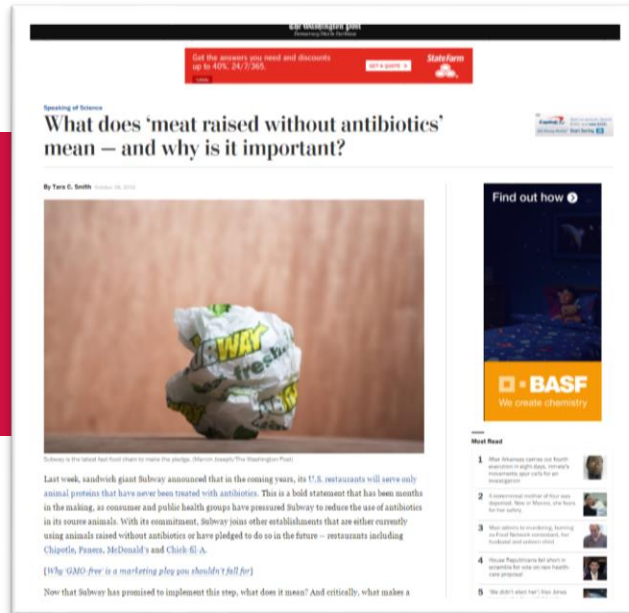


Veterinary Products and Novel Food Label Statements

Jesse J. Sevcik
Elanco Animal Health
jsevcik@elanco.com
May 4, 2017

Antibiotic Statements in Food Labeling

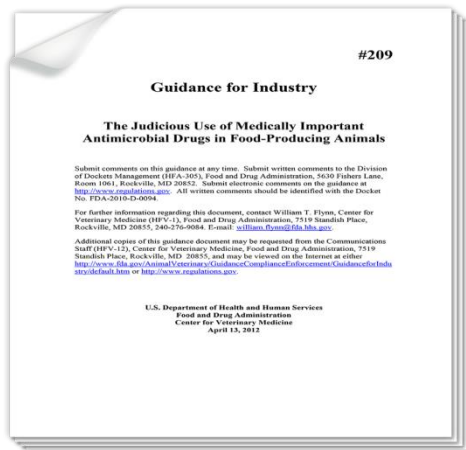


Important to know about antibiotics

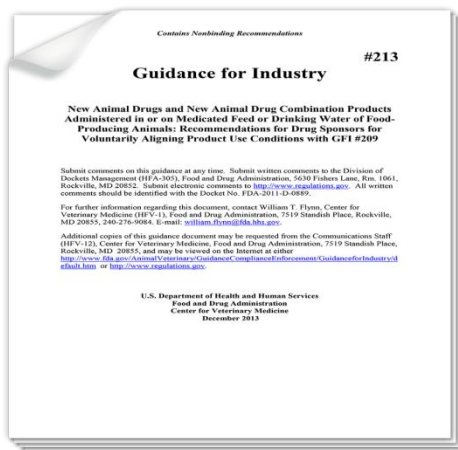
- USDA prohibits illegal residues of antibiotics in food.
- FDA evaluates food safety prior to approval of food animal medicines.
- USDA regulates the meat and poultry labels under the meat acts. Labels must be approved prior to interstate commerce.

Responsible Use of Antibiotics

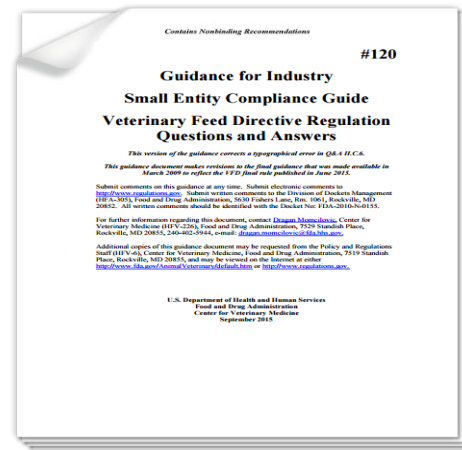
FDA issued guidance(s) to modify the use of medically important antibiotics in food-producing animals



Guidance for Industry (GFI) #209 – The
“What”



