

#### **National Milk Producers Federation**

# Regulatory Register

Volume 19, Issue 2

**Summer 2017** 

## **Food Safety**

## **NCIMS Tetracycline Testing Program Launches July 1**

Bulk milk tank trucks will be tested for the tetracycline family of drugs beginning July 1 as part of the NCIMS Pilot Program. The new tests will be conducted in addition to long-standing screening for beta-lactam drugs as required by the Pasteurized Milk Ordinance (PMO). NMPF has been engaged in both developing the program and educating the producer community about its details.

NMPF assisted with the development of the pilot program through the NCIMS Appendix N Modification Committee. To help educate producers, National Milk has hosted three webinars for cooperative members over the past year to provide information about the requirements of the program. Most recently, NMPF staff contributed an educational article, "Tetracycline will be new focus of residue screening," in the <u>June 2017 issue</u> of Hoard's Dairyman, that describes the pilot program's general requirements (i.e. which facilities are expected to participate, rate of testing, test kits that will be



used), as well as emphasizing the need for producers to work with veterinarians and to have a valid VCPR. The testing program will be conducted for 18 months, after which the FDA will examine the results and determine next steps.

For more information about the pilot program, please see the NCIMS Pilot Program website.

Contact: Beth Briczinski

### **Food Safety**

# Study Declares Raw Milk "Significant" Food Safety Risk; NMPF Challenges Expanded Access



A study published in June 2017 by researchers with EpiX Analytics examined outbreak-related data associated with unpasteurized cow's milk and cheese between 2009-2014. The authors concluded that

unpasteurized (raw) milk and cheese were the reason for 96 percent of illnesses caused by all dairy products, and that unpasteurized dairy products cause 840 times more illnesses and 45 times more hospitalizations than pasteurized products.

Despite the well-established concerns associated with consuming unpasteurized milk, the number of states where its sale is permitted continues to increase. NMPF has repeatedly engaged with state lawmakers across the country, urging them to reject

bills that would allow or expand the direct sale of raw milk and milk products to consumers. Most recently, NMPF and the International Dairy Foods Association submitted a joint letter to the New Jersey Economic Growth Committee on S1414, which would establish a raw milk permit program.

Recently, a <u>citizen petition</u> was submitted to FDA asking the agency to exercise enforcement discretion over the prohibition on interstate shipments of unpasteurized milk products, citing support by executive orders and memoranda from the president that are intended to reduce regulatory burdens. The petition asserts that consumers could be adequately protected through warning statements and handling instructions. NMPF will submit comments opposing the petition by the deadline of October 23, 2017.

Contact: Beth Briczinski

### In this issue

Page 2
NMPF Enjoys
Success at
Biennial NCIMS
Conference

Page 4
NMPF Calls for
Changes to EPA
Regulations

Page 6
FSMA
Sanitary Food
Transportation
Rule Takes Effect

Page 8

NMPF Scholarship

Winners

Announced

...and more!

# NMPF Enjoys Success at Biennial NCIMS Conference on Labeling, FSMA, Drug Testing

The National Conference on Interstate Milk Shipments (NCIMS) met in Grand Rapids, Mich., from May 12-17 to review 98 proposals submitted to revise the Pasteurized Milk Ordinance (PMO) and its related documents. NMPF attended the conference to advocate positions of interest to dairy cooperatives and their producer members. Many NMPF members also attended and played key roles in deliberations. NMPF achieved a major victory in introducing and winning support for a resolution asking FDA for more action on the mislabeling of plant-based dairy imitators.

A special <u>NCIMS edition</u> of the NMPF Regulatory Register has been published online detailing all actions from the 2017 NCIMS conference.

#### Key items of note:

 State milk safety regulators voted unanimously in favor of NMPF's resolution intended to clarify the responsibilities of FDA and state programs in ensuring the proper use of standardized dairy product names. The NCIMS delegates acknowledged that states need federal assistance in the regulation of all products utilizing standardized dairy terms, especially plant-based dairy imitators misusing dairy names.

- The NCIMS Liaison Committee, representing a collaborative effort of industry and states, successfully made additional changes to the PMO to harmonize it with the Food Safety Modernization Act (FSMA) Preventive Controls for Human Food final rule, which was issued after the 2015 NCIMS conference. The NCIMS Liaison Committee proposal placed the new FSMA-based requirements in a new appendix (Appendix T) to minimize confusion and highlight the new program criteria.
- Delegates also passed three proposals to clarify various aspects of Appendix N Section VI, related to requirements when using non-beta-lactam test kits that have not been evaluated by FDA and accepted by the NCIMS. Additional clarity will be resolved through the Proposal #217 study committee prior to the 2019 conference.

