

The September 30, 2015 meeting held by the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Centers for Disease Control (CDC) was one step in a long process of regulating and monitoring the use of medically important antimicrobial drugs in food-producing animals. The meeting with various stakeholders including producers and consumers was called by the three agencies to “obtain input on possible approaches for collecting additional on-farm antimicrobial drug use and resistance data” (<http://tinyurl.com/pocohq9>).

Concern on the part of the FDA over the use of antibiotics in animal feed can be traced back to a 1970 report on “The Use of Antibiotics in Animal Feed” which recommended “that antimicrobial drugs used in human clinical medicine that failed to meet certain guidelines established by the [FDA] Task Force [that issued the report] should be prohibited from growth promotion and any subtherapeutic use in food-producing animals by certain dates. Furthermore, those antimicrobials that failed to meet the guidelines should be limited to short-term therapeutic use and use only by a veterinarian or on a veterinarian’s prescription” (<http://tinyurl.com/352ks4e>).

There were further activities in the late 1970s and early 1980s as the relationship between antibiotic use in animals and hazards to human health was examined. In 1987 the National Cattlemen’s Beef Association issued producer guidelines for the “Judicious Use of Antimicrobials” as a part of the Beef Quality Assurance program. The guidelines “outline the appropriate use of these products:

- “Avoid using antibiotics that are important in human medicine.
- “Use a narrow spectrum of antimicrobials whenever possible.
- “Treat the fewest number of animals possible [and]
- “Antibiotic use should be limited to prevent and control disease and should not be used if the principal intent is to improve performance” (<http://tinyurl.com/nc5okot>).

Since then there have been reports by the Institute of Medicine (1988, 2003), the World Health Organization (WHO) (1997 and 2000, 2011), the National Research Council (1999), the US Government Accountability Office (1999, 2004), the European Commission’s Scientific Steering Committee on Antimicrobial Resistance (1999), a Joint Food and Agriculture Organization/World Organization for Animal Health (OIE)/WHO Expert Workshop (2003, 2004), Institute of Food Technologists and the IFT Foundation (2006), and the American Academy of Microbiology (2009),

all looking at the issue of antibiotic resistance as the result of their subtherapeutic use in food animals.

In April 2012, the FDA issued Guidance for Industry #209 (GFI #209), “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” to “provid[e] a framework for the voluntary adoption of practices to ensure the appropriate or judicious use of medically important antimicrobial drugs in food-producing animals. The first principle set forth in GFI #209 says, “The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health.” Principle 2 sets forth the idea that “The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation” (<http://tinyurl.com/352ks4e>).

Based on those principles, the FDA issued GFI #213, “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209” which “calls on animal drug sponsors of approved medically important antimicrobials administered through medicated feed or water to voluntarily remove production (growth promotion and feed efficiency) uses from their product labels, and bring the remaining therapeutic uses of these products (to treat, control, or prevent disease) under the oversight of a veterinarian by the end of December 2016” (<http://tinyurl.com/pocohq9>).

The September 30 meeting provided a chance for stakeholders to share their ideas and concerns. Those unable to attend the meeting have the opportunity to share their thoughts with the three agencies by submitting “either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, by [November 30, 2015]. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>” (<http://tinyurl.com/pocohq9>).

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