Certified Responsible Antibiotic Use Standard (CRAU): Beef

Antibiotics with analogues in human medicine are not allowed for:

» Disease prevention;

» Growth promotion;

» Feed efficiency; or

» Weight gain.

Antibiotics with analogues in human medicine can only be used therapeutically to:

» Treat disease in cattle diagnosed with bacterial disease; and

» Control disease in cattle exposed to infectious bacteria.

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ANTIBIOTIC RESISTANCE ACTION CENTER

CRAU is managed by the Antibiotic Resistance Action Center at the Milken Institute School of Public Health at the George Washington University

ANTIBIOTIC RESISTANCE ACTION CENTER
CRAU
CERTIFIED RESPONSIBLE ANTIBIOTIC USE
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Veterinary prescribed antibiotics only to treat illness

Background & Purpose

In working to improve husbandry and optimize animal health, the beef industry can reduce the need for antibiotics, while improving antibiotic stewardship and helping to preserve the future efficacy of life-saving medicines. The attached Certified Responsible Antibiotic Use Standard for beef production provides a clear, actionable definition for responsible antibiotic use and stewardship for producers who choose to reduce antimicrobial use, improve their management practices and provide more accountability to their buyers and the public.

We urge the beef industry and its customers to incorporate this Standard into production and purchasing decisions. We encourage producers to enter the CRAU Beef program as early as feasible, and to continually improve their antibiotic reduction strategies to move from CRAU Bronze to Silver and ultimately to Gold level practices.

The original CRAU beef standard was developed by Natural Resources Defense Council (NRDC) in 2018 and entrusted to ARAC to manage in 2019. In 2023 ARAC updated, clarified and strengthened the standard.

Certified Responsible Antibiotic Use Standard For Beef Production

Overview

Increasingly scientists, medical associations, public interest organizations, business leaders and consumers are calling for livestock and poultry production that relies on responsible antimicrobial use practices. In conformance with the clear and auditable practices encompassed by this standard, beef producers can improve animal husbandry and optimize cattle health while reducing the need for antimicrobials and minimizing the potential for antimicrobial resistance. This will help to ensure that existing antimicrobials remain effective longer for treating sick humans and animals.

Scope

Under this standard, a beef producer certifies the production of cattle at one of three levels, in conformance with all provisions set forth below (summarized in Table 1).

Certified Responsible Antibiotic Use Standard For Beef Production

Definition of Terms:

Antimicrobials refer to agents used against microbial infections. This document uses antibacterial interchangeably with antimicrobial, unless otherwise noted. This standard specifically does not address antifungals, antiparasitic drugs, or metals.

Medically important antimicrobials means any antimicrobial drug composed wholly or partly of any drug or derivative of a drug from a class listed as "Important", "Highly Important" or "Critically Important" by the World Health Organization (WHO) in the most recent version of its Critically Important Antimicrobials for Human Medicine publication (summarized in Tables 2 and 3).[1]

Non-medically important antimicrobials are those antimicrobials added to animal feed that do not belong to drug classes also used in human medicine, including ionophores or coccidiostats, as well as metals added to animal feeds such as copper and zinc.

Based on language adopted in May 2018 by the World Organization for Animal Health (WOAH, formerly OIE)[2], the CRAU Beef Standard defines the following terms:

Disease prevention means antimicrobial use in an individual or group of animals in the absence of clinical infectious disease. This Standard prohibits the use of medically important antimicrobials for disease prevention.

Disease control (also called metaphylaxis) means antimicrobial use in a group of animals containing both sick and healthy animals, to reduce or resolve the clinical signs of infection and to prevent further spread of the disease. Under this standard, disease control is not to be considered a form of disease prevention.

Disease treatment means antimicrobial use in an individual or group of animals showing documented, clinical signs of an infectious disease. Once infection resolves, application of the antimicrobial ceases.