Guidance for Industry (GFI) #213 – The
“How”



Guidance for Industry (GFI) #120 – The
“VFD”

The 3-Step Risk Assessment Process

✓ An antibiotic must select for foodborne bacteria that acquire antibiotic-resistance in food animals during treatment

✓ Release

✓ A person must ingest meat from a treated animal that is contaminated with those same antibiotic-resistant foodborne bacteria

✓ Exposure

✓ The person that ingests these bacteria must become sick with a bacterial infection that cannot be appropriately treated with antibiotics as a result of those animal-derived antibiotic-resistant bacteria

✓ Consequence

No Risk vs. Low Risk: Macrolides

The use of macrolides in food animals could potentially compromise human health risk; all of the risk criteria are met

- ✓ An antibiotic must select for foodborne bacteria that acquire antibiotic-resistance...
- ✓ A person must ingest meat from a treated animal that is contaminated...
- ✓ The person that ingests these bacteria must become sick with a bacterial infection...

Ionophore Risk

The use of ionophores in food animals does not create a risk to human health because none of the risk criteria are met.

- ✗ An antibiotic must select for foodborne bacteria that acquire antibiotic-resistance...
- ✗ A person must ingest meat from a treated animal that is contaminated...
- ✗ The person that ingests these bacteria must become sick with a bacterial infection...

“One key exception is the ionophore group. Not only are they unrelated to anything used in human medicine, but they have a unique mechanism of action which has not been demonstrated to select for any type of human resistance, even through co-selection.”

– Dr. Mike Apley, Kansas State University

Raised Without Antibiotics

What does this mean?

Raised Without Antibiotics

Prohibits all antibiotics.

Raised Without Antibiotics
Important to Human Medicine

Prohibits all antibiotics
important to human medicine.
This allows products such as
ionophores to be used.



Source: <http://fsis.usda.gov>, accessed on 26 April 2017. USDA allows similar terms to raised without antibiotics. These are the larger categories of the label.

Raised Without Antibiotics

What it does not mean?

Raised Without Antibiotics

Raised Without Antibiotics
Important to Human Medicine

These farms never use antibiotics.

Generally, these farms will treat the animals that experience illness with medically important antibiotics.



Source: <http://fsis.usda.gov>, accessed on 26 April 2017. USDA allows similar terms to raised without antibiotics. These are the larger categories of the label.

IMMUNOLOGY, HEALTH, AND DISEASE

M.-L. Gaucher,^{*,1,2} S. Queney,^{*} A. Letellier,^{*} J. Arsenault,¹ and M. Bonhôte^{1,2}

*Research Chair in Meat Safety, Pathology and Microbiology Department, Veterinary Faculty, University of Montreal, CP 5080, St-Hyacinthe, Quebec, Canada J2S 7C6; †Chair in Poultry Research, Clinical Sciences Department, Veterinary Faculty, University of Montreal, CP 5080, St-Hyacinthe, Quebec, Canada J2S 7C6; ‡Sene and Poultry Infectious Disease Research Centre (CIRPA), Pathology and Microbiology Department, Veterinary Faculty, University of Montreal, CP 5080, St-Hyacinthe, Quebec, Canada J2S 7C6

[illegible]

Key words: broiler chicken, drug-free, growth performance, gut health, *Clostridium perfringens*

The benefits of antibiotics used as growth promoters (AGPs) were discovered during the 1940's and have largely contributed to the rapid expansion of the poultry industry worldwide (Dihner and Richards, 2002; Newbold, 2007). AGPs are recognized to contribute to the establishment of a healthy and functional intestinal tract, allowing, in part, poultry producers to obtain maximum benefits of the high-yield broilers' genetics (Cooper et al., 2012; Daaninen et al., 2011;

© 2013 Probing Science Association Inc.
Received January 21, 2013.
Accepted April 3, 2013.
*Corresponding author: nurhan.buduneli@univ.tu.ac

