



McDonald's Antibiotic Policy for our Beef Supply Chain



Revision History:

Date	Revision #	Page (s)	Description of change(s)	Superseded Document
2022-Dec-5	3.0	1, Title	Renamed policy from "Antibiotic Policy for Beef and Dairy Beef" to "McDonald's Antibiotic Policy for our Beef Supply Chain"	2.0 -2022-March-23
		3, Purpose	Updated and streamlined for consistent messaging across all McDonald's ABX policies	
		4 & 5, Policy Requirements	Restructured content for clarity. No changes were made to content	
		6 & 7, Progress and Planned Actions	Changed "Implementation and Timelines" to "Progress and Planned Actions," outlining our progress to date, and included McDonald's responsible use targets	
		9 & 10, Definitions	Streamlined all definitions to last page of document	
2022-March-23	2.0	3, Purpose	Removed the reference to our Top 10 sourcing markets, as our purchasing changes year after year. Our focus will remain on the markets outlined in 2018 (Australia, New Zealand, France, Germany, Ireland, Poland, UK, Canada, USA, and Brazil).	1.2 – 2018-December-07
		6, Timelines and Implementation	Added 2022 Policy Progress, Revised Commitment and Next Steps	

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PURPOSE



This Policy identifies McDonald's expectations with respect to antibiotic use in its beef supply chain. This Policy applies to the sourcing of beef in/from the following countries: Australia, Brazil, Canada, France, Germany, Ireland, New Zealand, Poland, the U.K., and the U.S., while ensuring compliance with all applicable local laws and regulations. This species-specific Policy is informed by: McDonald's Global Vision for Antibiotic Stewardship in Food Animals (VAS) issued in 2017; the World Health Organization (WHO) Guidelines on the Use of Medically Important Antimicrobials in Food Producing Animals¹; the World Animal Health Organization (WOAH; formerly recognized as OIE) List of Antimicrobial Agents of Veterinary Importance (May 2018)²; Codex Alimentarius Code of Practice to Minimize and Contain Antimicrobial Resistance CAC/RCP 61-2005; and, additional country specific guidance including, but not limited to, the U.S. Food and Drug Administration, Animal Medical Drug Use of Clarification Act, Responsible Use of Medicines in Agriculture (RUMA), European strategic action plan on antibiotic resistance, and German Antimicrobial Resistance Strategy (DART). McDonald's reserves the right to update the VAS and this Policy.

As acknowledged by the WHO, "overuse and misuse of antibiotics in animals and humans is contributing to the rising threat of antibiotic resistance." Concurrently, the WOAH has established judicious use guidelines for the veterinary community, allowing the attending veterinarian to exercise their professional oath³ for the benefit of society, the protection of animal health and welfare, the prevention and relief of animal suffering, the conservation of animal resources, the promotion of public health, and advancement of medical knowledge. We view the guidance provided by the WHO and WOAH as complimentary and in the best interest of maintaining healthy human and animal populations. Healthy animals provide McDonald's with the ability to serve our customers safe food, and safe food is our number one global priority. Responsible antibiotic use is a critical component of our global commitment to improving the health and welfare of animals in our supply chain.

Antibiotic use should not be a substitute for good husbandry or adequately designed and implemented management systems. When appropriate, antibiotics should be considered an acceptable veterinary treatment complementing good management, good nutrition, vaccination, biosecurity, and on-farm hygiene. McDonald's recognizes the critical role of the producer, veterinarian, nutritionist, pharmaceutical industry, and industry leadership in creating awareness, providing producer training and education, and implementing measurement systems that will drive accountability resulting in responsible use and associated reductions in antibiotic administration over time.

McDonald's global position on antibiotics is one of responsible use, where effective treatment includes antibiotic selection with oversight from a qualified veterinarian through a valid Veterinary Client Patient Relationship (VCPR), considering spectrum of activity and medical importance based upon identification of cause(s) and associated susceptibility pattern/profile(s). McDonald's is committed to working with processors, leadership in agriculture, the veterinary community, and pharmaceutical companies to promote a "One Health" approach that addresses antibiotic resistance by focusing on disease prevention, not solely disease treatment. McDonald's will exercise a preference for beef supplied through progressive farming practices employing responsible antibiotic use in combination with alternate disease prevention strategies inclusive of holistic biosecurity and herd health management

¹ https://www.who.int/publications/i/item/9789241550130

² https://www.woah.org/app/uploads/2021/03/a-oie-list-antimicrobials-may2018.pdf

³ <u>Veterinarian's Oath | American Veterinary Medical Association (avma.org)</u>



programs. McDonald's views this Policy as an extension to the 3 R's Framework – Refine, Reduce, and Replace, which promotes practical and evidence-based solutions to refine, reduce, and 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. As one of the world's largest food companies we will collaboratively do our part to advance practices related to the responsible use of antibiotics.

PRINCIPLES

The following principles informed the development of this Policy and its requirements.