Bronze Level

1. Level of production.
   a. Bronze Level requirements apply to the last 180 days of life of any cattle produced in the facility or facilities being certified under the Standard. Cattle may spend the entire 180 days on a feedlot; if cattle under the Standard have spent any portion of those 180 days at another facility, prior to entering the feedlot, then written records must be available to auditors as well as on-site verification confirming conformance with the Standard's requirements at all facilities.
   b. All cattle falling under Bronze Level requirements must be kept segregated and readily identifiable for the purpose of animal management and veterinary oversight.

2. Veterinary oversight. All antimicrobial use is directed by a licensed veterinarian in the context of a valid veterinarian-client-patient relationship (VCPR), as defined in federal code.[3]
   a. Applicants shall develop an antimicrobial stewardship plan with their veterinarian(s) that includes production practices to reduce, and where possible eliminate, the need for antimicrobials. Examples include (but are not limited to) a focus on healthy breeding stock; sourcing of healthy animals; vaccination; use of non-antimicrobial feed agents such as prebiotics, probiotics or other approved alternatives to antimicrobials; reductions in animal density; reduced stress; improved cattle mixing or transportation practices; improved hygiene and biosecurity; improved feed nutrition; and close observation for early signs of disease.
   b. When used, antimicrobials shall be administered to as few cattle as possible, and only for as long as necessary (e.g. shortest duration as approved by FDA).
   c. Medically important antimicrobials may not be administered to more than 33% of cattle in all facilities enrolled by the applicant under this Standard. All cattle slaughtered within the relevant audit time frame (6 months for Bronze level, 12 months for Silver and Gold levels) shall count towards the total number of cattle in the calculation.

3. Permitted uses of medically important antimicrobials. Medically important antimicrobials may be used only when administered:
   a. Under a veterinary prescription or veterinary feed directive, and when the antimicrobial in question is *both* FDA-approved for use in the U.S. as well as approved for use by the equivalent agency in the country where the certified facility is in operation.
   b. To individual cattle that develop an infection related to a specific surgery or medical procedure, e.g. castration, dehorning, caesarian section.
   c. For disease treatment and disease control, as previously defined, with the following limitations:
      i. Antimicrobials classified by the WHO as Critically Important in Human Medicine (Table 3) shall only be used for disease treatment or disease control when the most recent culture and sensitivity results for the bacterium known to have caused the disease indicate that the antimicrobial in question is the only option.

Bronze Level cont.

4. Prohibited drug use.
   a. Medically important antimicrobials are not permitted for growth promotion, feed efficiency, weight gain, disease prevention, reduction in incidence of liver abscesses, or any other repeated or regular pattern of use.
   b. WHO Classified Highest-Priority Critically Important Antimicrobials, or HPCIAs, are not permitted for disease control use.
   c. Administration of any antimicrobial prohibited by FDA for use in cattle is disallowed.

5. Record-keeping. In seeking initial recognition under the Standard, an applicant must submit the following:
   a. An antimicrobial stewardship plan and other documentation demonstrating that the applicant is currently in conformance with the Standard for each facility where cattle to be sold under the Standard are being raised;
   b. Cattle nearing the end of their last 180 days prior to slaughter at the time of initial audit would be eligible for CRAU program approval if proper documentation and records of conformance are available for the preceding 4 months;
   c. For subsequent semi-annual or annual audits, documentation of practices and conditions over the previous 12 months must be maintained to demonstrate conformance over the entire period. At a minimum, such documentation is to be updated each quarter (three-month interval), and shall include:
      i. The total number of cattle produced in the facility for each year, broken down by # of slaughtered steers/bullocks/bulls; # of slaughtered heifers and cows; and # of slaughtered calves/young cattle;
      ii. The number, age and type of cattle arriving at the facility;
      iii. The number, age and type of cattle having left the facility, due to death or other reason, prior to slaughter;
      iv. Documentation of veterinary approval for each medically important antimicrobial administered, as well as its intent or purpose;
      v. Age and number of cattle to which this medically important antimicrobial was administered (i.e., receiving this antimicrobial at least once);
      vi. Name, dose and concentration of each medically important antimicrobial administered;
      vii. Average dose per animal per day and number of days of use for each medically important antimicrobial administered;
      viii. Written treatment protocols describing use of non antimicrobial measures; and
      ix. Documentation of diagnosis and susceptibility testing for treatment of conditions requiring antimicrobials.