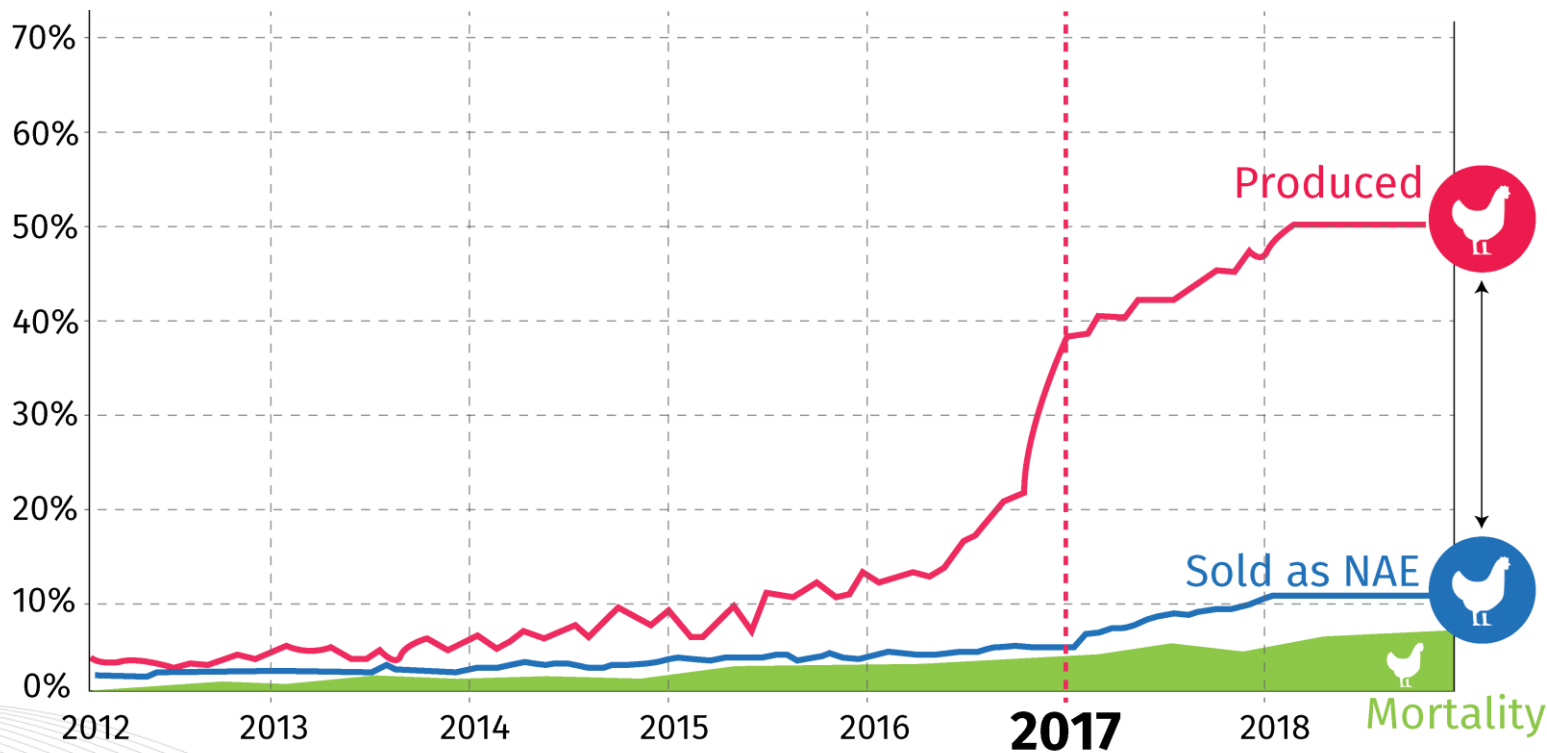
Hayesbuhl et al., 2011). However, many of the antimicrobial agents in animal feed systems were expressed about the possible development of resistant bacteria (Dittmer and Richter, 2005). In the last two decades, many aspects of antimicrobial use, including long-term sub-therapeutic usage in intensively reared food-producing animals, have been identified to contribute to the development and spread of resistant bacteria (Aasrøp et al., 2000; Aasrøp et al., 2001; Aas et al., 2007; McDermott et al., 2002; Shaw, 2004). Evidence from many studies suggest that bacteria carrying antibiotic resistance genes that can be transferred from animals to humans (Forsberg et al., 2002; Luzzatoglinchi et al., 2006; Salda et al., 2012; Doolittle et al., 2011; White et al., 2002). Based on

