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## Certified Responsible Antibiotic Use Standard (CRAU)

No administration of antibiotics pre-hatch.

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 poultry diagnosed with bacterial disease; and
- » Control disease in poultry exposed to infectious bacteria.

Milken Institute School  
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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.*



## Background & Purpose

The CRAU standard is managed by the Antibiotic Resistance Action Center (ARAC) at the Milken Institute School of Public Health at the George Washington University. It was initially developed by School Food Focus in 2014 to minimize the use of antibiotics in poultry production and give schools an option to purchase poultry raised with responsible antibiotic use. Staff from ARAC worked closely with School Food Focus over the years to help develop and ensure the CRAU standard is rooted in the latest scientific developments. In late 2017, School Food Focus formally transferred management of the standard to ARAC.

Poultry producers in conformance with CRAU are prohibited from using antibiotics with analogues in human medicine in any regular pattern of use for any reason, including growth promotion, weight gain, feed efficiency and disease prevention. Use of antibiotics with analogues in human medicine must be rare, well documented with medical justification, and prescribed by a licensed veterinarian. Antibiotics that do not have analogues in human medicine have no further restrictions, as their use at this time is believed to present minimal risk to public health. ARAC will change its CRAU standard if scientific evidence reveals a link.

CRAU builds on the following ‘judicious use’ principles of practice that were developed by FDA in cooperation with the American Veterinary Medical Association:

- » Emphasis on sound preventive programs, including vaccination and testing;
- » Documented need for antibiotics and demonstration that no viable alternative exists;
- » Veterinarians consulted prior to use of antibiotics;
- » Records kept of treatment and outcome;
- » Treatment for grouped animals is done at barn/house level. Animals in adjacent housing should not be treated if not exposed;
- » Environmental contamination is minimized;

- » See “*Judicious Use of Antimicrobials for Poultry Veterinarians*” by Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine.

The CRAU standard improves upon the above ‘judicious use’ principles with amendments to FDA guidelines that explicitly restrict and document antibiotic use from pre-hatch through slaughter:

1. Medically important antibiotics are used only if prescribed by a licensed veterinarian.
2. A written veterinary report to ARAC is required whenever medically important antibiotics are used in more than two consecutive growing cycles (growing cycle encompasses hatchery to slaughter). This report must describe the underlying problem(s) and outline a plan of action to correct it if not already resolved. If the problem is not resolved, the site is no longer CRAU approved and will be removed from the ARAC and USDA official listing of approved programs. Reinstatement procedures are spelled out in the auditor checklist.
3. Growers and/or integrators maintain records of all FDA-defined feed and water additives for each growing cycle for the most current two years.
4. Regular 3<sup>rd</sup> party verification of antibiotic use documentation and on-site practices by the U.S. Department of Agriculture (USDA) is required.
5. No antibiotics allowed pre-hatch.
6. The classes of antibiotics with analogues in human medicine are specifically listed in the CRAU audit guidance documents.
7. ARAC specifically defines its use of the terms “therapeutic” and “non-therapeutic” in the CRAU standard.



## Responsible Antibiotic Use

1. CRAU drug classes restricted to therapeutic use only include:
- » Aminoglycosides (Spectinomycin, Neomycin)
  - » Lincosamides (Lincomycin)
  - » Macrolides (Tylosin, Erythromycin, Tilmicosin, Oleandomycin)
  - » Penicillin (Penicillin G procaine)
  - » Streptogramins (Virginiamycin)
  - » Sulfonamides (Sulfantran, Sulfadimethoxine, Sulfamethazine, Sulfaquinoxaline, Sulfathiazole)
  - » Tetracyclines (Chlortetracycline, Oxytetracycline)

2. In CRAU, “therapeutic use” refers to antibiotics with analogues to human drugs, i.e. veterinary antibiotics that are identical or very closely related to drugs used in human medicine. CRAU defines “therapeutic use” as follows:

- » The use of antibiotics with analogues to human drugs in poultry diagnosed with bacterial disease (treatment); or
- » The use of antibiotics with analogues to human drugs after poultry is exposed to infectious bacteria but before onset of clinical signs (control/metaphylaxis).
- » There must be a valid veterinarian-client-patient relationship (VCPR) as defined in 21 CFR 530.3(i). A valid VCPR is defined as one in which:

**A.** A veterinarian is responsible for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) is responsible for following the instructions of the veterinarian;

**B.** The veterinarian is responsible for having sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

- C.** The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.
- » If antibiotics are used therapeutically as defined above, records of diagnosis, treatment [antibiotic(s) prescribed, dosage, duration, estimated # of animals treated], and outcome must be retained for auditor review.

### Therapeutic vs Non-Therapeutic

These terms are widely used and can have different meanings in different contexts. The U.S. Food and Drug Administration (FDA) describes “therapeutic use” broadly, as the treatment, prevention, and control of disease. CRAU defines both terms more specifically and prohibits prevention uses of medically important antibiotics.

3. If any antibiotics with analogues to human drugs are used for more than two consecutive growing cycles within the same poultry barn/house, a written veterinary statement must be submitted to ARAC stating the underlying problem(s) that required the use of medically important antibiotics and a plan of corrective action to rectify the problem(s). If the underlying problem has been resolved, the veterinary statement may indicate that a successful solution has been found that does not include the use of antibiotics, and that no further plan of action is needed. In all cases, a written veterinary report of antibiotic use, including documentation of treatment and outcomes that includes culture and sensitivity reports, must be retained for audit purposes.



## Responsible Antibiotic Use *cont'd...*

4. Non-therapeutic use of antibiotics with analogues in human medicine is disallowed. CRAU defines “non-therapeutic use” as the administration of medically important antibiotics for growth promotion, feed efficiency, weight gain, and disease prevention.

- » Prevention is the use of antibiotics in the absence of bacterial disease or exposure to disease as documented by a veterinarian through testing or other means that a pathogenic organism is present in the flock or barn.

5. Use of drugs with no analogues in human medicine—aminocoumarins, glycolipids, ionophores, and oligosaccharides—is allowed. These permitted veterinary drugs have no relationship to human drugs and are not used in treating human disease. At this time they are the only drugs with no analogues in human medicine that are approved for use by the FDA and currently used by poultry producers.

6. A feed containing a Veterinary Feed Directive drug (a VFD feed) shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian’s professional practice and within the confines of a valid veterinarian-client-patient relationship.

## Required Management Principles

- » Emphasis on sound preventive programs, including vaccination and serologic monitoring for disease exposure;
- » Treatment for grouped animals is done at barn/house level. Animals in adjacent housing will not be treated if not exposed; and
- » Growers and/or integrators will maintain records of all FDA-defined feed and water additives for each growing cycle for the most current two years for auditor review.

## Assurance of Conformance

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

\* The relevant processes/facilities subject to audit include hatcheries, feed mills, grow out farms/barns, and slaughter/processing/packaging sites. The audit must document systems for proper identification and segregation of CRAU product through live delivery, slaughter, further processing and packaging.