

## REGULATORY REGISTER

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## FDA-Funded Studies Released on Antibiotic Use on Dairy Farms

Results from FDA-funded studies on farm-level antimicrobial use in animal agriculture were published in November in a special issue of *Zoonoses and Public Health*, an international journal that publishes integrated and global approaches to disease transmission and public health at the interface of human and animal health. The funds were awarded in 2016 in the form of cooperative agreements.

These funded data-collection efforts were intended to provide information on antimicrobial use practices in various animal production settings and to inform the development of long-term strategies for collecting and reporting such data in a nationally representative manner. Data were collected from records of participating dairy and feedlot cattle operations, swine companies, and broiler and turkey companies.

The research resulted in three peer-reviewed articles about antibiotic use on dairy farms:

Antimicrobial use quantification in adult dairy cows – Part 1 standardized regimens as a method for describing antimicrobial use Nora F. D. Schrag, Michael D. Apley, Sandra M. Godden, Brian V. Lubbers, Randall S. Singer

This study describes a process to acquire and convert farm treatment records into a standardized regimen format. The method established in this project will inform future research, surveillance, and policy.

### Antimicrobial use quantification in adult dairy cows—Part 2 developing a foundation for pharmacoepidemiology by comparing measurement methods

Nora F. D. Schrag, Michael D. Apley, Sandra M. Godden, Randall S. Singer, Brian V. Lubbers

In this article, experts compare nine measures of antimicrobial use pertaining to adult cows in U.S. dairy systems based on treatment records standardized to a single format. Their findings may allow those developing dairy antimicrobial stewardship programs to better understand the potential effects of measurement selection on driving changes in antimicrobial use.

## Antimicrobial use quantification in adult dairy cows – Part 3 – Use measured by standardized regimens and grams on 29 dairies in the United States

Nora F. D. Schrag, Sandra M. Godden, Michael D. Apley, Randall S. Singer, Brian V. Lubbers

This study reports on antimicrobial use in terms of standardized regimens per cow year and grams per cow year for 29 U.S. dairies in 2016 and 2017. The research team's findings highlight the need for a more complete understanding of the relationship between antimicrobial use measures and their relationship to antimicrobial resistance selection pressure.



# Antimicrobials Sold for Use in Food-Producing Animals Low, FDA Says in Annual Report

Antimicrobials sold and distributed for use in food-producing animals rose 3 percent in 2019, still the third -lowest year on record, according to the FDA's annual report on animal antibiotics used in agriculture, released Dec. 15.

The report, first released in 2009, monitors market changes related to antimicrobial drug products for food-producing animals and slow the development of antimicrobial resistance. Use has dropped 36 percent since 2015, the peak year of antimicrobial sales. The <u>full report</u> breaks down antimicrobial drug sales by class and medical importance, noting that the antimicrobials sold doesn't equate to antimicrobials used.

NMPF supports FDA's work to increase the oversight of antimicrobial usage and has made veterinarian- client-patient relationships a cornerstone of the FARM program to help ensure judicious use.



#### **CDC Recommends Food and Ag Workers Get Priority Vaccine Status**

The food and agriculture sector, one of 16 critical infrastructure sectors part of the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (DHS-CISA) has successfully advocated for food and ag workers to be prioritized for vaccines, quickening the pace at which workplaces can return to something resembling normal in 2021.

The critical infrastructure sectors have been deemed vital to the United States, meaning that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof. The vaccine, which began in earnest in December after vaccines produced by Pfizer and Moderna received FDA approval for emergency distribution, includes a multitiered system, comprised of groups 1a, 1b, 1c, 2 and 3.

NMPF Senior Vice President and staff counsel Clay Detlefsen has been central to the efforts to prioritize food and agriculture, serving as the private-sector chair of the Food and Agricultural Sector Coordinating Council, which coordinates industry and government

response to disruptions in the food chain. Thanks to the hard work of the food and ag sector, food and ag workers have been put into group 1b which includes "Frontline essential workers such as fire fighters, police officers, corrections officers, food and agricultural workers, United States Postal Service workers, manufacturing workers, grocery store workers, public transit workers, and those who work in the educational sector (teachers, support staff, and daycare workers.)" The work of DHS-CISA has been essential to ensure that food and agriculture workers have been protected during the COVID-19 pandemic. The food and agriculture sector advocated for its workforce to be listed as essential workers for prioritization of personal protective equipment in food processing plants.

While states have the ultimate decision on who they prioritize for vaccines, many do follow CDC recommendations which include the recommendations from DHS-CISA. While the vaccination process has gotten off to a rocky start, NMPF remains hopeful it will improve. And, for now we can take solace in the fact that nationwide food and agriculture workers are being recognized as essential and respected for what they do.