1290

49.02

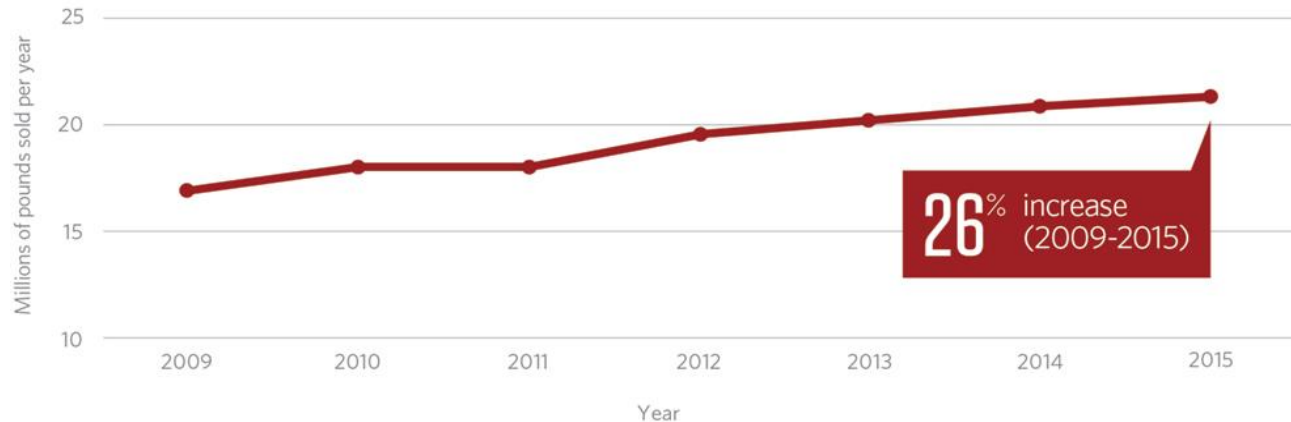


RWA Exceeding Demand, Increased Mortality



Sales of Medically Important Antibiotics is Trending Up

Drivers behind 26% increase from 2009 to 2015 unclear due to data limitations



Source: U.S. Food and Drug Administration

© 2017 The Pew Charitable Trusts

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE:
TYSON FOODS INC., CHICKEN
RAISED WITHOUT ANTIBIOTICS
CONSUMER LITIGATION

Civil Action No.: R

MEMORANDUM OPINION

A class of Consumer Plaintiffs sued Defendant Tyson Foods, Inc. ("Tyson's "Raised Without Antibiotics" ("RWA") promotional claims about its meat were misleading, and asserting claims under state consumer protection statutes. The Parties have reached a settlement agreement. Now pending is Plaintiffs' Approval of Settlement (Paper No. 99), Class Counsel's Motion for Award of Costs and Expenses (Paper No. 101), and Friends for Neighborhood Progress, Inc.'s Motion to be Included as a Cy Pres Recipient (Paper No. 118). A Fairness Hearing was held on April 22, 2008, at the conclusion of which this Court approved the settlement. Accordingly, for the reasons stated, the above motions are GRANTED.

BACKGROUND

On January 25, 2008, Sanderson Farms, Inc. and Perdue Farms, Inc. ("Sanderson and Perdue Farms, Inc. v. Tyson Foods, Inc.", Civil No. RDB-08-210. The Sanderson and Perdue Farms, Inc. plaintiffs alleged that Tyson's RWA promotional claims about its chicken products were misleading. On April 22, 2008, this Court granted the plaintiffs' motion for a permanent injunction, holding that certain RWA claims were literally false and that other

PETITION BEFORE THE UNITED STATES
FOOD SAFETY AND INSPECTION SERVICE

ANIMAL LEGAL DEFENSE FUND

170 E. Cotati Ave.
Cotati, CA 94931
707-779-2055

Petitioner,

Filed with:

TOM VILSACK

in his official capacity as Secretary,
United States Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250

and

ALFRED ALMANZA

in his official capacity as Administrator
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250

CITIZEN'S PETITION SEEKING MANDATORY
TO PREVENT THE SALE OF

I. INTRODUCTION

Pursuant to applicable Food Safety and Inspection Service (FSIS) regulations, 9 CFR § 392, and the Administrative Procedure Act, 5 U.S.C. § 551, the Animal Legal Defense Fund ("ALDF") submits this petition for review to the United States Department of Agriculture's ("USDA") FSIS to



Food Labeling: Is Mandatory Antibiotic Claim Labeling Needed?

