

# McDonald's Global Vision for Antimicrobial Stewardship in Food Animals\*

## *"Preserving antimicrobial effectiveness in the future through ethical practices today"*

As the body of scientific evidence grows, and scientific consensus emerges, we recognize the importance of continuing to evolve our position on antimicrobial use. In 2014, McDonald's assembled a team of experts from around the world to study, debate and comment on antimicrobial use in food animals. These experts represented veterinarians, physicians, academicians, clinical pharmacologists, epidemiologists, ethicists, animal health and welfare experts and other food animal production experts, and developed recommendations for antimicrobial stewardship in food animals, building on McDonald's 2003 global policy on antibiotic use in food animals.

We anticipate the body of knowledge on antimicrobial use in food animals and its impact on antimicrobial resistance in animal and human populations will continue to evolve. As a global enterprise conducting business in more than 100 countries, we also understand the complexities of different global industry structures, government bodies and regulations, and regulatory oversight where we conduct business, making it difficult to implement a single approach that has the same impact globally. It is our intent to work with governments, non-government organizations (NGOs), veterinary and university extension networks, industry leaders and retailers in roundtables to gain alignment and identify paths forward.

Our vision for antimicrobial stewardship is "*Preserving antimicrobial effectiveness in the future through ethical practices today*".

To achieve this vision, the guiding principles for judicious use of antimicrobials should be understood, implemented and verified on all farm operations raising food animals (see Appendix I). Second, meaningful veterinary oversight is imperative when antimicrobial use is required to maintain the health and welfare of animals. Third, we support the World Health Organization's (WHO) characterization of critically, highly and important antimicrobials in human medicine (see Appendix II). We acknowledge antimicrobials differ in terms of their importance in both human and animal health care, and those differences were considered. Four criteria have been outlined to guide our work and will serve as goals for our supply chain:

- I. Prohibit the use of antimicrobials in food animals that are by WHO definition "critically important" to human medicine, and not presently approved for veterinary use.
- II. Classes of antimicrobials that are currently approved as dual use (for use in both human and veterinary medicine) for **treatment or prevention** of animal disease can only be used in conjunction with a veterinary-developed animal health care program.
- III. Prohibit the use of any medically important antimicrobials for growth promotion in food animals, as defined by WHO.
- IV. Utilize animal production practices that reduce, and where possible eliminate, the need for antimicrobial therapies and adopt existing best practices and/or new practices that would result in subsequent reductions of antimicrobial use. Successful strategies will be shared broadly.

McDonald's recognizes the importance of decisions made by beef, pork, poultry, dairy and egg producers in managing the animals entrusted to their care. We are familiar with the extensive educational support and producer collaboration that has been developed and implemented in many areas of the world, and where industry trade groups have localized quality assurance programs that focus on continuous improvement through education and collaboration. We strongly support the implementation of all education, training and outreach programs and seek the development of verification programs for judicious antimicrobial use in all species to achieve our vision for antimicrobial stewardship.

McDonald's has prioritized the following initial areas of focus:

1. Establish principles and criteria for antimicrobial use
2. Develop field projects, as needed, to serve as Centers of Innovation (i.e. demonstration farms) for each species in an effort to demonstrate the benefits of judicious antimicrobial use
3. Develop methods to verify judicious antimicrobial use and establish goals for measuring progress.

\* Food animal(s) are defined in this document as beef, pork, poultry, dairy and eggs. See Appendix III.

We will achieve these priorities by elevating the conversation through stakeholder engagement in each area of the world where we do business, seeking alignment on principles and criteria for antimicrobial use and develop specific action plans and timelines for each species.

McDonald's will verify antimicrobial use in supply chains where we have dedicated supply (supplier relationships and supply chain visibility of the animals/birds). Dedicated suppliers will maintain records of antimicrobial use and document compliance which will be verified by third party audits. Where we don't have dedicated supply, we will work within each area of the world with stakeholders, including suppliers, industry partners, government agencies, NGOs, veterinary and university extension networks, and other retailers to gain alignment on expectations and developing timelines for implementation and verification criteria that would reduce the use of medically-important antimicrobials in food animals.

Through this collaboration, if changes are warranted, we will update this document or draft a new policy.

## Appendix I. Guiding Principles for Judicious Use of Antimicrobial Drugs

The judicious use of antimicrobial drugs is the foundation of McDonald's Global Vision for Antimicrobial Stewardship in Food Animals.

