WHITE PAPER

NEW PROGRAM CERTIFIES PRODUCTS AS *RAISED WITHOUT ANTIBIOTICS*

Certification helps consumers identify animal products that do not contribute to the growth of antibiotic-resistant bacteria

Public health agencies around the world agree: The spread of antibiotic-resistant bacteria is a high-priority public health concern. Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections, according to the U.S. Centers for Disease Control and Prevention (CDC). A 2015 report commissioned by the Prime Minister of the United Kingdom found that globally 700,000 people die of antibiotic resistant bacterial infections each year and if the problem remains unchecked, drug-resistant infections will kill more people than cancer by 2050.[1]

In recent years, public health officials in the UK, Europe and North America have also voiced serious concerns about the overuse of antibiotics in agriculture and livestock production. Over half of the antibiotics in the United States are used in livestock production, according to the U.S. Department of Agriculture.[2]

MINIMIZING THE THREAT OF ANTIBIOTIC-RESISTANT BACTERIA

Regulators and public health agencies around the world are calling for action:

- The World Health Organization (WHO)
- United Nations (UN)
- U.S. Centers for Disease Control and Prevention (CDC)
- European Centre for Disease Prevention and Control (ECDC)

1 *Review of Antimicrobial Resistance*, Antimicrobials in agriculture and the environment: reducing unnecessary use and waste. Dec 8 2015.

2 Stacy Sneeringer, James MacDonald, Nigel Key, William McBride, and Ken Mathews. Economics of Antibiotic Use in U.S. Livestock Production, ERR-200, *U.S. Department of Agriculture, Economic Research Service*, November 2015.

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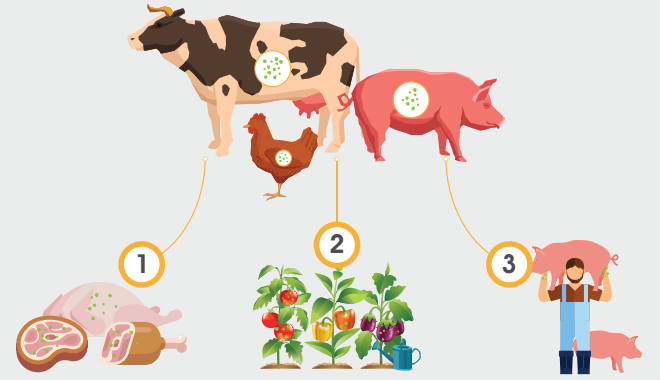
Antibiotics are used to fight off infections and promote growth in livestock. But, according to the CDC and other public health agencies, overuse of antibiotics can cause drug-resistant bacteria to develop in the animal population.

These antibiotic-resistant bacteria can spread to humans in three ways:



Antibiotic resistance rises each time bacteria are exposed to antimicrobials. This resistance opens the door to treatment failure for even the most common pathogens and leads to an increasing number of infections. For example, the CDC recently reported a Nevada woman died in 2016 from a bacterial infection found to be resistant to all antimicrobial drugs available in the United States.[3] It is not known if this infection is in any way linked to antibiotic overuse in livestock. While antibiotics fed to livestock have been linked to human health risks, the extent of these risks is difficult to quantify.

NSF International's mission is to protect and improve human health. This white paper provides an overview of the concern about the widespread development of antibiotic-resistant bacteria and the use of antibiotics in food animal production. It also explains how NSF's new certification protocol—*Raised Without Antibiotics*—will help consumers identify and purchase animal products that have been raised without exposure to antibiotics.

BACTERIA: THE GROWING PROBLEM

Humans developed antimicrobials to destroy disease-causing microorganisms. Many different types of antimicrobials exist—antivirals, antifungals and antiparasitics, for example—but the most commonly known antimicrobials are antibiotics. An antibiotic is a medicine, such as penicillin, that inhibits the growth of or destroys microorganisms. Penicillin, the first commercialized antibiotic, was developed by Alexander Fleming in 1928. It was later called a "miracle drug" because it was used to great effect during World War II to fight surgical and wound infections among Allied Forces.