By Brian Sylvester

Amid increasing consumer concerns of developing bacterial resistance to antibiotics, meat and poultry producers are racing to market chicken, beef, and pork raised without antibiotics. The hot-button issue of superbug antibiotic resistance in humans has fomented an upswing in consumer advocacy groups questioning the adequacy of the regulatory framework governing the use of antibiotics in food-producing animals and, in particular, the marketing claims applied to meat and poultry products indicating the use or nonuse of antibiotics.¹

As it stands, the key federal agency regulating antibiotic marketing claims, the U.S. Department of Agriculture (USDA),

does not mandate that labeling state the use or nonuse of antibiotics in meat or poultry products. However, the Animal Legal Defense Fund (ALDF) has petitioned the USDA, calling for mandatory antibiotic claim labeling. ALDF argues that the use of antibiotics in food-producing animals poses a risk to human health and, as such, consumers expect meat and poultry product labels to indicate the use or nonuse of antibiotics in food production.² As of this writing, ALDF's petition remains under review by USDA as a rulemaking petition. This article contends that mandatory antibiotic labeling is not needed because existing federal law and policy serve to adequately inform consumers of the nonuse of antibiotics in food-producing animals, effectively providing antibiotic-free options to consumers concerned about the potential adverse health effects of consuming antibiotic-treated meat and poultry.

The Regulatory Framework

Overview

The labeling of meat and poultry products primarily falls under the jurisdiction of USDA's Food Safety and Inspection



Brian P. Sylvester is an Associate at Keller and Heckman LLP in Washington, DC. Prior to entering private practice, he served as a regulatory lawyer at USDA from 2009 to 2014.

FDLI

March/April 2015 | UPDATE

29

Consumers Want Meaningful Information



72%

Widespread antibiotic use in food animals...creating new superbugs that cause illnesses that antibiotics cannot cure.



67%

Of the U.S. consumer who purchase RWA 67% do so because they don't want to contribute to antibiotic resistance in people.



7 of 10

Consumers who purchase RWA do so because they are concerned about resistant infections and antibiotic effectiveness in people.

A closer look at why consumers purchase RWA



Responses from the 29% who say they regularly purchase RWA.

86%

Nearly all (86%) purchase beef, pork or poultry labeled as “produced without antibiotics” because it is “healthier for their family and them.”

54%

54% do so because they believe purchasing products labeled “produced without antibiotics” reduces the use of medically important antibiotics in animal production.

67%

67% do so because they “don’t want to contribute to human antibiotic resistance.”



Source: Why Consumers Purchase Meats and Poultry Raised Without Antibiotics, ORC International, January 2017.

Conclusion

Labeling and advertising statutes require statements to be truthful and not misleading. Both conditions are important.