The following principles of judicious use draw from existing frameworks including the World Veterinary Association's *Prudent Use of Antibiotics Global Basic Principles* and the American Veterinary Medical Association's *Judicious Therapeutic Use of Antimicrobials General Principles*.

- 1. People first:** Antimicrobial drugs that are approved for both human and food animal use may be used in food animals for disease treatment or prevention only in accordance with applicable regulatory requirements and after thorough consideration of alternatives, including the use of antimicrobial drugs belonging to classes not used in human medicine.
- 2. Quality and safety:** McDonald's is committed to ensuring wholesome and safe food for our customers. Safe food is McDonald's number one priority and is central to all company operations.
- 3. Animal health and welfare:** Treating animals with care is integral to McDonald's animal health and welfare program. Disease prevention strategies, such as good husbandry and hygiene, routine health monitoring, immunization, and other preventative options should be emphasized before the use of antimicrobial drugs.
- 4. Antimicrobial drugs for animals:** Judicious use of antimicrobial drugs is an integral part of an overall animal health and welfare program. These principles do not preclude the judicious use of antimicrobial drugs to treat or, where appropriate, prevent disease.
- 5. Veterinary Oversight:** Veterinary oversight through a valid veterinary client patient relationship is core to judicious use of antimicrobials. Antimicrobials shall be used in accordance with applicable regulatory requirements, and shall be used only in accordance with the product license requirements and as directed by a veterinarian.
- 6. Limit exposure:** Antimicrobial drug use should be confined to appropriate clinical indications. Exposure to antimicrobial drugs for disease treatment or prevention should be minimized by limiting treatment to ill animals or animals at risk of a specific disease. The use of antimicrobial drugs for disease prevention should be regularly reassessed by a veterinarian. Extra-label therapies\* must be prescribed only after other antimicrobial treatment options have been exhausted, and must be prescribed in accordance with the most up-to-date laws and regulations that govern drug use. \*Extra-label therapies are defined as when the drug is used not in accordance with labelled directions. This includes but is not limited to a different dosage, time interval, route/application method, clinical indication, or species.
- 7. Record keeping:** Accurate records of treatment and outcome should be used to evaluate antimicrobial regimens. Identify, track and maintain medication and treatment records for all treated animals.

## Appendix II. World Health Organization List of Medically Important Antimicrobials

- Classes of antimicrobial drugs that are by WHO definition “critically important” to human medicine (those antimicrobial drugs which meet both Criterion 1 and Criterion 2 defined in *3<sup>rd</sup> Revision 2011 Critically Important Antimicrobials for Human Medicine*), and not presently approved for use in food animals, **will be prohibited for use in food animals in McDonald’s Supply Chain**. As specific examples, the following categories of antimicrobial drugs, as well as any new classes of antimicrobial drugs developed for human therapy and which are not approved for use in food animals, are prohibited from use in food animals in the McDonald’s supply chain.
  - **Lipopeptides**
  - **Oxazolidinones**
  - **Glycopeptides**
  - **Carbapenems**
  - **Third (or newer) generation tetracyclines** (e.g., glycylicyclines)
  - **Fifth (or newer) generation Cephalosporins** (e.g., ceftaroline)
- Antivirals
  - *Note: While antivirals do not meet the standard definition of an antimicrobial drug as used in this document, the use of these drugs in food animals is not acceptable to McDonald’s, pending evaluation of their safety, especially related to viral resistance.*
- For those classes of antimicrobial drugs identified as critically important to human medicine, **and currently approved for food animal use** (as defined in the *OIE List of Antimicrobials of Veterinary Importance*), use in food animal health care is contingent on local regulations, as well as veterinary authorization (after confirmation of diagnosis) or use under a veterinary care program developed in conjunction with and approved by a herd/flock veterinarian. McDonald’s encourages veterinarians and producers worldwide to rely on husbandry practices, rather than antimicrobials to prevent disease in food animals.

## Medically Important Antimicrobials Listed by the World Health Organization

### CRITICALLY IMPORTANT ANTIMICROBIALS

- |  |                             |   |
|--|-----------------------------|---|
| • Aminoglycosides  | • Glycopeptides*            | • Oxazolidinones  |
| • Carbapenems and other penems                                     | • Glycylcyclines            | • Penicillins (natural, aminopenicillins, and antistaphylococcal)         |
| • Cephalosporins (3 <sup>rd</sup> and 4 <sup>th</sup> generation)* | • Lipopeptides              | • Polymyxins  |
| • Cyclic esters  | • Macrolides* and ketolides | • Rifamycins  |
| • Flouro- and other quinolones*                                    | • Monobactams               | • Drugs used solely to treat tuberculosis or other mycobacterial diseases |

\* Designated by the WHO as “Highest Priority Critically Important Antimicrobials.”

