



Antibiotic Use Policy for Beef and Dairy Beef

Purpose

This Policy identifies McDonald's expectations and anticipated implementation plans for McDonald's Antibiotic Use Policy for beef and dairy beef from our Top 10 beef sourcing countries (*Australia, New Zealand, France, Germany, Ireland, Poland, UK, Canada, USA and Brazil*), while ensuring compliance with local laws and regulations are met. These expectations are based on McDonald's Global Vision for Antibiotic Stewardship in Food Animals ("VAS") issued in 2017, and the World Health Organization (WHO) Guidelines on Use of Medically Important Antimicrobials in Food Producing Animals¹. McDonald's reserves the right to periodically update the VAS and this Policy.

McDonald's takes great pride in serving its customers around the world every day with safe, quality products that it strives to ensure are socially, environmentally and economically sustainable. The ability of System Suppliers to consistently deliver safe and quality products that meet McDonald's requirements, as well as all applicable laws and regulations is of critical importance to the continued success of the McDonald's System.

McDonald's recognizes that antibiotic use is under continuous review by scientists, regulatory bodies' and non-profit organizations worldwide. As acknowledged by World Health Organization Guidelines on Use of Medically Important Antimicrobials in Food Producing Animals (Policy Brief November 2017), "*overuse and misuse of antibiotics in animals and humans is contributing to the raising threat of antibiotic resistance.*" Globally, McDonald's position on antibiotic use is one of responsible use, where effective treatment includes selection of the most narrow spectrum antibiotic based upon identification of causes and associated susceptibility pattern/profile.

Macrolide antibiotics are considered Critically Important for human medicine by WHO and will be subject to the use restrictions outlined in this policy. We have considered the European Medicines Agency position on the use of Macrolide antibiotics and the associated risk assessment resulting in a classification of low/limited risk to public health. With evidence continuing to emerge specific to Macrolide antibiotics, this policy follows the WHO classification. Therefore, in line with this policy, the use of Macrolide antibiotics may be permitted based upon the advice of a qualified veterinarian and informed by susceptible testing if no other drug is available to treat infected animals.

Aligned with responsible use, McDonald's is committed to reducing the need for antibiotics in food animal production, and has a preference for raw materials supplied through progressive farming practices including, but not limited to:

- Preventive medicine strategies
- Farm hygiene practices
- Animal husbandry and vaccination programs

As one of the world's largest food companies we will use our scale for good, partnering with industries in transparent conversation to advance practices related to use of antibiotics and susceptibility testing.

Building upon the VAS, the following principles further shaped the development of this Policy.

- Producers, veterinary professionals and the biopharmaceutical industry share a responsibility for proactively developing and implementing effective "preventive medicine" strategies to reduce, and where possible eliminate the need for antibiotic use.
- Animal health and welfare is our primary objective and we require those responsible for the care of animals entering our supply chain to treat sick animals.
- When antibiotics are prescribed by a veterinarian, McDonald's global position is one of responsible use, informed by resistance monitoring and susceptibility testing
- McDonald's will encourage producers to adopt a tiered approach to antibiotic use; the lowest importance human drugs ranked as the first choice, and Highest Priority Critically Important Antibiotic's restricted to last choice.

1. http://www.who.int?foodsafety/areas_work/antimicrobial-resistance/cia_guidelines/en/

Policy Requirements for Antibiotic Reduction in McDonald's Supply Chain

This Policy refers to categories of antibiotics as defined by the World Health Organizations list of Critically Important Antimicrobials for Human Medicine (WHO CIA list). This Policy is further shaped by McDonald's strategy of responsible use supported by the 3 R's framework - Refine, Reduce and Replace.

