School Food FOCUS-The Pew Charitable Trusts Standard to Minimize the Use of Antibiotics in Poultry 12/5/14

Introduction and Rationale

The School Food FOCUS National Procurement Initiative (NPI) and The Pew Charitable Trusts (Pew) have honed a standard that reflects the concerns of FOCUS school districts about the public health impact of antibiotic overuse in food animal production. This program seeks to minimize antibiotic use to protect these drugs, which are the world's most important, and most vulnerable, tools for combating infectious disease. It also acknowledges the value of some antibiotic applications, in very limited circumstances, for the treatment of certain illnesses in poultry.

The non-medical use of antibiotics to promote growth or to compensate for the effects of overcrowded and unsanitary conditions in livestock production seriously compromises their efficacy in treating human disease. **People who eat meat and poultry and people who do not are equally affected, as drug resistant bacteria can spread beyond animals and animal foods and into produce and the environment.** While any use of antibiotics can potentially contribute to the development of bacterial resistance, the routine use that is common on American farms has clearly hastened the process.¹ Excessive agricultural use has resulted in a perilous situation that, if not soon contained, will profoundly affect the future well being of today's children. The World Health Organization warns of a "return to the pre-antibiotic era"² and recognizes non-therapeutic use on farms as a culprit. Other major health authorities are in strong agreement with this position.³

Overuse of medically important antibiotics occurs not just on poultry farms, but throughout the American livestock industry.⁴ FOCUS has singled out poultry as its starting place because of the exceptionally large amount of chicken that its member districts buy. Chicken is the most popular protein served in schools, offered daily in many cafeterias across the nation. FOCUS districts will buy tens of millions of pounds of chicken during 2015–16 academic year.

As this project moves forward, it is important to note that the poultry currently served in schools is safe and wholesome. The use of antibiotics in raising poultry does not compromise its nutritional value, and properly cooked chicken and turkey do not spread antibiotic-resistant pathogens. This antibiotics program is based on the understanding of the current and longer-term environmental and public health consequences of inappropriate and excessive drug use. FOCUS, composed of the nation's leading institutional purchasers of food for children, is in a unique position to catalyze reform. The goal of the FOCUS – Pew collaboration is an industry-wide cessation of inappropriate antibiotic use in animal production.

(Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals,

http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf).

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¹ Centers for Disease Control and Prevention, "ANTIBIOTIC RESISTANCE THREATS in the United States, 2013." Page 11. September 2013. http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf

² World Health Organization, "WHO's first global report on antibiotic resistance reveals serious, worldwide threat to public health." April 2014.

http://www.who.int/mediacentre/news/releases/2014/amr-report/en/

³ These include the Centers for Disease Control and Prevention, the Food and Drug Administration, the American Medical Association, the American Academy of Pediatrics, the American Public Health Association, the American College of Preventative Medicine, the Union of Concerned Scientists, Consumers Union, the Infectious Diseases Society of America, and the Institute of Medicine.

⁴ The amount of antibiotics sold for U.S. food animal production in 2011 was 29.9 million pounds, the majority of which are medically important. This means the drugs are within antibiotic classes that the World Health Organization has determined are important in treating human illnesses.

Background

The standard that Pew and FOCUS recommend is necessarily technical. The following information will help purchasers understand enough of the details to engage credibly and effectively with poultry producers.

"Therapeutic" vs. "Non-therapeutic" Use

Food-service buyers need to be very clear with producers when they talk about "therapeutic" and "non-therapeutic" applications of antibiotics. These terms are widely used and can mean different things in different contexts. The US Food and Drug Administration (FDA) describes "therapeutic use" broadly, as the treatment, prevention, and control of disease.⁵

The Pew/FOCUS standard defines "therapeutic use" more tightly and more specifically to mean the use of antibiotics with analogues to human drugs *only* under the following circumstances:

a) In poultry with diagnosed bacterial disease; or

b) In healthy poultry only if there is a medical reason, determined and documented by a licensed veterinarian, to believe that the birds are at significant risk for developing a clinical bacterial infection (prophylaxis).

Pew/FOCUS refer to any non-medical use of antibiotics (e.g., for growth promotion or given in the absence of disease) with analogues to human drugs as "non-therapeutic."