### HIGHLY IMPORTANT ANTIMICROBIALS

- |   |                                    |   |
|---|------------------------------------|---|
| • Aminopenicillins  | • Penicillins (Antistaphylococcal) | • Streptogramins  |
| • Amphenicols   | • Pleuromutilins                   | • Sulfonamides, Dihydrofolate reductase inhibitors and combinations |
| • Cephalosporins (1 <sup>st</sup> and 2 <sup>nd</sup> generation) and cephamycins | • Pseudomonic acids                | • Sulfones  |
| • Lincosamides  | • Riminofenazines                  | • Tetracyclines   |
|   | • Steroid antibacterials           |   |

### IMPORTANT ANTIMICROBIALS

- Aminocyclitols
- Cyclic polypeptides
- Nitrofurantoin
- Nitroimidazoles

## Appendix III. Definitions

**Antimicrobial drug:** This document references the WHO definition of any substance of natural, synthetic, or semisynthetic origin which at low concentrations kills or inhibits the growth of micro-organisms but causes little or no host damage. **This definition includes antimicrobials**, but excludes anticcocidials, disinfectants and antiseptics, metals such as zinc, and other compounds such as natural oils.

*Clarification for Ionophores: Ionophores meet the definition of both an antimicrobial and an anticcocidial. They are not classified as medically important by current global consensus. This document addresses those antimicrobial drugs which are medically important.*

**Antimicrobial resistance (AMR):** Antimicrobial resistance (AMR) is resistance of a microorganism to an antimicrobial drug that was originally effective for treatment of infections caused by it. Resistance should be based on clinical standards approved by organizations such as the Clinical and Laboratory Standards Institute (CLSI) or the European Committee on Antimicrobial Susceptibility Testing (EUCAST).

**Food Animals:** This document applies to beef, poultry, pork, dairy and eggs purchased by McDonald's.

**Veterinarian:** Referencing OIE's definition, "*Veterinarian refers to a person with appropriate education, registration or licensed by the relevant veterinary statutory body of a country to practice veterinary medicine/science in that country*"

**Medically Important Antimicrobials:** The designation of medically-important antimicrobial drugs in this document is based on the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) publication entitled *Critically Important Antimicrobials for Human Medicine, 3<sup>rd</sup> revision, 2011*. This document considers medically important to include antimicrobial drugs listed as critically important, highly important, and important in the WHO AGISAR publication (see Appendix II). It also includes any new class of antimicrobial drugs developed for human therapy.

**Antimicrobial Stewardship:** "*Preserving antimicrobial effectiveness in the future through ethical practices today*"

Antimicrobial stewardship refers to coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration. Antimicrobial stewards seek to achieve optimal outcomes related to antimicrobial use, minimize toxicity and other adverse events, reduce the costs of health care for infections, and limit the selection for antimicrobial resistant strains. We support all the efforts of stewardship in human medicine and extend them to include the judicious use of antimicrobials in food animal medicine

**Intent of use:** Three categories of use are referred to in this document. They are **Treatment, Prevention, and Growth Promotion**. These definitions are adapted from the *Codex Alimentarius Code of Practice to Minimize and Contain Antimicrobial Resistance. CAC/RCP 61-2005*.

**Disease Treatment/Therapeutic Use:** Treatment/therapeutic use refers to the use of antimicrobial drug(s) for the specific purpose of treating an animal(s) with a clinically diagnosed infectious disease or illness.

**Disease Prevention/Prophylactic Use\*:** Prevention/prophylactic use refers to the use of an antimicrobial drug(s) in healthy animals considered to be at risk of infection or prior to the onset of clinical infectious disease. This includes:

- Control of the dissemination of a clinically diagnosed infectious disease identified within a group of animals, and
- Prevention of an infectious disease that has not yet been clinically diagnosed. The disease threat must be established by a veterinarian, the antimicrobial drug used only for the time period in which the threat exists, and alternative methods to eliminate the disease threat constantly reviewed.

*\*The term "prevention" includes both prevention and control as well as other terms including prophylaxis, metaphylaxis, mass-medication, and mass-treatment.*

**Growth Promotion:** Growth Promotion refers to the use of an antimicrobial drug to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. Growth promotion is considered to be any use of an antimicrobial drug which does not meet the above definitions for treatment or prevention.