NMPF expresses sincere appreciation to all NCIMS conference participants – including NMPF member cooperatives, processors, state dairy program regulators and FDA – for their efforts to work in a spirit of collaboration to ensure the safety and integrity of Grade "A" dairy products.

Contact: Beth Briczinski

#### **Nutrition**

## Schools Will Again Be Able to Serve Low-fat Flavored Milk

Low-fat flavored milk will again be an option in school cafeterias this fall, following separate actions by Congress and Secretary of Agriculture Sonny Perdue. NMPF, which has worked on this issue for five years, praised the new flexibility for schools, noting it could help reverse declines in school milk consumption.

Congress mandated that the U.S. Department of Agriculture allow states to grant waivers to schools to re-introduce low-fat milk in chocolate and other flavors, so long as schools show that milk consumption has declined or waste has increased. Although it is up to states whether to grant the waivers, USDA strongly encouraged them to do so in a guidance memorandum, and took steps to minimize the burden on schools to demonstrate eligibility for the waiver.

This applies to the upcoming 2017-18 school year, although because many schools have already contracted for milk, quick adoption could be limited. NMPF led a meeting of dairy groups to develop strategies for encouraging schools to take advantage of the waiver opportunity.

Separately, USDA Secretary Perdue announced he will propose a new regulation to let schools offer low-fat milk

freely, beginning in the 2018-19 school year, without any need for state waivers. NMPF and the International Dairy Foods Association met recently with USDA officials to encourage them to develop the regulation rapidly, since both schools and fluid milk processors need adequate time to prepare.

Secretary Perdue also delayed through 2020 any further reductions in the maximum sodium content for school meals. Under existing regulations, schools have already reduced sodium levels to "Target 1," but many have said it will be extremely difficult to further reduce them to Targets 2 and 3. Meeting those targets would likely have led schools to offer less cheese on their menus, but for now schools can remain at current levels.

NMPF opposed the original regulation, which banned low-fat flavored milk in schools, predicting it would cause a decline in milk consumption and therefore be averse to children's health. The Dietary Guidelines for Americans encourage consumption of low-fat or fat-free milk, but do not say that flavored milk should be fat-free.

Contact: Beth Briczinski

### **Food Labeling**

## NMPF Says Dairy Foods Should be Allowed "Healthy" Claims

More dairy foods should be eligible to be labeled as "healthy," NMPF told FDA on April 26. In response to FDA's consideration of which foods should be defined as "healthy," NMPF said that because the Dietary Guidelines for Americans (DGA) identify dairy as a nutrient-dense food and say most Americans should consume more, FDA should promote a consistent message by modernizing its rules so that most dairy foods can be labeled as "healthy."

FDA is considering updating its rules for "healthy" claims, partly because the current guidelines reflect outdated science. Notably, current rules place strict limits on total fat content, but it is well-established that previous advice to limit total fat consumption was misguided.

NMPF wrote that foods recognized as nutrient-dense in the DGA should be able to make a "healthy" claim, regardless of whether they comply with the present restrictions on saturated fat, cholesterol or sodium. Reduced-fat forms of dairy foods should be able to call themselves "healthy" if they are a good source of one or more beneficial nutrients. NMPF also commented to FDA that the agency should remain open to adapting "healthy" criteria in the future to recognize evolving



science, such as the growing body of research that shows health benefits of dairy at all fat levels.

In developing its comments, NMPF worked closely with the National Dairy Council and the International Dairy Foods Association, which also submitted comments.

Contact: Beth Briczinski

### **Food Labeling**

## **Support for DAIRY PRIDE Act grows in Congress**

NMPF continues to work with members of Congress to garner support for the DAIRY PRIDE Act (DPA) in both the House and Senate (H.R. 778 and S. 130, respectively). Since the last *Regulatory Register* issue, NMPF has generated additional bipartisan support for both bills from key members of Congress, including Ranking Member of the Senate Agriculture Committee Debbie Stabenow (D-MI), totaling 20 House and Senate members.

The DPA would require FDA to enforce the long-standing regulation that milk must come from an animal, thus prohibiting plant-based "milks" from using dairy terminology on their labels.

With support for the DPA growing in Congress, NMPF has also seen increased activity by dairy farmers encouraging lawmakers to act on this legislation. More than 650 dairy advocates have contacted their members of Congress in support of the bills. Additionally, many in the dairy industry have spoken out publicly about the importance of this issue through op-eds in several major <u>regional newspapers</u>.

Increased pressure from the public and members of Congress are vital to force FDA to do their job and enforce labeling standards.

Uphold the integrity of dairy

bit.ly/DairyPrideAct

Contact: John Hollay

## **FDA to Extend Compliance Date for Nutrition Labeling Mandate**

On June 13, FDA announced its intent to <u>extend the</u> <u>compliance dates</u> to allow additional time to implement the new Nutrition Facts Label rules, thanks to feedback from NMPF, the larger food industry, and consumer groups regarding the compliance dates for the new label.