#### **Annual FDA Drug Residue Report Indicates Continued Progress**

Only 1 out of 10,400 milk tankers tested positive for antibiotic residues last year, according to the 2020 National Milk Drug Residue Database annual report released on Dec. 15 by the U.S. Food and Drug Administration.

The data illustrates the continued long-term national pattern of improvements in milk quality practices by the industry. Of the approximately 3.5 million milk pick-up tankers tested in the past year, only 334 (0.010%) yielded a positive result. The number of samples tested (tankers, packaged products, producer samples) and reported positive decreased from 556 in 2019 to 536 in 2020; not a single pasteurized packaged dairy product (26,614) tested was found to have an antibiotic residue. The full report is available <a href="https://examples.com/hereit/herei

#### Dairy a Key Component USDA Ag Innovation Agenda Research Strategy

The U.S. Department of Agriculture (USDA) released Jan. 12 the <u>U.S. Agriculture Innovation Strategy Directional Vision for Research</u> summary and <u>dashboard</u> that will help to guide future research decisions within USDA. The strategy synthesizes the information USDA collected as part of a public announcement earlier this year engaging the public on research priorities under the <u>Agriculture Innovation Agenda</u>.

NMPF, Newtrient LLC, and the Innovation Center for U.S. Dairy submitted a series of comments to USDA on their request for comments on the Ag Innovation Agenda. These wide-ranging comments helped USDA put forth a clear and comprehensive research strategy specific for the U.S. dairy industry under four aspirational goals:

- Production Aspirational Goal: Increase agricultural production by optimizing yield and/or quality with higher input use efficiency;
- Production Capability Aspirational Goal: Increase agricultural production capabilities of soil, water, and air by developing and implementing sustainable farming tools and practices;
- Market Expansion and Diversity Aspirational goal: Increase market diversity and product utility of the farming system to expand value, reach, and resiliency; and
- Data Aspirational Goal: Standardize, align, and integrate agricultural research and operational data to enable and energize a broad informatics ecosystem to drive tomorrow's agricultural operations and State and Federal programs.

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#### NMPF Joins Maui Guidance Comments With Animal Agriculture Groups

NMPF signed on to comments generally supporting the draft guidance released by EPA detailing how to apply the Supreme Court decision County of Maui v. Hawaii Wildlife Fund decision under the Clean Water Act's National Pollutant Discharge Elimination System Permit Program. The comments, submitted Jan. 11, included support from the National Cattlemen's Beef Association, the American Farm Bureau Federation, the United Egg Producers and others.

The draft guidance was released by EPA after the Supreme Court in Maui ruled that a National Pollutant Discharge Elimination System permit (NPDES) is required for a discharge of pollutants from a point source that reaches "waters of the United States" after traveling through groundwater if that discharge is the "functional equivalent of a direct discharge from the point source into navigable waters." It also clarifies the threshold conditions for triggering the requirement for a NPDES permit.

The comments make three main points-

- Agreement that the majority of discharges through groundwater are not the functional equivalent of a direct discharge and thus, remain outside the scope of NPDES permitting;
- Agreement that the Maui case did not change the requirement that there be a point source discharge before regulatory jurisdiction can be established under the Clean Water Act; and
- The draft guidance correctly reinforces that an actual discharge is a threshold condition that must be satisfied before the functional equivalent even applies.

The comments can be found <u>here</u>. NMPF will continue to monitor this issue closely.



#### Jonker Appointed to USDA Animal Disease Preparedness Board

Dr. Jamie Jonker, NMPF Vice President Sustainability & Scientific Affairs, was appointed as an *ex officio* member to the USDA APHIS Veterinary Services' National Animal Disease Preparedness and Response Program (NADPRP) Consultation Board in January.

NADPRP was established as part of the 2018 Farm Bill to provide funds to eligible entities to conduct high-value projects that will help prevent the introduction and spread of foreign and emerging animal diseases that threaten U.S. agriculture.

Its board includes 12 voting members and 4 *ex officio* non-voting members. The United States Animal Health Association (USAHA) coordinates the nomination of ten members, including three State Animal Health Official representatives, four industry representatives (one each from cattle, swine, poultry, and small ruminants), and three academic representatives. USDA's Agricultural Research Service (ARS) will nominate one member, and APHIS' tribal liaison will nominate one member to represent interests from tribal organizations. The 4 *ex officio* members are also nominated by USAHA to represent additional animal agricultural industries with interest in participating in NADPRP.

The NADPRP Board is charged with representing the interests of all eligible entities and supporting the program by:

- Developing and consulting with Veterinary Services on annual funding priorities;
- Nominating experts to review and rank proposals;
- Providing input on and approving the program's annual spending plan; and
- Providing feedback to improve the program's processes.