General Guidelines and Explicit Restrictions

The Pew/FOCUS standard for antibiotic use in poultry is based 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 blood 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.⁷

Pew/FOCUS have improved on the above 'judicious use' principles as follows:

- a. Medically important antibiotics are used only if prescribed by a licensed veterinarian.
- b. A written veterinary report to FOCUS is required whenever antibiotics are used for prophylaxis for more than two consecutive growing cycles. This report must describe the underlying problem(s) and outline a plan of action to correct it if not already resolved.
- c. Growers will maintain records of all feed and water additives for each growing cycle for the most current two years.

These three amendments to FDA guidelines *explicitly* restrict antibiotic use on the farm. **Producers in compliance** with the Pew/FOCUS standard will not be in a position to use antibiotics with analogues in human medicine routinely or without clear medical justification.

Antibiotics used in animal production that do not have analogues in human medicine have no further restrictions in this standard, as their use at this time is believed to present minimal risk to public health. The text of the standard is clear about which drugs are in this category.⁸

 $^{^5} www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/ JudiciousUseofAntimicrobials/UCM095590.pdf$

⁶ "Antibiotics with analogues to human drugs" refer to veterinary antibiotics that are the same as or very closely related to drugs used in human medicine.

⁷ For instance, antibiotics excreted into manure are not released into the environment until there has been adequate time allowed for them to break down. This can take hours, days, or months, depending on the drug in question.

⁸ The permitted veterinary drugs listed in this standard have no relationship to human drugs and have no use 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.

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The following language can also be incorporated into a school district RFP for poultry purchase.

Use of antibiotics in poultry production, if practiced, must be minimal. Use of drugs with analogues in human medicine must be rare.

Restrictions on antibiotic use:

- 1. No administration of antibiotics pre-hatch.
- 2. Antibiotics with analogues in human medicine can only be used therapeutically. Drug classes that fall in this category include:
 - Aminoglycosides (Spectinomycin, Neomycin)
 - Lincosamides (Lincomycin)
 - Macrolides (Tylosin, Erythromycin, Tilmicosin, Oleandomycin)
 - Penicillin (Penicillin G procaine)

- Streptogramins (Virginiamycin)
- Sulfonamides (Sulfanitran, Sulfadimethoxine, Sulfamethazine, Sulfaquinoxaline, Sulfathiazole)
- Tetracyclines (Chlortetracycline, Oxytetracycline)

"Therapeutic use" is defined as follows:

- The use of antibiotics with analogues to human drugs in poultry diagnosed with bacterial disease; or
- The use of antibiotics with analogues to human drugs in healthy poultry if there is a medical reason, determined and documented by a licensed veterinarian, to believe that the birds are at significantly increased risk for developing a clinical bacterial infection or after an exposure to infectious bacteria but before the onset of clinical signs or laboratory confirmed disease (prophylaxis)
- 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.

- **3.** If antibiotics with analogues to human drugs are used for prophylaxis for more than two consecutive growing cycles, there must be a written veterinary statement indicating the underlying problem(s) and a plan of action to correct 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 prophylactic use of antibiotics, and that no further plan of action is needed. In such cases, a written veterinary report of antibiotic use, including documentation of treatment and outcomes that includes culture and sensitivity reports, must be retained for auditor review.
- 4. Non-therapeutic use of antibiotics with analogues in human medicine is disallowed. "Non therapeutic use" is defined as use in the absence of microbial disease, known (documented) disease exposure, or a medical reason FOCUS Pew AB Standard 12/5/14 3 of 4

to believe there is a significant risk for developing a clinical bacterial infection. Non-therapeutic use includes administration of antibiotics for growth promotion, feed efficiency, weight gain, or in the absence of documented exposure.

- 5. Use of drugs with no analogues in human medicine—aminocoumarins, glycolipids, ionophores, and quinoxalines—is not disallowed.
- 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;
- Growers will maintain records of all feed and water additives for each growing cycle for the most current two year for auditor review; and
- Environmental contamination is minimized.

Assurance of compliance

[FOCUS] requires a third-party certifier [e.g. USDA Process Verified Program (PVP) or Quality System Assessment (QSA)] to audit that the producer/complex* is in compliance with the above restrictions and requirements. Entities that are current on the Official Listing of Approved USDA Process Verified Programs for "No Antibiotics Ever" and audited for compliance with the Pew-FOCUS checklist are considered to meet (and exceed) this standard for antibiotic use.

*The relevant processes/facilities subject to audit include hatcheries, feed mills, grow out farms/barns, and slaughter/processing/packaging sites.