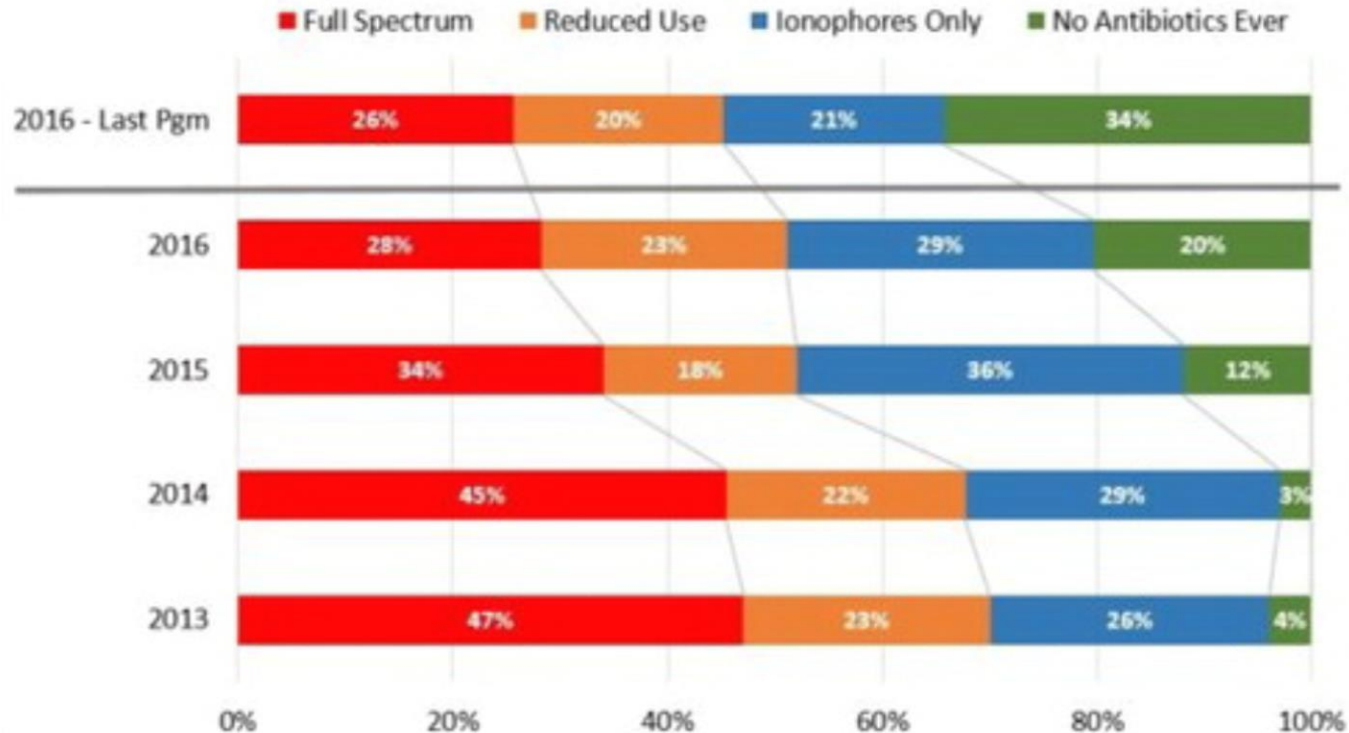
7 of 10 Consumers who purchase RWA do so because they are concerned about resistant infections and antibiotic effectiveness in people.¹

We need a refined approach that builds on acceptance of label and desired public health outcomes for responsible use of medically important antibiotics.

Thank you!