- Producers, veterinary professionals, and the biopharmaceutical industry share a responsibility for
 proactively developing and implementing effective best management 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 qualified veterinarian, McDonald's global position is one of responsible use, informed by VCPR history, expected treatment outcomes, resistance monitoring and susceptibility testing.
- When multiple effective treatment options exist, McDonald's encourages adoption of a tiered approach to antibiotic selection with the least important to human medicine being the first choice, and Highest Priority Critically Important Antibiotics (HPCIAs) reserved for last resort.

POLICY REQUIREMENTS

This Policy refers to categories of antibiotics as defined by the WHO's list of Critically Important Antimicrobials for Human Medicine⁴ (WHO CIA list).

This Policy establishes the following in furtherance of the principles <u>outlined in VAS version 2.1, 16</u> <u>August 2017:</u>

- 1. Adopting a tiered approach, for antibiotics defined by the WHO as medically important antimicrobials (and further defined in the WHO Critically Important Antimicrobials for Human Medicine 6th revision) and administered at the last premise (farm, feed yard, or ranch) prior to transport for slaughter, the following would apply:
 - A. Any use of antimicrobial agents in food animal production shall be in accordance with WOAH standards on the responsible and prudent use of antimicrobials, as defined in the Terrestrial Animal Health Code, Section 6.
 - B. Use of antibiotics, defined by the WHO as medically important for human medicine, are not permitted for growth promotion in food-producing animals in McDonald's supply chain.

⁴ World Health Organization. (2019). Critically important antimicrobials for human medicine, 6th. https://apps.who.int/iris/handle/10665/312266



- C. Habitual use of medically important antibiotics for disease prevention is a probable indication of an underlying herd-specific and/or management issue and is not permitted except in the following narrowly defined situations: 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 and when effective multiple treatment options exist, McDonald's encourages adoption of a tiered approach to antibiotic selection— least important to human medicine being the first choice, with HPCIAs reserved for last resort.
- D. Critically Important antibiotics for human medicine are not permitted for the control within a group or treatment of a group for a clinically diagnosed infectious disease identified within a population of food-producing animals in McDonald's supply chain. Allowances can be made for the immediate treatment of animals exhibiting clinical signs when a qualified veterinarian determines that the critically important antimicrobial is the best or only treatment option available to prevent suffering and/or death. Routine surveillance based on culture and sensitivity testing should be conducted when using medically important antibiotics. In some clinical scenarios involving highly infectious organisms or highly transmissible conditions, one case may be more likely to lead to another; therefore, careful analysis of the situation and treatment outcomes should inform decisions on future treatments. Where 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 preventive strategies that will reduce the need for future treatments.
 - Macrolide antibiotics are considered HPCIAs for human medicine by the WHO and will be subject to the use restrictions outlined in this Policy. With evidence continuing to emerge specific to Macrolide antibiotics, this Policy follows the WHO classification. Therefore, the use of Macrolide antibiotics may be permitted based upon the advice of a qualified veterinarian and informed by susceptibility testing if no other drug is available to treat infected animals.
- 2. Medically important antibiotics <u>not currently approved for food animal production</u> are not allowed in McDonald's supply chain. Active pharmaceutical ingredients (API's) with no established or defined safety withdrawal time or efficacy requirements are not permitted.
- 3. 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.
- 4. When deemed necessary, antibiotic use must follow guidance provided by the attending qualified veterinarian with a valid VCPR and their veterinarian-developed herd health plan. When used, antibiotics must be administered in accordance with national/local regulation and requirements, and veterinary direction for dose, duration, route of administration, frequency, withholding period, and withdrawal times.

Additionally, Ionophores such as Lasalocid and Monensin are categorized by the WOAH 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 responsible use of lonophores and Coccidiostats is permissible, subject to applicable laws and regulations.

PROGRESS AND PLANNED ACTIONS

Establishment of Market-Specific Responsible-Use Targets

- Working with suppliers and producers, we conducted global pilot tests to collect market-specific
 data on antibiotic use at commercial feedlots, small farm operations, and dairies. The pilots
 focused on Australia, Brazil, Canada, France, Germany, Ireland, New Zealand, Poland, the U.K.,
 and the U.S. markets, which represented our top 10 beef sourcing markets and accounted for
 over 80% of our global beef supply chain as of the end of 2021.
- Collaboration with industry leaders, academics, suppliers, veterinarians, and other subject
 matter experts, in combination with data received from our pilot tests, have informed
 establishment of market-specific responsible-use targets for medically important antibiotics
 (defined by the WHO) in our beef supply chain.
- Due to vast differences between and within in-scope markets, including in cattle production systems, local conditions, disease pressures, and management, comparison of use data at the farm-level is discouraged and, accordingly, variation in use is expected. Therefore, these targets remain market-specific, not producer-specific, and data associated with the latter will not be used as part of a responsible-use comparative analysis.
- This Policy focuses on responsible-use for in-scope markets across our global beef supply chain. This Policy also recognizes the shared responsibility for development and implementation of proactive strategies that prevent disease and, in combination with responsible use, reduce the need to treat with medically important antibiotics as defined by the WHO, aligned with the One Health approach and the 3 R's (Reduce, Refine and Replace).
- We recognize antibiotic availability and selection may contribute to appreciable differences
 observed in total use under identical treatment plans. We have and will continue to utilize
 knowledge gained to make appropriate and important adjustments to this Policy and/or
 responsible use targets over time.
- McDonald's will continue to support timely scientific research across the supply chain on the responsible use of antibiotics in food producing animals

