Certified Responsible Antibiotic Use Standard (CRAU): Pork

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 hogs diagnosed with bacterial disease; and

» Control disease in hogs exposed to infectious bacteria.

Milken Institute School of Public Health
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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 pork industry can reduce the need for antibiotics, improving antibiotic stewardship and helping to preserve the future efficacy of life-saving medicines. The attached Certified Responsible Antibiotic Use (CRAU) Standard for pork 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 pork industry and its customers to incorporate this Standard into production and purchasing decisions. We encourage producers to enter the CRAU Pork 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 Pork 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 Pork 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, pork producers can improve animal husbandry and optimize hog 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 producer certifies the production of hogs for pork at one of three levels, in conformance with all provisions set forth below (summarized in Table 1). These provisions apply to all phases of hog production, including breeding, farrowing, weaning and grower-finishing operations.

Certified Responsible Antibiotic Use Standard For Pork 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 Table 2).[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 Pork 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. 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; vaccination; later weaning; use of non-antimicrobial feed agents such as prebiotics, probiotics or other approved alternatives to antimicrobials; reductions in animal density; reduced stress; improved hygiene and strict biosecurity; improved feed nutrition; and close monitoring for disease exposure.
   b. When used, antimicrobials shall be administered to the fewest hogs as possible, at a scale no greater than the barn/house/pen level, and only for as long as necessary (i.e. shortest duration as approved by FDA).
2. 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 hogs that develop an infection related to a specific surgery or medical procedure.
   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 2) shall only be used for disease treatment or control when a specific diagnosis has been confirmed via culture or equivalent means; and
      ii. The most recent susceptibility testing of that bacterium indicates resistance to other antimicrobials approved for the disease; and, further
      iii. Medically important antimicrobials may not be administered to more than 33% of hogs in all facilities enrolled by the applicant under this Standard. All hogs that have spent any time in the facilities covered under the Standard shall count towards the total number of hogs in the calculation.
3. Prohibited drug use:
   a. Medically important antimicrobials are not permitted for growth promotion, weight gain, feed efficiency, disease prevention, or any repeated or regular pattern of use in the absence of confirmed disease.
   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 hogs is disallowed.

Bronze Level cont.

4. Record-keeping. In seeking initial recognition under the Standard, an applicant must submit an antimicrobial stewardship plan and other documentation demonstrating that the applicant is currently in conformance with the Standard for each facility or barn where hogs to be sold under the Standard are being raised. 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:
   a. Documentation of veterinary approval for all medically important antimicrobials administered, as well as their intent or purpose;
   b. Name, dose and concentration of each medically important antimicrobial administered;
   c. Average dose per animal per day and number of days of use for each medically important antimicrobial administered (including amount added to feed or water);
   d. Category of hog receiving the medically important antimicrobial (sows, weaners, finishers, etc.);
   e. Total number of hogs raised in this facility over the previous 12 months, (or other audit period if different than 12 months), as well as the number of hogs to which this medically important antimicrobial was administered (i.e., receiving this antimicrobial at least once).

Silver Level

For recognition at the Silver Level, all criteria at the Bronze Level 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 four hogs (25%) across all of the facilities where hogs under this Standard are being raised. All hogs that have spent any time in the facilities covered under the Standard shall count towards the total number of hogs in the calculation.

A facility previously certified at Silver Level where a subsequent annual audit finds that greater than 25% of hogs 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 criteria at the Bronze Level must continue to be met. In addition, over the previous 12 months medically important antimicrobials may not have been administered to more than 5% of hogs across all of the facilities where hogs under this Standard are being raised. All hogs that have spent any time in the facilities covered under the Standard shall count towards the total number of hogs in the calculation.

A facility previously certified at Gold Level where a subsequent annual audit finds that greater than 5% of hogs 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.

Full Lifecycle Certification

Pork producers seeking certification under this Standard must ensure that antimicrobials administered to hogs from facilities certified under this Standard conform to all aspects of the Standard, throughout the hogs' entire lifecycle. A party selling pork products from animals that were raised fully or in part by others is responsible for obtaining a signed affidavit from the previous producer(s) confirming conformance with this Standard, in addition to copies of the records required above documenting conformance as well as allowing on-site verification by auditors if requested.

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

The applicant may elect to certify hogs from some or all of their facilities or barns. However, certified and non-certified facilities or barns must be separated physically and hogs may not be commingled between them.

TABLE 1: Responsible Antimicrobial Use Standard – Summary

	Bronze Level	Silver Level	Gold Level
1. Antimicrobial administration is under veterinary supervision.	Yes. Veterinary supervision must include an antimicrobial stewardship plan (ASP), under which antimicrobials may not be used if a viable non-antimicrobial alternative exists.	Same as Bronze Level, but ≤ 25% of hogs have received medically important antimicrobials, for any purpose.	Same as Bronze Level, but ≤ 5% of hogs have received medically important antimicrobials for any purpose.
2. Limited allowed uses of medically important antibiotics:	All require a veterinary prescription, or a veterinary feed directive (VFD).[a]		
a. For disease treatment	Yes, but additional restrictions are placed on use of fluoroquinolones, 3rd generation cephalosporins, and macrolides.		
b. For certain other limited, exceptional (non-routine) purposes:	Permitted: 1. When determined by the veterinarian to be necessary in the case of an individual hog that develops an infection related to a specific surgical or medical procedure. 2. For disease control of documented infection.		
3. Disallowed uses of medically important antibiotics:	Medically important antibiotics are not permitted for disease prevention, growth promotion, feed efficiency or weight gain.		
4. Record-keeping	Maintained and updated no less than quarterly.		
5. USDA third party verification (PVP or QSA)	Required.		

TABLE 2: Medically Important Antimicrobials Currently Listed by the WHO

Critically Important Antimicrobials

(*Designated as "Highest Priority Critically Important Antimicrobials)

- Aminoglycosides
- Ansamycins
- Carbapenems and other penems
- Cephalosporins (3rd, 4th, 5th gen)*
- 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

Highly Important Antimicrobials

- Amphenicols
- Cephalosporins (1st, 2nd generation) and cephamycins
- Lincosamides
- Penicillins (Amidinopenicillins, antistaphylococcal, narrow spectrum)
- Pseudomonic acids
- Riminofenazines
- Steroid antibacterials
- Streptogramins
- Sulfonamides, dihydrofolate reductase inhibitors and combinations
- Sulfones

Highly Important Antimicrobials

- Aminocyclitols
- Cyclic polypeptides (Bacitracin)
- Nitrofuran derivatives
- Nitroimidazoles
- Pleuramutilins

Animal-Only Antimicrobials in Pork Production (not listed as medically important)

- Ionophores (Narasin, Salinomycin)
- Orthosomycin (Avilamycin)
- Phosphoglycolipid (Bambermycins)
- Quinoxalines (Carbadox)

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).