This Policy for antibiotic use in beef and dairy beef establishes the following in furtherance of the principles outlined in VAS version 2.1, 16 August 2017:

- Adopting a tiered approach, antibiotics defined by the WHO as medically important antimicrobials and further defined in the WHO Critically Important Antimicrobials for Human Medicine 5th revision² and while administered at the last finishing farm, dairy or feed lot for prior to slaughter, the following would apply:
 1. Use of Antibiotics defined by WHO as Medically important antibiotics for human medicine are not permitted for the purpose of growth promotion in food-producing animals in McDonald's Supply Chain.
 2. Routine use of medically important antibiotics for prevention of disease is not permitted. Medically important antibiotics for human medicine are not permitted for the prevention of infectious diseases in food-producing animals in McDonald's Supply Chain except in the following narrowly-defined non-routine situation: Based upon the determination of a qualified veterinarian familiar with the disease history in the herd, non-routine prevention uses may be permitted if there is a high risk of contraction of a particular infectious disease. If use is deemed necessary, antibiotic selection should start with those antibiotics of least importance for human health and ladder up to important, then highly important and then critically important in human medicine according to WHO CIA list.
 3. Critically Important antibiotics for human medicine are not permitted for the control and/or treatment of the dissemination of a clinically diagnosed infectious disease identified within a group of food-producing animals in McDonald's Supply Chain. Allowances can be made for the immediate treatment of animals exhibiting clinical signs as defined by the case definition leading to a clinical diagnosis as prescribed by a qualified veterinarian who deems that the critically important antimicrobial is the best option. Routine surveillance based on culture and sensitivity testing should be conducted on farms in McDonald's Supply Chain when using Medically Important antibiotics, as these tests can provide important epidemiological information on the specific bacteria present on the farm, and as one clinical case may very likely lead to another, future treatment of additional clinical cases will be better informed. Where critically or medically important antibiotics are used for the prevention, treatment and/or control of clinical disease, the veterinary herd health plan should be reviewed and adjusted to employ tailored preventative strategies that will reduce the need for future treatments.
 4. Application of 1-3 above is expected to result in an overall reduction in the use of medically important antibiotics for human medicine in food-producing animals in McDonald's Supply Chain.
- Medically important antibiotics that are not currently approved for use in food animal production are not permitted in McDonald's Supply Chain.
- Any new class of antibiotics or new antimicrobial combination developed for humans will be treated the same as those *Critically Important for human medicine* unless otherwise classified by the WHO.
- When antibiotic use in food animals is deemed necessary, it must follow the guidance provided by the attending herd veterinarian and a veterinarian-developed herd health plan. When used, antibiotics will be used in accordance with label and veterinary direction for dose, duration, route, frequency, withholding period and withdrawal times.

Additionally, Ionophores such as Lasalocid and Monensin are categorized by the World Organization for Animal Health (OIE) as "essential for animal health" because they are used to control intestinal parasitic coccidiosis, (*Eimeria* spp.) where there are few or no alternatives available. Coccidiostats are not considered antibiotics of medical importance to human health and have not been linked to the development of resistance to medically important antibiotics in bacteria that cause diseases in humans, and they are not used in human medicine. Continued use of Ionophores and Coccidiostats is permissible, subject to applicable laws and regulations.

- **Disease Treatment:** Drug administered to animals exhibiting clinical signs of disease
- **Disease Control:** Drug administered to a group of animals when a proportion of the animals in the group exhibit clinical signs of disease
- **Disease Prevention:** Drug administered to a group of animals, none of which are exhibiting clinical signs of disease, in a situation where disease is likely to occur if the drug is not administered.

2. <http://www.who.int/entity/foodsafety/publications/cia2017.pdf>

Implementation Strategy and Timeline

McDonald's will establish regional pilot tests in order to begin the implementation of this Policy. These pilots will be inclusive of the diversity of the food animal production systems that exist across our supply chain, and will help further develop this Policy. These pilot tests will establish a baseline use of medically important antibiotics in each market, and they will inform how we ultimately embed our requirements for Refine, Reduce and Replace into our beef sustainability strategy while we continue to gain a deeper understanding of the impacts on animal health and production associated with antibiotic use reduction in the beef and dairy beef supply chains.

