Antibacterial agents have been commercialized for therapeutic indications of prevention, control or treatment of infectious disease in food animals, and for improved productivity. The animal health pharmaceutical industry has developed many antibacterial products, most of which are analogs of human-use antibiotics originating from human antibacterial research programs. The main classes of antimicrobial agents include tetracyclines, beta lactams (which include cephalosporins), macrolides, fluoroquinolones, phenicols, aminoglycosides, sulfas, lincosamides, pleuromutilins, streptogramins and polypeptides. These are administered via injection, water, feed or other routes, usually to groups of animals.

Beginning in the 1970s, and continuing into the 1980s, the use of antibiotics as feed additives, particularly within the same antibiotic class as those used in humans, was evaluated in Europe and the U.S. for selection of antibiotic resistant food borne bacteria and potential human disease treatment impacts (1). In the 1990s, various international consultations and national agencies continued to evaluate the situation and proposed wide-ranging recommendations for risk management interventions intended to minimize and contain antibiotic resistant food borne bacteria of animal origin, usually without conducting a risk assessment (1). During the mid-1990s and early 2000s, several international organizations (e.g WHO, OIE and Codex) held consultations to establish proactive interventions for the use of medically important antibiotics in food animals which would minimize and contain antimicrobial resistant food borne microorganisms (1-4). The main recommendations of these organizations are 1) responsible use guidelines, 2) antimicrobial resistant food borne bacterial surveillance, 3) antibiotic sales or use data collection, and 4) risk assessment for product evaluations, with research programs as supportive.

Responsible use guidelines provide direction to the various stakeholders in the food animal production system, including the animal health companies, veterinarians, regulatory authorities, distributors of products, educators and others. Veterinary organizations have further developed animal-species specific and overall antibiotic practice guidelines based on common sense approaches that include disease prevention, appropriate diagnosis, administration of antibiotics per label directions or justification for extra-label use, and documentation of use and clinical evaluation of effectiveness. Regulatory authorities in the US, Canada, Japan, Australia and other countries have implemented a risk assessment requirement for new antibiotic indications as well as applying the process to reviews of existing feed additive antimicrobials, consistent with the recommendations of WHO. The EU regulatory authorities have used “Reflection Papers”, which are essentially detailed reviews with recommendations, in order to obtain input and then place label restrictions on the use of certain antimicrobial classes. Additionally, the EU used a legislative mandate in 1998 to eliminate the label indication of performance from food animal antimicrobial products, without using a risk assessment process. This is often referred to as the “growth promoter ban”. For clarification, it should be noted that therapeutic uses for were not affected by the legislation.

An assumption made in the OIE responsible use guidelines (3), is that each nation would have legislation in place that describes a prescription system, which would provide for veterinarian oversight of antibiotic use regardless of the route of administration and indication. In fact, some countries do not have such legislation and some do not yet have a provision for veterinarian involvement in antibiotic use decisions.

In the private sector, some restaurant companies have established their own antibiotic use policies for the providers of their meat, milk and eggs. Some food animal companies have developed their own guidelines to minimize on-farm antimicrobial use.

The Codex Alimentarius ad hoc Intergovernmental Task Force on Antimicrobial Resistance has completed work on risk analysis guidelines (having been graciously hosted by the Republic of Korea in 2007-2010), which offer yet another pathway for national authorities to properly evaluate and implement risk management interventions (5). As a prelude to the development of this document, both WHO and OIE developed a list of “critically important antimicrobials” for the purpose of assisting national authorities to prioritize work to be done. The comprehensive nature of the document includes all potential use of antimicrobial agents, whether in food...
Risk Management of Antibiotic Use in Food Animals

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Risk Management of Antibiotic Use in Food Animals

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animals (terrestrial or aquatic), crops, or other applications and a variety of risk management options that are best evaluated for implementation by using risk assessment procedures. This document will likely become a useful framework in the future as an overarching tool to help guide authorities through the complexity of the issue managing antimicrobial resistant food borne microorganisms.

One area of risk management that has been overlooked is the potential for development of unique veterinary antimicrobial products that do not compromise human use antibiotic classes. While the interventions listed above are likely to have some decrease of success, they have also increased the business and scientific challenge for successful development of new antimicrobial products for use in food animal health (6). In order to meet the worlds’ increasing demand for animal protein, it is imperative that innovative antibacterial products are developed, commercialized and used in a manner that will satisfy public health, food safety and animal health needs.

References


Risk-Risk Assessment of Antibiotic Use in Food Animals

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Concern is not risk

Based on the latest microbiological science and increased surveillance data, the hazard of antimicrobial resistance (AMR) bacteria is creating a valid concern. A hazard is some agent (e.g. microbial or chemical) that may cause harm to a living entity (FDA 2004; FAO 2003; FDA 2003). Many hazardous materials can be found in the average household (FEMA 2010). However they do not pose much risk because the amount and duration of exposure is usually minimized by various risk management steps.

The use of antibiotics in the production of food animals is thought to contribute significantly to the presence of the hazard, AMR bacteria. AMR bacteria can be found on most farms using antibiotics (Sengelov 2003; Furtula 2010; Chander 2008) or in flies (Graham 2009), or in ground water (Sapkota 2007) around some farms. However, the presence of a hazard or concern does not necessarily constitute a risk (Singley 2004.). A valid risk assessment will include a measurable definition of risk. Risk must include two features; exposure (or likelihood of event) and consequence should the event occur or exposure be “significant” (Eason 2011; Society for Toxicology 2011). Risk assessment (RA) is an important policy tool that aids in decision making about many potential hazards. For example, to address concerns about the risk of nuclear energy, the NRC stated “Probabilistic risk assessment should be used to reduce unnecessary conservatism associated with current regulatory requirements …” (NRC 1995). Risk assessment should also include evaluation of multiple management or mitigation options for reducing risk. Evaluation of these options provides decision makers more ways to solve a problem than simply banning a hazard. Risk management options for on farm antibiotic use are multiple and varied.