The hope at the time was a future free of harmful microorganisms. But Fleming understood how bacteria adapted and warned against "thoughtless" application of antibiotic treatments shortly after winning the Nobel Prize in 1945. Penicillin was so effective at fighting bacterial infections it quickly became an over-the-counter drug. Over time, new classes of antibiotics were discovered and subsequently overused in medicine and agriculture.

As Fleming warned, the world's bacteria adapted. Today, more than 2 million illnesses per year in the U.S. are caused by bacterial resistance to antibiotics, according to the CDC. An estimated 23,000 deaths annually in the U.S. can also be attributed to antibiotic-resistant bacteria.

A good example is *Enterobacteriaceae*, one of three bacteria named by the CDC in 2013 as an "urgent" drug-resistant threat. This family of bacteria, which includes *Escherichia coli*, causes bloodstream infections and is on the rise in medical settings. Carbapenem-resistant *Enterobacteriaceae*, or CRE, is of great concern because it is resistant to all or nearly all of the antibiotics available today. Half of hospital patients who acquire CRE die from the infection.[4] Antibiotic-resistance in other common bacteria, such a *Staphylococcus aureus* and *Campylobacter*, is also on the rise.

3 Chen L, Todd R, Kiehlbauch J, Walters M, Kallen A. Notes from the Field: Pan-Resistant New Delhi Metallo-Beta-Lactamase-Producing Klebsiella pneumoniae — Washoe County, Nevada, 2016. Morbidity and Mortality Weekly Report 2017; 66:33.

4 About Antibiotic Resistance, www.cdc.gov. Sept. 8, 2015

Discovery and development of new antibiotics has slowed in recent decades, which underscores the need to protect the viability of existing antibiotics.

GLOBAL PUBLIC HEALTH COMMUNITY RESPONDS

Regulatory and public health agencies around the world have responded to this threat by issuing warnings about the overuse of antibiotics in livestock production and the subsequent risks to human health. These agencies have issued guidance and legislation in an attempt to reduce the usage of antibiotics in livestock production.

> In the European Union (EU), a ban on the use of antibiotics to promote growth and feed efficiency has been in effect since 2006. However, farmers can still use antibiotics for veterinary purposes (to treat sick animals). Voluntary guidelines are in effect to help reduce antibiotic use in livestock, especially antibiotics that are important to human health.

> In the United States, the FDA has issued voluntary guidelines to minimize use of antibiotics to promote growth of livestock and enhance feed efficiency. Effective in 2017, a veterinary prescription is required to treat sick animals.

HOW ANTIBIOTIC RESISTANCE SPREADS

A complex chain of events can cause bacteria to develop resistance to antibiotics. The process starts in the gut, where antibiotics act to kill bacteria causing illness as well as good bacteria protecting the body from infection. The remaining drug-resistant bacteria are now able to grow and take over. Some even pass drug resistance on to formerly harmless bacteria, causing further problems.[5]

Antibiotic-resistant bacteria can be found in raw or undercooked meat.

INCREASING CONSUMER DEMAND

As they look to minimize negative health effects from the foods they eat, a growing number of consumers are demanding transparency in food production methods. Many consumers want more information about how their food is produced, including whether animals were raised in cages, what they were fed and whether they were exposed to hormones, steroids or antibiotics.

The food industry is responding to the growing public health concern with several major restaurant chains making public commitments to remove antibiotics from their menus — significantly impacting their dairy and protein supply chains.

Resistant bacteria can appear in the guts of humans or animals. In humans, drug-resistant bacteria can be spread through interpersonal contact in a community or through patients or care providers in a hospital setting. In livestock, these drug-resistant bacteria can reach us in several ways:

The bacteria can spread to humans through improperly handled or cooked meat products.

Food crops may be exposed to fertilizer or water run-off containing drug-resistant bacteria from animal feces.

Farmers and food processing workers can be exposed to antibiotic-resistant bacteria and subsequently pass them along to other humans.

5 About Antimicrobial Resistance, www.cdc.gov/drugresistance/about.html.

Raised Without Antibiotics

Perhaps the single most important way to slow down the development and spread of antibiotic-resistant bacteria is to change the way antibiotics are used. According to the U.S. CDC, reducing unnecessary antibiotic-use would help minimize the proliferation of drug-resistant bacteria.

Recently, NSF International developed an independent certification—*Raised Without Antibiotics*—to certify animal products that have been produced without exposure to antibiotics. Consumers can be assured that products carrying the certification mark are not contributing to this global public health crisis.

