McDonald's Global Vision for Antibiotic Stewardship in Food Animals ("VAS") "Preserving Antibiotic effectiveness in the future through ethical practices today"

McDonald's Global Vision for Antibiotic Stewardship in Food Animals ("VAS") serves as a framework for developing future species specific policies. Such future policies will demonstrate McDonald's commitment to the Responsible Use of Antibiotics in Food Animals used within the McDonald's System, detailing business segment participation, measures, reporting and timelines as we've defined in our August 2017 release "McDonald's Antibiotic Use Policy for Broiler Chickens."

As the body of scientific evidence grows, and consensus emerges, McDonald's recognizes the importance of continuing to evolve its policies regarding Antibiotic use in Food Animals. In 2014, McDonald's assembled a team of experts from around the world to study and comment on Antibiotic use in Food Animals. These experts included veterinarians, physicians, academicians, clinical pharmacologists, epidemiologists, ethicists, animal health and welfare experts and other food animal production experts. Together, they developed recommendations for Antibiotic Stewardship in Food Animals and developed the 2015 McDonald's Global Vision for Antibiotic Stewardship in Food Animals (the "2015 VAS"), which replaced McDonald's 2003 global policy on Antibiotic use in Food Animals. This VAS replaces the 2015 VAS.

We anticipate that the body of knowledge on Antibiotic use in Food Animals (beef, chicken, pork, dairy cows and laying hen production) and the impact of such use on Antibiotic resistance in animal and human populations will continue to evolve. As a global enterprise, we also understand the complexities of different global industry structures, government bodies and regulatory oversight, making it difficult to implement a single global approach. We are committed to working with our System Suppliers, industry leaders, government agencies, non-government organizations (NGOs), veterinary and university extension networks and other retailers to gain alignment and identify appropriate paths forward, and will work to develop timelines for implementation and verification criteria via 3rd party, resulting in reduction of antibiotic use in Food Animals.

As such, McDonald's is committed to reducing the need for Antibiotics, and has a preference for raw materials (beef, poultry, pork, dairy cows and laying hens and defined as "Food Animals") supplied through progressive farming practices including the Responsible Use of Antibiotics. As one of the world's largest food companies, we will seize the opportunity to use its scale for good, to influence industry change on the issue of Responsible Use of Antibiotics.

To achieve this vision, the guiding principles for Responsible Use of Antibiotics should be understood, implemented and verified on all farm operations raising Food Animals for the McDonald's System (see Appendix I). Second, veterinary oversight is imperative when Antibiotic use is required to maintain the health and welfare of Food Animals. Third, we support the WHO's categorization of Highest Priority Critically Important, High Priority Critically Important, Highly Important and Important Antibiotics in human medicine (see Appendix II). We acknowledge Antibiotics differ in terms of their importance in both human and animal health care, and those differences were considered in our review of the WHO Classifications, in the Animal Health *List of Antimicrobial Agents of Veterinary Importance, May 2015 and Critically Important Antimicrobials for Human Medicine – 5th Rev. Geneva: World Health Organization; 2017.*

Seven criteria have been outlined to guide our work and will serve as goals for System Suppliers:

- I. Antibiotics can only be used in conjunction with a veterinary-developed animal health care program.
- II. Source raw material (meat) from Food Animals (beef, chicken, pork, dairy cows and laying hens) that are not treated with HPCIA.
- III. Antibiotics identified as High Priority Critically Important, Critically Important, Highly Important and Important for human medicine <u>and</u> currently approved for veterinary use, should <u>not be used as first line treatment</u>, and only be used after susceptibility testing of the diseased animals has shown other classes of Antibiotics to be ineffective as determined by the attending veterinarian.
- IV. Source raw material (meat) (beef, chicken, pork, dairy cows and laying hens) from Food Animals that are not treated with Antibiotics used solely for Growth Promotion.
- V. Routine Prevention use of Antibiotics is not permitted. For clarity, however, System Suppliers may continue to use Ionophores subject to applicable laws and regulations.

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version and Date:	Version 2.1, 16 August 2017
Replaces:	Version 1, 02 March 2015 and Version 2, 07 August 2017
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- VI. Utilize a nimal production practices that reduce, and where possible eliminate, the need for Antibiotic therapies in Food Animals and a dopt existing best practices and/or new practices that would result in subsequent reductions of Antibiotic use.
- VII. Benchmarking and measurement of Antibiotic usage is required to track performance. Successful strategies resulting in antibiotic use reductions will be shared broadly within the McDonald's System.

McDonald's recognizes the importance of decisions made by Food Animal 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 business segments, 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 Responsible Use of Antibiotics in all species to achieve our vison for Antibiotic Stewardship.