## Dietary Guidelines Reaffirm Dairy's Nutritional Benefits; Fats Review Urged

NMPF thanked USDA and HHS in December for its work on the 2020-2025 Dietary Guidelines for Americans (DGA), which reaffirmed dairy's central role in the diet as a provider of essential nutrients that are often underconsumed in American diets. NMPF also pledged to continue to advocate for consideration of the latest science on dairy fats in the next examination of the federal guidelines, which are released twice each decade.

The latest update to the guidelines restates dairy's importance to diet. Highlights include:

- A recommendation of three servings of dairy in the Healthy U.S. Eating pattern and Healthy Vegetarian Eating patterns, in keeping with past guidelines;
- Dairy's continued recognition as a distinct food group;
- A recognition that Americans aren't consuming enough dairy to meet their nutritional needs;
- Dairy's reaffirmation as a source of four nutrients of public health concern, including potassium, calcium, and vitamin D, as well as iodine for pregnant women; and
- A recommendation of milk, yogurt, and cheese in the first-ever healthy eating patterns geared toward infants and toddlers ages birth to 23 months.

The DGA have significant implications for numerous government policy areas, including guiding the types of milk served in school meal programs and setting the parameters for how nutrition programs are implemented and developed.



#### CDFA Fights Back Against Miyoko's Kitchen, NMPF Positions Asserted

The California Department of Food and Agriculture (CDFA) has filed a motion for summary judgment in the litigation brought against it by Miyoko's Kitchen. The motion echoes NMPF's position that Miyoko's use of the word "butter" is misleading and in violation of state and federal laws.

The Attorney General's Office of California is defending CDFA and filed the motion on Dec. 10, 2020. CDFA also properly stated that their actions do not violate the 1st Amendment, especially with respect to Miyoko's assertion that their product is "hormone-free" and "revolutionizing dairy with plants." Given that both of those claims are false, they are not entitled to any protection under the 1st Amendment.

The motion points to the long history of the standard of identity for butter which Congress created in 1923. The motion also noted that a dairy-based spread cannot call itself butter and vegan spreads should not be allowed to either, a point that NMPF has made on several occasions.

CDFA also asserts there is no First Amendment dispute over

whether a governmental agency has a substantial interest in regulating advertising and marketing to avoid consumer confusion. The agency points out that enforcing the standards of identity advances that interest, and their regulation is tailored to accomplish that goal. California requires products like Miyoko's to satisfy the standard of identity for butter if they want it to be called butter -- and if CDFA were to approve Miyoko's label as is, that would be inconsistent with federal law. California requires food products to have their labels reviewed prior to use.

CDFA also rebuts Miyoko's assertion that other non-dairy products in the marketplace use dairy terminology, such as peanut butter or fruit butter. CDFA correctly states, as NMPF has repeatedly pointed out when confronted with this issue, those products do not purport to be butter or a butter substitute.

A hearing on CDFA's motion scheduled for Feb. 24 has been postponed until April 29. Miyoko is expected to file a crossmotion in March. If the hearing on the motions does not resolve the case, a trial date of Aug. 23 has been set in San Francisco.



#### Low-Fat Flavored Milk Advocated Via Joint Comments, NMPF-Led Letter

NMPF submitted joint comments Dec. 23 with the International Dairy Foods Association and led an industry letter finalized Dec. 28, including member cooperatives and state dairy associations, urging USDA to finalize its proposed rule allowing low-fat flavored milk to be served in schools.

This proposed rule, which would restore not only milk provisions but also grant wider flexibilities for sodium and whole grain, comes after the original 2018 rule was overturned by a Maryland district court earlier this year on a procedural error. The 2018 rule made low-fat flavored milk available in the school lunch program.

Dairy organizations have pushed for greater flexibility on low-fat flavored milk since a 2012 school meals rule only allowed for fat-

free flavored milk to be served in schools, causing a plunge in milk consumption. The proposed rule would give the nation's schools more options while maintaining high nutrition standards.

"We agree that the flexibilities proposed by USDA, particularly those related to milk and sodium, would continue to allow schools to provide healthy and appealing meals and beverages to students, while maintaining the key nutritional requirements of the Child Nutrition Programs," NMPF and IDFA state in their joint comments.

Due to the change in administrations, work on this rule has been tabled for the time being.

#### **FARM Continuing Quick Convos Series**

The National Dairy FARM Program hosted a "Quick Convo" Jan. 6 on the Antibiotic Stewardship program area. This series of online informational sessions began in November and feature FARM staff and industry stakeholders discussing program expectations and available resources in a quick, 30-minute conversation. Workforce Development was featured on Jan. 16.

Streamed on Zoom and Facebook Live, these sessions offer farmers and others in the value chain a chance to engage and ask questions about FARM. Registration, recordings of the previous conversations, supplementary material, and the full schedule of topics are available on the FARM Quick Convos webpage.

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