The *Raised Without Antibiotics* certification can be granted to a wide variety of animal products, including meat, poultry, seafood, dairy, eggs, leather and certain supplement ingredients.

The *Raised Without Antibiotics* protocol was developed in partnership with the food animal industry and veterinary stakeholders. Under the program, animals cannot receive antibiotics at any time. This third-party verification will enable consumers to identify and choose products with confidence.

THE PROTOCOL

The protocol provides for the independent review of farm practices and health management procedures, inspection and sampling on the farm to verify compliance and detect violations, and supply chain traceability to ensure accurate representation of packaged goods certified as *Raised Without Antibiotics*. The supply chain systems review includes:

> Documentation and record-keeping

> Product integrity and traceability

> Storage/transport/packaging

> Internal quality control and compliance

> Unscheduled sampling and testing

> Training

> Supplier approval and monitoring

The Raised Without Antibiotics certification can be granted to a wide variety of animal products, including meat, poultry, seafood, dairy, eggs, leather and certain supplement ingredients.

If a producer becomes certified, an annual review is conducted. Unscheduled audits and sample collections are conducted, verifying that the producer continues to meet the requirements of the *Raised Without Antibiotics* program.

CERTIFICATION PROCESS

The certification process begins with the producer filing an application to be considered for the *Raised Without Antibiotics* program. NSF International conducts a pre-inspection review, followed by on-site inspection and sampling. A post-inspection review allows NSF International to issue a certification decision.

If this inspection reveals non-compliance issues, a resolution process begins to allow the producer to qualify for another post-inspection review. Additional unscheduled audits and sample collections may be made during this process.

If the producer becomes certified, an annual review is conducted. Unscheduled audits and sample collections are still conducted, verifying that the producer continues to meet the requirements of the *Raised Without Antibiotics* program.

To maintain the health and welfare of farm animals, the program encourages preventive measures such as:

> Vaccination

> Alternative treatments

> Litter management techniques

> Appropriate stocking density

If sick animals require antibiotics for treatment, they can receive veterinary care but must be removed from the *Raised Without Antibiotics* program.

The *Raised Without Antibiotics* certification can be granted to a wide variety of animal products, including meat, poultry, seafood, dairy, eggs, leather and certain supplement ingredients. The certification provides independent verification of on-package claims and is the only certification that covers all animal products.

UNDERSTANDING TYPES OF ANTIBIOTICS

Not every antibiotic is the same. Some antibiotics, like vancomycin, are crucial for human health and combating particularly harmful bacteria like *C. difficile*. Others, such as ionophore chemical coccidiostats, are not used in human medicine but can be useful in maintaining the health of livestock.

> **Antibiotics** are medicines (such as penicillin or its derivatives) that inhibit the growth of or destroy microorganisms. As chemical substances produced by various microorganisms and fungi, they have the capacity to inhibit the growth of or to destroy bacteria and other microorganisms.

> **Coccidiostats** are chemical agents added to animal feed (as for poultry) that serve to retard the life cycle or reduce the population of pathogenic coccidia to the point that disease is minimized and the host develops immunity.

> **Ionophores** are any molecule, as of a drug, that increases the permeability of cell membranes to a specific ion.

Ionophore chemical coccidiostats are sometimes used to encourage growth in animals and prevent a variety of ailments that threaten the overall health of flocks and herds. They are not considered useful for therapeutic use in humans and do not contribute to the spread of antibiotic-resistant bacteria.

While antibiotics are not permitted under the *Raised Without Antibiotics* protocol*, ionophore chemical coccidiostats may be permitted to prevent infections, depending on regulations in the region of product sale.

What's permitted under the *Raised Without Antibiotics* protocol?

	For products sold in the United States	For products sold in the UK & Europe
Antibiotics	Not permitted	Not permitted
Ionophores	Not permitted	Permitted
Chemical coccidiostats	Not permitted	Permitted

* If sick animals require antibiotics for treatment, they can receive veterinary care but must be removed from the *Raised Without Antibiotics* program.

Learn more about NSF International's *Raised Without Antibiotics* protocol at **www.nsf.org** or email **consumervalues@nsf.org**.

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