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

- 1. Establish principles and criteria for Responsible Use of Antibiotics in Food Animals.
- 2. Develop field projects, as needed, to serve as Centers of Innovation (i.e. demonstration farms/flagship farms) for each species in an effort to demonstrate the benefits of Responsible Use of Antibiotics.
- 3. Develop methods to verify Responsible Use of Antibiotics and establish goals for measuring progress.

We aim to achieve these priorities by elevating the conversation through stakeholder engagement within Business Segments, seeking alignment on principles and criteria for Responsible Use of Antibiotics and develops pecific action plans and timelines for each species of Food Animal, with a special focus on the HPCIA.

Definitions

The capitalized terms used in the VAS, and not otherwise defined, shall have the meanings designated below.

McDonald's	McDonald's Corporation and its majority-owned subsidiaries
McDonald's GQS	The Global Quality Systems Department of McDonald's.
McDonald's System	The comprehensive system for the ongoing development, operation and maintenance of McDonald's branded restaurants, operated by Franchisees.
Franchisees	Collective group of independent individuals and entities operating McDonald's branded restaurants, including franchisees, developmental licensees, joint venture partners, and majority-owned subsidiaries of McDonald's Corporation.
System Purchasers	Persons or entities within the McDonald's System that are authorized to purchase, distribute or use products or services, including without limitation, independent distribution centers and Franchisees.
System Suppliers	Suppliers within the McDonald's System that supply products and services to System Purchasers.
Antibiotic	Natural chemical substances produced by one microorganism, with the capacity to dilute or kill another microorganism. For purposes of this Policy, Antibiotics specifically excludes, Coccidiostats and Ionophores.
AntibioticTreatment	Use of Antibiotics for the specific purpose of treating an animal with a clinically diagnosed infectious disease or illness.
Antibiotic Ste wardship	The preservation of Antibiotic effectiveness in the future through ethical practices today through coordinated interventions designed to improve and measure the appropriate use of Antibiotics by promoting the selection of the optimal Antibiotic drug regimen, dose, duration of therapy, and route of administration. Antibiotic stewards seek to achieve optimal outcomes related to Antibiotic use, minimize toxicity and other adverse events,

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Authorized by:	VP – Global Quality Systems and VP – Strategic Sourcing Food
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	reduce the costs of health care for infections, and limit the selection for Antibiotic resistant strains.
Broiler Chicken	Chicken raised specifically for meat production for the purpose of providing food for humans.
High Priority Critically Important Antibiotics	High priority critically important antibiotics as defined by the WHO CIA LIST.
Coccidiostat	A drug that arrests the development of coccidia, a type of protozoa, at specific stages of its lifecycle. The use of a Coccidiostat is intended to provide the host time to develop immunity, and in some countries it may be classified as an 'antibiotic', but has not been linked to the development of resistance to bacteria that cause disease in humans, and is not used in human medicine.
EU & EEA (European Economic Area) plus U.K, Azerbaijan, Belarus, Bosnia, Croatia and Ukraine	The following countries: Austria, Azerbaijan, Belarus, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Ireland, Italy, Kazakhstan, Latvia, Lithuania, Luxembourg, Malta, Moldova, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Switzerland, Sweden, United Kingdom, Ukraine
Food Animals	Beef, Broiler Chickens, pork, dairy cows and laying hens raised for the purpose of providing food for humans.
Growth Promotion	Any use of an Antibiotic which does not meet veterinary requirements for treatment or prevention of illness and involves the use of an Antibiotic to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means.
HPCIA	Highest priority critically important antimicrobials as defined by the WHO CIA LIST.
lonophores	A drug that increases the permeability of cell membranes to a specific ion, and in some countries may be classified as an 'antibiotic', but has not been linked to the development of resistance to bacteria that cause disease in humans, and is not used in human medicine.
Medically Important Antibiotics	Medically important antimicrobials categorized as "highest priority critically important," "high priority critically important," "highly important" and "important" for human medicine by the WHO CIA LIST.
OIE	The World Organization for Animal Health is the intergovernmental organization responsible for improving animal health worldwide. It is recognized as a reference organization by the World Trade Organization (WTO) and in 2017 has a total of 181 Member Countries. The OIE maintains permanent relations with 71 other international and regional organizations and has Regional and sub-regional Offices on every continent.
Prophylactic Use	The administration of Antibiotics to healthy Food Animals prior to an expected exposure to an infectious agent or, following such an exposure prior to onset of laboratory-confirmed clinical disease.
Routine Prevention	The repetitive administration of Antibiotics to Food Animals to compensate for systemically poor hygiene or where improvement in animal husbandry would reduce or eliminate the need for the Antibiotic.
Responsible Use	The use of Antibiotics in Food Animals which maximizes therapeutic effect and minimizes the development of Antibiotic resistance.
Veterinarian	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.
WHO	The World Health Organization, which is a specialized agency of the United Nations that is concerned with international public health.
WHO CIA List	Critically Important Antimicrobials for Human Medicine - 5 th rev. Geneva: World Health Organization; 2017. License: CC BY-NC-SA 3.0 IGO

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Appendix I. Guiding Principles for Responsible Use of Antibiotics in Food Animals

The Responsible Use of Antibiotics is the foundation of McDonald's Global Vision for Antibiotic Stewardship in Food Animals.

