



## Certified Responsible Antibiotic Use Standard (CRAU): Pork

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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.

Consistent with our commitment to the protection of public and animal health, we support conformance with the attached Certified Responsible Antibiotic Use standard for pork production.

We urge the pork industry and its customers to incorporate the standard into production and purchasing decisions. We look forward to collaborating with pork producers interested in responsible antibiotic use to finalize implementation details to meet the requirements of this CRAU standard.



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

*The pork standard was developed by the Natural Resources Defense Council.*

***The following additional organizations endorse this Certified Responsible Antibiotic Use standard in CRAU Pork standard:***

***ANTIBIOTIC RESISTANCE ACTION CENTER, AT THE MILKEN INSTITUTE SCHOOL OF PUBLIC HEALTH, THE GEORGE WASHINGTON UNIVERSITY***

***FOOD ANIMAL CONCERNS TRUST***

***FRIENDS OF THE EARTH (US)***

***HEALTHCARE WITHOUT HARM***

***JOHNS HOPKINS CENTER FOR A LIVABLE FUTURE***

***NATURAL RESOURCES DEFENSE COUNCIL***

***U.S. PUBLIC INTEREST RESEARCH GROUP***

# 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 with the use of fewer antimicrobials. In conformance with the clear and auditable practices encompassed by this standard, pork producers can improve animal husbandry and optimize pig health while reducing the need for antimicrobials and minimizing the potential for antimicrobial resistance. This will help to ensure that existing antimicrobials remain effective for 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 (and summarized in Table 1). These provisions apply to all phases of swine production, including breeding, farrowing, weaning and grower-finishing operations.

## DEFINITION OF TERMS:

**Antimicrobials** refer to agents used against microbial infections, and include antibacterials, antifungals, and antiparasitic drugs and metals. This document uses antibiotic interchangeably with antimicrobial, unless otherwise noted.

**Medically important antimicrobial** 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).<sup>1</sup>

**Non-medically important antimicrobials** are drugs commonly added to animal feed, including ionophores or coccidiostats, as well as metals such as copper and zinc.

Based on language adopted in May 2018 by the World Organization for Animal Health (OIE)<sup>2</sup>, the standard defines the following terms:

**Disease prevention** means antimicrobial use in an individual or group of animals in the absence of clinical infectious disease in any individual or group of animals.

**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.

### ENTRY 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.<sup>3</sup>
  - a. Producers shall develop a stewardship plan with their veterinarian(s) that includes production practices to reduce, and where possible eliminate, the need for antimicrobials.<sup>4</sup> Examples include a focus on healthy breeding stock; vaccination; delayed 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 monitoring for disease exposure.
  - b. When used, antimicrobials are to be administered to the fewest pigs as possible, at a scale no greater than the barn/house/pen level, and only for as long as necessary (e.g. shortest duration).<sup>5</sup>
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<sup>6</sup>;
  - b. To individual pigs, in relation to a specific surgery or medical procedure carrying risk of infection.
  - 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) should only be used for disease treatment or control when a specific diagnosis has been confirmed via culture or equivalent means<sup>7</sup>; and
    - ii. The most recent susceptibility testing of that bacterium indicates resistance to other antimicrobials approved for the disease; and, further
    - iii. Use of the Highest-Priority Critically Important Antimicrobials, or HPCIA, more specifically is not permitted.
  - d. Medically important antimicrobials are not permitted for growth promotion, weight gain, feed efficiency, disease prevention, or any other repeated or regular pattern of use.
3. **Record-keeping.** In seeking initial recognition under the standard, a producer must submit a stewardship plan and other documentation demonstrating that the facility is currently in conformance with the standard for each facility or barn where pigs to be sold under the standard are being raised. For subsequent annual audits,

documentation of practices and conditions over the previous 12 months must be maintained that are sufficient to demonstrate conformance over the entire period. At a minimum, such documentation is to be updated each quarter (three-month interval), and should 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. Total weight in kilograms of the medically important antimicrobial administered (including amount added to feed or water);
- d. Category of pig receiving the medically important antimicrobial (sows, weaners, finishers, etc.);
- e. Total number of pigs raised in this facility over the previous 12 months, (or other audit period if different than 12 months), as well as the number of pigs to which this medically important antimicrobial was administered (i.e., receiving this antimicrobial at least once).

## LEVEL TWO

For recognition of this facility at Level Two, all criteria at the Entry Level must be met.

In addition, over the previous 12 months, medically important antimicrobials may not have been administered to more than one in every four pigs (25%) across all of the facilities where pigs under this standard are being raised. All pigs that have spent any time on the facilities covered under the standard shall count towards the total number of pigs in the calculation.

## LEVEL THREE

For recognition at Level Three, all criteria at the Entry Level must be met.

For Level Three, documentation requirements from paragraph 3a-e also apply to animal-only antimicrobials including ionophores, orthosomycins, phosphoglycolipids and quinoxalines.

In addition, over the previous 12 months antimicrobials of *any* class, including animal-only antimicrobials, may not have been administered to more than 5% of pigs across all of the facilities where pigs under this standard are being raised.