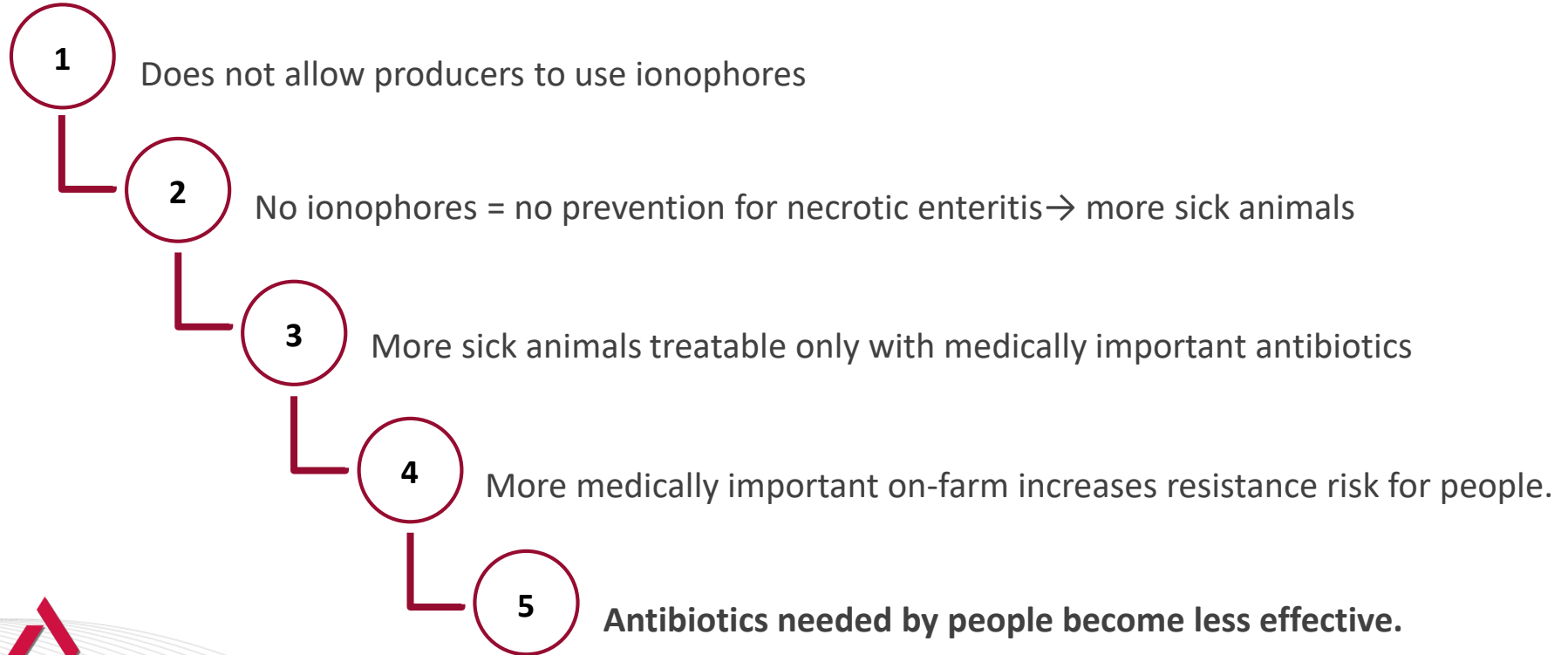


U.S. Broiler-Feed Tonnage by Program Type

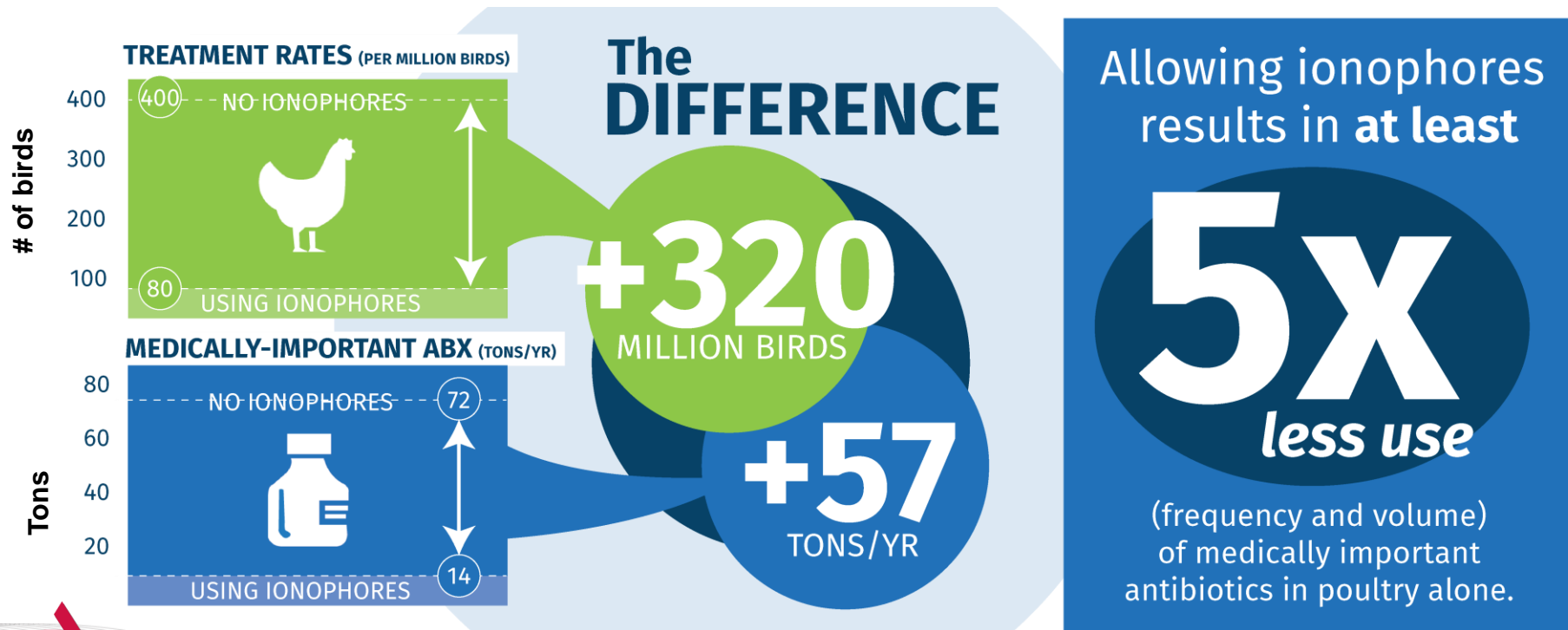


© Copyright 2017. Rennier Associates Inc. All rights reserved.

Impact of current “Raised Without Antibiotics” Labeling Policy



RWA Label Driving Increased Use of Medically Important Antibiotics



Pet Products and FTC Enforcement

May 4, 2017

2017 FDLI Annual Conference

Richard Cleland*
Assistant Director
Division of Advertising Practices
Federal Trade Commission

* Mr. Cleland's statements reflect his own views, and do not necessarily reflect the views of the Commission or any individual Commissioner.

Mars Petcare US, Inc. (Dec. 13, 2016)

- The FTC's complaint alleged that Mars' representations that
 - With Eukanuba brand dog food, dogs live 30 percent or more longer than their typical lifespan; and
 - Eukanuba brand dog foods enable dogs to live exceptionally long lives,Were false, misleading, or unsubstantiated.

Mars Petcare US, Inc.

- The FTC's complaint also alleged that Mars falsely represented that:
 - Scientific tests prove that, with Eukanuba, dogs live 30 percent or more longer than their typical lifespan; and
 - Scientific tests prove that Eukanuba brand dog foods enable dogs to live exceptionally long lives.

Mars Petcare US, Inc.

- According to the complaint:
 - “Among other things, the evidence relied on by [Mars] for its representations concerning the Eukanuba brand dog food consisted primarily of results from a single study, the results of which showed no significant difference in the median age at death of the dogs in the study relative to the typical age at death of the dogs of the same breed.”