Table 1. McDonald's Market-Specific Target/Guidance for Responsible Use of Antibiotics: Beef^A

Market and Sector	Total Use of Medically Important Antibiotics ^B
Australia, Brazil, Canada, U.S., New Zealand: Dairy	<50 mg/kg
Australia, Brazil, Canada, U.S., New Zealand: Beef	<35 mg/kg
France, Germany, Ireland, Poland, U.K. Dairy ^C	<21.5 mg/PCU total



France, Germany, Ireland, Poland, U.K. Beef^C

<10 mg/PCU total

Data Tracking and Measurement

Partnership and collaboration are critical to helping drive positive outcomes. McDonald's and our suppliers will engage all in-scope beef supply chains and industries to share expectations for a tiered, responsible-use approach to antibiotic use and adherence to criteria contained within this Policy. We will partner in the collection of antibiotic use data associated with beef and dairy industries across all inscope markets. Gaining access to increasing quantities of antibiotic use data will help understand pointin and over-time use within our in-scope markets. We intend to leverage independent third party/parties to facilitate data aggregation. Our goal is to help drive positive behavioral change and transparency. We plan to share an update on this journey by year-end 2023.

3R's - A Commitment to Refine, Reduce, and Replace

The 3 R's is a suggested framework for shaping the responsible use of antimicrobial stewardship in veterinary medicine and agriculture. This framework promotes practical and evidence-based solutions to refine, reduce, and 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 through a Veterinary Client Patient Relationship (VCPR), to promote antimicrobial stewardship amongst producers and compliance with veterinary prescriptions, to ensure the correct medication, route of administration, duration, frequency, withdrawal period and means of waste disposal are all observed in the administration of treatments to animals
 - Antibiotic use compliance per valid herd health management systems that are third-party audited
 - o First considering those antibiotics of least importance to human medicine

Ascope is the last farm, feed yard, or ranch prior to slaughter. For dairy cows, scope is the 365 days prior to slaughter. The overall reduction of medically important antibiotics² associated with responsible use should not negatively impact use rates of HPCIAs,² the latter of which should be considered treatment of last resort.

^BAs defined by the WHO and measured in mg of active ingredient/kg of live weight slaughtered. Antibiotic availability and selection may contribute to appreciable differences observed in total use under identical treatment plans.

^cPreviously established threshold by Responsible Use of Medicines in Agriculture (RUMA)/ European Medicines Agency (EMA). Target for 'beef' adopted by European Roundtable for Beef Sustainability in 2017.



- Identifying appropriate benchmarking measures that include use, antibiotic concentration and the inclusion of additional key variables based on cattle assessment and antibiotic resistance
- The use of diagnostic testing where appropriate, to ensure the most appropriate, effective treatment is selected for the case
- 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
- **Reduce** means reducing the annual usage of antibiotics in animal agriculture, while preserving animal health and welfare. The 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
 - Formalizing and adopting biosecurity measures, designed to prevent the introduction, spread of disease(s), and improve animal health overall
- **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:
 - Replacing the use of HPCIAs with more sustainable alternatives, or with antibiotics of lower importance to human medicine where appropriate, as per the tiered approach previously described
 - 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 to support improved health outcomes
 - Direct fed microbials
 - Vaccination programs
 - Immunomodulators
 - Dietary best practices (i.e., increased roughage intake)

Definitions

The following definitions are included for the purpose of establishing a mutual understanding of terms used in this Policy:

• Case definition: A case definition is used to standardize cases of interest within and between disease outbreaks. Case definitions should include criteria like the animal description, farm location, and clinical signs and onset of disease.



- 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 veterinarian or trained personnel under the guidance of a valid Veterinary, Client,
 Patient Relationship (VCPR).
- Clinical signs: Denoting the symptoms, change in behavior in an animal during a disease.
- **Disease Control/Metaphylaxis:** Administration of an antimicrobial to a group of animals containing sick and healthy individuals (presumed to be infected) to minimize or resolve clinical signs and to prevent further spread of the disease. When used for disease control/metaphylaxis, medically important antimicrobials should only be used based on epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.⁵
- Disease Prevention/Prophylactic Use: Administration of an antimicrobial to an individual or group
 of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is
 likely to occur if not administered.⁵
- **Disease Treatment/Therapeutic Use:** Administration of an antimicrobial to an individual or group of animals showing clinical signs of infectious disease.⁵
- **Growth Promotion:** Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained.³
- Habitual Use: Repeated preventive use that is not based upon health history and diagnostic tests
 ordered by a licensed veterinarian having a Veterinary Client Patient Relationship (VCPR) to the
 herd.
- Qualified veterinarian: A veterinarian in good standing that is practicing under a valid Veterinary Patient Client Relationship (VCPR).
- 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 veterinary emergency coverage, and continuing care and treatment.
 - The veterinarian provides oversight of treatment, compliance, and outcome.
 - Animal health records are maintained.

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⁵ https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B61-2005%252FCXC 061e.pdf