In May 2016, FDA issued the Nutrition Facts final rules and set the compliance date for July 26, 2018, with an additional year to comply for manufacturers with annual food sales of less than \$10 million. After careful consideration, FDA determined that additional time would provide manufacturers covered by the rule with necessary guidance from FDA, and would help them complete and print updated nutrition facts panels for their products before the compliance date.

As a result of information shared by food producers, the FDA intends to extend the compliance dates to provide the additional time for implementation. The framework for the extension will be guided by the desire to give industry more time and decrease costs, balanced with the importance of minimizing the transition period during which consumers will see both the old and the new versions of the label in the marketplace.

FDA will provide details of the extension through a *Federal Register* notice at a later time.

Contact: Beth Briczinski

#### **Environment**

## **NMPF Calls for Changes to EPA Regulations**

National Milk joined 45 agriculture trade associations, dairy cooperatives and organizations in May to provide recommendations to the U.S. Environmental Protection Agency (EPA) about regulations the agency should repeal, replace or modify. The comments identified 11 different regulations that need to be eliminated or modified, with the Waters of the U.S. (WOTUS) rule topping the list.

NMPF's input to the EPA was prompted by a Feb. 24 presidential executive order that called for the "alleviation of unnecessary regulatory burdens on the American people."

Regarding WOTUS, NMPF recommended repealing the existing rule and implementing a separate one that closely adheres to the language in the Clean Water Act (CWA) and aligns with recent Supreme Court decisions. EPA said it intends to follow through, and that the process to eliminate the current WOTUS rule is now at the Office of Management and Budget (OMB) for review. When that process is complete, EPA will begin a second round of rulemaking to create a revised WOTUS rule.

NMPF also asked EPA to repeal the application of the Spill Prevention Control and Countermeasures (SPCC) rule for farms. The SPCC rule impacts approximately 400,000 farms. EPA has the authority and flexibility to exempt farms, but previously chose not to do so.

NMPF also requested the repeal of a provision in the Worker Protective Standard, which allows anyone claiming to be a "designated representative" to gain access to a farmer's proprietary records on pesticide use. The provision, as drafted, is ambiguous and provides no protection from fraudulent and counterfeit claims.

NMPF raised concern with EPA's Total Maximum Daily Load



regulations under the Clean Water Act. In recent years, the line of authority between the federal and state governments' roles has become blurred, and many state agencies are not able to develop plans to effectively achieve water quality standards. NMPF asked EPA to provide clarity and ensure the states have the authority to set pollutant allocations within their borders.

Most importantly, NMPF asked EPA to address the April 11 U.S. Court of Appeals ruling that eliminated the exemption for air emissions from manure under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and the Emergency Planning Community Rightto-Know Act (EPCRA). Specifically, NMPF asked for EPA to enact regulations confirming that manure is not regulated under CERCLA or EPCRA. The organizations also called for exempting manure under the Resource Conservation and Recovery Act (RCRA).

Contact: Clay Detlefsen

Regulatory Register | Page 4

# **Livestock Organizations Seek Rehearing of Ruling on CERCLA and EPCRA Reporting**

Dairy farmers and other livestock producers are asking a federal appeals court to rehear a case to determine if they should have to file manure-related air emissions reports with local first responders.

At issue is whether an April 11 court ruling will impose new paperwork requirements on livestock producers or whether the issue is successfully appealed and resolved in a less burdensome manner. If the appeals court decision stands, cattle, pork and poultry farmers will have to file reports that, in virtually every case, local emergency response agencies can't use and don't want.

The National Pork Producers Council (NPPC), in collaboration with NMPF, filed for a rehearing of the decision. If a rehearing is denied, EPA will have 14 days to file a motion to stay the mandate to vacate the exemption.

In 2008, <u>EPA exempted</u> most farms from the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) and the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) reporting requirements for air releases from animal waste. Both rules were originally created to address accidental hazardous air emission emergencies. Initially, EPA did not say these measures warranted the inclusion of animal agriculture operations, but the recent appeals court ruling said EPA cannot simply ignore a statute because the reporting requirements "aren't worth the trouble." The final rule required CAFOs to continue reporting air emissions under EPCRA, but not under CERCLA; smaller farms were exempted from both rules.

On May 25, 28 U.S. Senators sent EPA Administrator Scott Pruitt a <u>strongly worded letter</u> urging EPA to "take immediate action to prevent the waste of federal, state and local resources designated for emergency response programs," and urged



EPA to "challenge the D.C. Circuit decision to provide America's farmers and ranchers with regulatory relief through agency direction and rulemaking." In the letter to EPA, the senators estimated that 100,000 additional farms and ranches would need to file emissions reports, more than four times the number filed last year.