Silver Level

For recognition at the Silver Level, all Bronze Level criteria must continue to be met. In addition, over the previous 12 months, medically important antimicrobials may not have been administered to more than one in every 4 cattle (25%) in all facilities enrolled by the applicant under this Standard. All cattle that have spent any time in the facilities covered under the Standard shall count towards the total number of cattle in the calculation.

A facility previously certified at Silver Level where a subsequent audit finds that greater than 25% of cattle have been administered at least one medically important antimicrobial over the previous year will be placed on probation. If the 25% threshold has not been met by the next annual audit, the facility will lose its Silver Level certification.

Gold Level

For recognition at the Gold Level, all Bronze Level criteria must continue to be met.
In addition, over the previous 12 months medically important antimicrobials of any class may not have been administered to more than 5% of cattle from all facilities enrolled by the applicant under this Standard. Any cattle that have spent any time in the facilities covered under the standard shall count towards the total number of cattle in the calculation.

A facility previously certified at Gold Level where a subsequent annual audit finds that greater than 5% of cattle have been administered any medically important antimicrobial over the previous year will be placed on probation. If the 5% threshold has not been met by the next annual audit, the facility will lose its Gold Level certification.

Assurance Of Conformance

CRAU requires USDA as the third-party certifier [i.e. USDA Process Verified Program (PVP) or Quality System Assessment Program (QSA)] to audit the producer/complex* to ensure conformance with the above restrictions and requirements and to submit audit reports to ARAC.
Auditors are:

- Independent;
- Allowed access to records documenting conformance with the Standard;
- Expected to comply with biosecurity procedures at applicant's facilities;
- Permitted to conduct spot checks of the premises and contents, including any testing deemed appropriate;
- Expected to conduct on-site audits of production facilities no less than once every 6 to 12 months depending on the nature of the audit (QSA or PVP respectively).

*The relevant processes/facilities subject to audit include feed mills or feed sources, feedlots or pasture, backgrounders, and slaughter/processing/packaging sites. The audit must document systems for proper identification and segregation of CRAU product from live production through live delivery, slaughter, further processing, packaging, and shipping.

Raising Animals Under Different Production Systems

Certified and non-certified facilities must be physically separated. Cattle and products may not be commingled between them.

TABLE 1: Responsible Antimicrobial Use Standard – Summary

	Bronze Level	Silver Level	Gold Level
1. Level of production	Last 180 days of life prior to slaughter.	Initial audit covers the last 180 days of life prior to slaughter. All subsequent audits cover the last 12 months of life prior to slaughter.	Last 12 months of life.
2. Antimicrobial administration is under veterinary supervision.	Yes, must include an antimicrobial stewardship plan (ASP); antimicrobials may not be used if a viable non-antimicrobial alternative exists. ≤ 33% of cattle have received medically important antimicrobials for any purpose.	Same as Bronze Level. But ≤ 25% of cattle have received medically important antimicrobials for any purpose.	Same as Bronze Level. But ≤ 5% of cattle have received medically important antimicrobials for any purpose.
3. Limited allowed uses of medically important antibiotics:	All require a veterinary prescription, or a veterinary feed directive (VFD).		
a. For disease treatment, and disease control:	With certain specified limitations on the use of Critically Important Antimicrobials, and Highest Priority Critically Important Antimicrobials (see text).		
b. For certain other limited, exceptional (non-routine) purposes:	Permitted when determined by the veterinarian to be necessary in the case of individual cattle that develop an infection related to a specific surgical or medical procedure, e.g. castration, dehorning, caesarian section.		
4. Disallowed uses of medically important antibiotics:	Medically important antibiotics are not permitted for disease prevention, growth promotion, feed efficiency or weight gain.		
5. Record-keeping	Records kept for all antimicrobials used, and total cattle produced under the standard. Total cattle shall be delineated by # of slaughtered steers/bullocks/bulls; # of slaughtered heifers and cows; and # of slaughtered calves/young cattle. Records must be maintained and updated no less than quarterly.		
6. USDA third party verification (PVP or QSA)	Required.		