The following principles of Responsible Use draw from existing frameworks including: World Veterinary Association's *Prudent Use of Antibiotics Global Basic Principles;* American Veterinary Medical Association's *Judicious Therapeutic Use of Antimicrobials General Principles* and WHO guidance WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food. Report of a WHO Consultation with the participation of the Food and Agriculture Organization of the United Nations and the Office International des Epizooties. Geneva, Switzerland. 5-9 June 2000 WHO/CDS/CSR/APH/2000.4 (http://apps.who.int/iris/bitstream/10665/68931/1/WHO CDS CSR APH 2000.4.pdf)

- 1. **People first:** Antibiotics that are approved for both human and Food Animal use, other than HPCIA, may be used in Food Animals for disease treatment or prevention only in accordance with a pplicable regulatory requirements and after thorough consideration of alternatives, including the use of Antibiotics 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 Antibiotics. We acknowledge that animals, like people, become sick and would expect sick animals to be responsibly treated. To not treat sick animals is inhumane and inconsistent with McDonald's belief that Food Animals within the McDonald's System supply chain are properly cared for throughout their lives.
- 4. Antibiotics for Food Animals: Responsible Use of any category of Antibiotic is an integral part of an overall animal health and welfare program. These principles do not preclude the Responsible Use of any category of Antibiotic, except for HPCIA, to treat or, where a ppropriate, prevent disease.
- 5. Veterinary Oversight: Veterinary oversight through a valid veterinary client patient relationship is core to responsible Antibiotic use. Antibiotics shall be used in a ccordance with all applicable regulatory requirements, and shall be used only in accordance with the product license requirements and as directed by a veterinarian.
- 6. Limit exposure: Antibiotic use should be confined to appropriate clinical indications. Exposure to Antibiotics for disease treatment or prevention should be minimized by limiting treatment to sick animals or animals at risk of a specific disease. The use of any category of Antibiotic for disease prevention should be regularly reassessed by a veterinarian. Usage of an Antibiotic in a manner that is not in accordance with labelled directions, including but not limited to a different dosage, time interval, route/application method, clinical indication or species may be prescribed only after other Antibiotic treatment options have been exhausted, and must be prescribed in accordance with the most up-to-date laws and regulations that govern drug use.
- 7. Record keeping: Accurate records of treatment and outcomes should be used to evaluate Antibiotic regimen. Identify, track and maintain medication and treatment records for all treated animals. Refer to species specific document for additional guidance/requirements.

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Appendix II. WHO CIA LIST

HIGHEST PRIORITY CRITICALLY IMPORTANT ANTIMICROBIALS (HPCIA)

- *Cephalosporins* (3rd, 4th, 5th and newer ٠ generation)
- Glycopeptides ٠
- ٠ Macrolides and ketolides
- Polymyxins ٠
- Quinolones

HIGH PRIORITY CRITICALLY IMPORTANT ANTIMICROBIALS

- Aminoglycosides ٠
- Ansamycins •
- Carbapenems and other penems
- Glycylcyclines

HIGHLY IMPORTANT ANTIMICROBIALS

- Amidinopenicillins •
- Amphenicols •
- Cephalosporins (1st and 2nd • generation) and cephamycins
- Lincosamides ٠

- Monobactams
- and antipseudomonal.)

Penicillins (anti-staphylococcal)

- Phosphonic acid derivatives ٠
- Drugs used solely to treat tuberculosis or other mycobacterial diseases
- Streptogramins
- Sulfonamides, dihydrofolate ٠ reductase inhibitors and combinations
- Sulfones
- Tetracyclines

IMPORTANT ANTIMICROBIALS

- Aminocyclitols
- Cyclic polypeptides •
- Nitrofurazones and Nitroimidazoles •
- Pleuromutilins •

Source: Critically Important Antimicrobials for Human Medicine - 5th rev. Geneva: World Health Organization; 2017. License: CC BY-NC-SA 3.0 IGO

•	Lipopeptides	
•	Monohactams	

- Penicillins (natural, aminopenicillins
- •
- ٠

Pseudomonic acids

Steroid antibacterials

Riminofenazines

٠

٠

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Oxazolidinones