Mars Petcare US, Inc.

- The order requires Mars to possess competent and reliable scientific evidence to substantiate claims about the health benefits of its pet foods.

Supporting Advertising Claims

- Establishment claims
- Reasonable basis claims

Establishment Claims

Where an advertisement represents, either expressly or by implication, that the claim is supported by a certain amount or level of substantiation, the advertiser must possess, prior to dissemination of the advertisement, at least that level of support for the claim.

Establishment Claims

- “Tests Prove . . .”
- “Doctors Recommend . . .”
- “Studies Show . . .”
- “Clinically Proven to . . .”

Evidence acceptable to the relevant scientific community to demonstrate that claims are true.

Determining the Reasonable Basis

- Relevant factors include:
 - the type of claim (health or safety claim?)
 - the product (experience or credence claim?)
 - the consequences of a false claim
 - the benefits of a truthful claim
 - the cost of developing substantiation for the claim
 - the amount of substantiation experts in the field believe is reasonable

Competent & Reliable

- Competent means that the evidence is relevant to the claim. It doesn't matter how good the evidence is if it doesn't match the claim.
- Reliable goes to the design and methodology of the study and asks can the results of the research be reasonably extrapolated to support the advertised claim?

Contact Information

Richard Cleland

Assistant Director

Division of Advertising Practices

Federal Trade Commission

Washington, D.C.

Phone: 202-326-3088

Email: rcleland@ftc.gov