All pigs that have spent any time on the facilities covered under the standard shall count towards the total number of pigs in the calculation.

## FULL LIFECYCLE CERTIFICATION

Pork producers seeking certification under this standard must ensure that antimicrobials

administered to pigs from facilities certified under this standard comply with all aspects of the standard, throughout the pigs' 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.

### **ASSURANCE OF CONFORMANCE**

A third-party certifier will verify that the producer is in conformance with the standard. Auditors are:

- allowed access to records documenting conformance with the standard;
- expected to comply with biosecurity procedures at producers' 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 12 months.

### **RAISING ANIMALS UNDER DIFFERENT PRODUCTION SYSTEMS**

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

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**Table 1: Responsible Antimicrobial Use Standard – Summary**

	Entry Level	Level 2	Level 3
1. Antimicrobial administration is under veterinary	Yes, as part of an antimicrobial stewardship plan (ASP)	Same as Entry Level. But ≤ 25% of pigs have received medically important antimicrobials, for any purpose.	Same as Entry Level. But ≤ 5% of pigs have received antimicrobials from any class for any purpose.
2. Limited allowed uses of medically important antimicrobials:	All require a veterinary prescription, or a veterinary feed directive (VFD) <sup>a</sup>		
a. For disease treatment	Yes. But additional restrictions are placed on use of fluoroquinolones, 3rd generation cephalosporins, and macrolides.		
b. For other limited purposes	Permitted: 1. When necessary in relation to surgery or a procedure; 2. For disease control of documented infection.		
c. For growth promotion	Not permitted <sup>b</sup>		
3. Record-keeping	Maintained no less than quarterly		
4. Third party verification	Yes		

<sup>a</sup> As amended and regulated by the Food and Drug Administration. See [www.federalregister.gov/articles/2015/06/03/2015-13393/veterinary-feed-directive#h-14](http://www.federalregister.gov/articles/2015/06/03/2015-13393/veterinary-feed-directive#h-14).

<sup>b</sup> Use of medically important antibiotics in animal feed for the purpose of growth promotion is no longer FDA-approved or legal as of January 2017.

## 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 (3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup> gen)\*
- Glycopeptides\*
- Glycylcyclines
- Lipopeptides
- Macrolides and Ketolides\*
- Monobactams
- Oxazolidinones
- Penicillins (antipseudomonal, aminopenicillins, and aminopenicillin with beta-lactamase inhibitors)
- Polymyxins\*
- Quinolones and Fluoroquinolones\*
- Drugs used solely to treat tuberculosis or other mycobacterial diseases

### HIGHLY IMPORTANT ANTIMICROBIALS

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

### IMPORTANT ANTIMICROBIALS

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

### Animal-Only Antimicrobials in Pork Production (not listed as medically important)<sup>5</sup>

- 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/foodsafety/publications/antimicrobials-sixth/en/> (accessed September 24, 2019).

## REFERENCES

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- <sup>1</sup> 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/foodsafety/publications/antimicrobials-sixth/en/> (accessed September 24, 2019).
- <sup>2</sup> World Organization for Animal Health (OIE). Press Release: Three new steps in the fight against antimicrobial resistance. May 25, 2018. <http://www.oie.int/en/for-the-media/press-releases/detail/article/oie-general-session-three-new-steps-in-the-fight-against-antimicrobial-resistance/> (accessed September 29, 2019).
- <sup>3</sup> A valid VCPR is defined in federal code, at CFR 21, Subpart A, §530.3(i). According to the American Veterinary Medical Association's Principles of Veterinary Medical Ethics, a VCPR is *required* to prescribe medication or otherwise treat an animal.
- <sup>4</sup> Non-antimicrobial approaches for reducing the need for antimicrobials, and the evidence for their effectiveness in doing so, are described comprehensively in the following: EMA and EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety (hereinafter RONAFA Report). [EMA/CVMP/570771/2015]. EFSA Journal 2017;15(1):4666, 245 pp. doi:10.2903/j.efsa.2017.4666; and Health and Food Safety Directorate-General, *Overview Report: Measures to Tackle Antimicrobial Resistance Through the Prudent Use of Antimicrobials in Animals* (hereinafter DG Health and Food Safety, Overview Report). Luxembourg: European Union, 2018. [http://ec.europa.eu/food/audits-analysis/overview\\_reports/act\\_getPDF.cfm?PDF\\_ID=1190](http://ec.europa.eu/food/audits-analysis/overview_reports/act_getPDF.cfm?PDF_ID=1190).
- <sup>5</sup> DG Health and Food Safety, Overview Report, page 3.
- <sup>6</sup> Medically important antimicrobials administered under a VFD are only lawful if issued in the context of a valid VCPR. <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm>.
- <sup>7</sup> Commission Notice, 2015 O.J. C 299/04 [hereinafter Guidelines for Prudent Use of Antimicrobials]. Official Journal of the European Union. [http://ec.europa.eu/health/antimicrobial\\_resistance/docs/2015\\_prudent\\_use\\_guidelines\\_en.pdf](http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf) (accessed September 29, 2019).