TABLE 2: Approved Medically Important[a] Antibiotics for U.S. Cattle Use, and by Delivery Route (Last Updated, 2017)

	Class	Antibiotic	Feed	Water	Injection	Intra mammary	Topical	Other
MEDICALLY IMPORTANT								
	Aminoglycosides	Dihydrostreptomycin			X	X		
		Gentamicin					X	
		Neomycin	X	X			X	X
		Spectinomycin			X			X
	Amphenicols	Florfenicol			X			
	Cephalosporins	Ceftiofur				X		
	Fluoroquinolones	Danofloxacin			X			
		Enrofloxacin			X			
	Lincosamides	Pirlimycin				X		
	Macrolides	Gamithromycin			X			
		Tildipirosin			X			
		Tilmicosin	X		X			
		Tulathromycin			X			
		Tylosin	X					
	Penicillins	Amoxicillin			X			X
		Ampicillin			X			X
		Cloxacillin				X		
		Penicillin			X	X		
	Polymyxins	Polymyxin					X	
	Polypeptides	Bacitracin [b]	X					
	Streptogramins	Virginiamycin	X					
	Sulfonamides (Sulfas)	Sulfadimethoxine		X	X			X
		Sulfamethazine	X	X	X			X
	Tetracyclines	Chlortetracycline	X	X				X
		Oxytetracycline	X	X	X		X	X
		Tetracycline		X			X	X
NON-MEDICALLY IMPORTANT								
	Aminocoumarins	Novobiocin				X		
	Ionophores	Laidlomycin	X					
		Lasalocid	X					
		Monensin	X					

[a] This table is based on medical importance as determined by the World Health Organization, Critically Important Antimicrobials in Human Medicine: Ranking of Medically Important Antimicrobials for Risk Management of Antimicrobial Resistance Due to Non-human Use, 6th ed., 2019. https://www.who.int/publications/i/item/9789241515528 (accessed October 31, 2022).

[b] While the WHO list is updated frequently, the FDA operates according to a list of medically important drugs last updated in 2003, and which does not consider polypeptides like bacitracin to be important to human medicine.

TABLE 3: Critically Important Antimicrobials (*Designated as "Highest Priority Critically Important Antimicrobials")

- Aminoglycosides
- Ansamycins
- Carbapenems and other penems
- Cephalosporins (3rd, 4th , 5th generation)*
- Glycopeptides*
- Glycylcyclines
- Lipopeptides
- Macrolides and Ketolides*
- Monobactams
- Oxazolidinones
- Penicillins (antipseudomonal, aminopenicillins, andaminopenicillin with beta lactamase inhibitors)
- Polymyxins*
- Quinolones and Fluoroquinolones*
- Drugs used solely to treat tuberculosis or other mycobacterial diseases

Source: World Health Organization, Critically Important Antimicrobials in Human Medicine: Ranking of Medically Important Antimicrobials for Risk Management of Antimicrobial Resistance Due to Non human Use, 6th ed., 2019. https://www.who.int/publications/i/item/9789241515528 (accessed October 31, 2022).

References

[1] World Health Organization, Critically Important Antimicrobials in Human Medicine: Ranking of Medically Important Antimicrobials for Risk Management of Antimicrobial Resistance Due to Non-human Use, 6th ed., 2019. https://www.who.int/publications/i/item/9789241515528 (Accessed October 31, 2022).
[2] World Organization for Animal Health (WOAH, formerly OIE). Press Release: Three new steps in the fight against antimicrobial resistance. https://www.woah.org/en/oie-general-session-three-new-steps-in-the-fight-against-antimicrobial-resistance/ (Accessed October 31, 2022).
[3] Medically important antimicrobials administered under a VFD are only lawful if issued in the context of a valid VCPR. See http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm. A valid VCPR is defined in federal code, at CFR 21, Subpart A,§530.3(i).