Implementation criteria and anticipated timelines are as follows and subject to modification as we learn more from our pilot tests.

- By December 2018, we will collaborate with producers in our supply chain to establish pilots in each of our top ten beef sourcing markets (Australia, New Zealand, France, Germany, Ireland, Poland, UK, Canada, USA and Brazil).
- By the end of 2020, we will establish market-specific reduction targets for medically important antibiotics, based on our pilot findings.
- Starting in 2022 – we will be reporting progress against antibiotic reduction targets across our top 10 beef sourcing markets.

Appendix

A Commitment to Refine – Reduce - Replace

The 3 R's is a framework for antimicrobial stewardship in veterinary medicine and agriculture. This framework promotes practical and evidence-based solutions to “refine, reduce and ultimately replace” the use of antibiotics, and is sufficiently flexible to allow tailored stewardship programs to be developed for individual species, production systems and farms across the world.

- **Refine** means, *refining the use of antibiotics in animal agriculture, by ensuring the responsible and informed selection and correct administration of antibiotics to animals that have a clinical indication for treatment.*
 - Veterinary education and oversight
 - Antibiotic use compliance per valid herd health management systems that are 3rd party audited
 - Sharing successful best practice strategies resulting in the reduction of all antibiotic use
 - Partnership with technology providers and progressive producers to support the development of automated systems (Vision Systems) that can anticipate sick animals based on behavior patterns improving case definition and outcomes
 - First using those antibiotics of least importance to human medicine
 - Identifying appropriate benchmarking measures that include use, antibiotic concentration and the inclusion of additional key variables based on cattle assessment and antibiotic resistance
- **Reduce** means, *reducing the annual usage of antibiotics in animal agriculture, while preserving animal health and welfare. Outcome of a successful reduction strategy could include the reduction of antibiotic resistance to target and foodborne pathogens in the beef supply chain, and could also include maintaining resistance at low levels if that is the case in the local market.*
 - Monitoring, reporting and therapy adjustment to target pathogen antibiotic resistance
 - Preventive medicine programs that decrease the need for herd level treatments or metaphylaxis
- **Replace** means, *replacing some of the antibiotics used in animal agriculture, with evidence-based and sustainable solutions to prevent diseases and protect animal health and welfare, such as vaccination and improved farm management and animal husbandry practices. This may include:*
 - Replacement of treating Bovine Respiratory Disease (BRD) with more sustainable alternatives
 - Non-antibiotic or alternate technologies that replace antibiotic use in current cattle production systems
 - Direct fed microbials
 - Vaccination programs
 - Immunomodulators

Definitions

- **Clinical signs** - denoting the symptoms, change in behavior in an animal during the course of a disease
- **Case definition** – a case definition is used to standardize cases of interest within and between disease outbreaks. Case definitions should include criteria such as the animal description, geographical location of the farm, and clinical signs and onset of disease.
- **Qualified veterinarian** – a veterinarian in good standing that is practicing under a valid veterinary, patient, client relationship (VCPR).
- **Clinical diagnosis** – the diagnosis of disease based on observation of clinical signs, symptoms, change in animal behavior or laboratory findings associated with the case definition. A clinical diagnosis can be made by a veterinarian or trained personnel under the guidance of a valid veterinary, client, patient relationship.
- **Veterinary Client Patient Relationship (VCPR)** is present when all of the following requirements are met:
 - The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animals and the client has agreed to follow the veterinarians' instructions.
 - The veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition of the patient. This means that the veterinarian is personally acquainted with the keeping and care of the patient by virtue of a timely examination of the patient by the veterinarian, or medically appropriate and timely visits by the veterinarian to the operation where the animals are managed.
 - The veterinarian is readily available for follow-up evaluation or has arranged for the following: veterinary emergency coverage, and continuing care and treatment.
 - The veterinarian provides oversight of treatment, compliance, and outcome.
 - Animal health records are maintained.