The letter noted that a reporting increase of this magnitude would be an enormous burden to the emergency response system – a point reinforced in early June by the National Association of SARA Title III Program Officials (NASTTPO), the association that represents the state, local and tribal emergency response communities. NASTTPO said reports about ammonia from animal manure management "are of no value to first responders, and they are generally ignored because they do not relate to any particular event."

NMPF staff recently met with EPA officials and asked them to intercede.

Contact: Clay Detlefsen

### **Food Safety**

## **Secure Milk Supply Releases Biosecurity Checklist, Manual, Templates**

In May, the <u>Secure Milk Supply</u> (SMS) released several new and revised documents. The Secure Milk Supply, supported by the U.S. Department of Agriculture and academic partners, is a Continuity of Business plan for dairy farmers, milk haulers, dairy cooperatives and proprietary processors during a Foot and Mouth Disease outbreak, with a goal to minimize disease spread and assure a continuous supply of milk and milk products to consumers. NMPF staff and members are vital contributors to the continued SMS development.

The new and revised documents include:

- An improved <u>Self-Assessment Checklist for Enhanced</u>
  Biosecurity for FMD Prevention
- A corresponding <u>Information Manual for Enhanced</u> <u>Biosecurity for FMD Prevention</u>
- A customizable <u>Biosecurity Plan Template</u>
- Instructions for creating a <u>Premises Map Using Google</u> Maps and more.

Contact: Jamie Jonker

### **Food Safety**

## **FSMA Sanitary Food Transportation Rule Takes Effect**

On April 7, 2017, the Sanitary Food Transportation Act went into effect for all businesses other than small operations with fewer than 500 employees or a motor carrier with less than \$27.5 million in annual receipts, which have an additional year to comply. Through the process, NMPF has continued to clarify that farms regulated under the Pasteurized Milk Ordinance (PMO) should not be covered by this regulation.

Congress allowed FDA to waive the requirements of this Food Safety Modernization Act (FSMA) rule, as it determined that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health. NMPF repeatedly argued for a waiver in the past, and FDA stated when the final rule was published that a waiver would be included for activities regulated under the PMO. On April 5, FDA published that long-sought waiver for PMO-regulated facilities, which would apply to the following:

Shippers, carriers and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Milk Safety program. This waiver only applies when Grade "A" milk and milk products—those produced under certain sanitary conditions— are being transported. FDA acknowledges that controls for such



transportation operations already exist under the NCIMS program, with State enforcement and FDA oversight.

While NMPF is pleased with the waiver, greater clarity is needed on whether the waiver applies when shipping non-Grade "A" products with Grade "A" as well. For facilities not regulated by the PMO, most of the requirements tend to follow standard industry practices.

Contact: Clay Detlefsen

### **Animal Health**

### **OIE 85th General Session Review**

NMPF staff attended the 85th General Session of the <u>World Organization for Animal Health</u> (OIE), held in Paris in May, which included several actions of note for the U.S. dairy industry.

The Terrestrial Health Code had several new and revised chapters including: (1) a final amendment to the chapter about the welfare of dairy cattle on stocking density, which now aligns with the National Dairy FARM Animal Care Program standards; (2) a new chapter on Salmonella control, which allows for the safe trade of dairy products by following CODEX Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004); and (3) a new chapter on Mycobacterium tuberculosis control to which the current USDA TB eradication program is compliant and allows for safe trade in dairy products by following CODEX Code of Hygienic Practice for Milk and Milk Products.

As part of the OIE activities relating to antimicrobial resistance (AMR), a <u>Technical Item</u> on the "Global action to

alleviate the threat of antimicrobial resistance: progress and opportunities for future activities under the 'One-Health' initiative" was presented. In November 2016, OIE published the <u>Strategy on Antimicrobial Resistance and Prudent Use of Antimicrobials</u> recognizing the importance of the 'One Health' approach encompassing human and animal health, as well as agricultural and environmental needs. Several recommendations have been made to guide countries and facilitate the 'One Health' approach, advocated by the Global Action Plan through awareness-raising activities, AMR surveillance and research, capacity-building and the implementation of international standards.

The <u>full meeting report</u> includes more detail on these and other actions. This activity is supported by the U.S. Dairy Export Council and Dairy Management Inc.

Contact: Jamie Jonker

#### **Animal Health**

# NMPF Questions Need for New National Organic Program Animal Production Standards

On June 9, NMPF submitted comments to the USDA National Organics Program on Organic Livestock and Poultry Practices seeking alignment between the FARM Program's animal care system and the USDA guidelines. USDA had requested comments on the implementation of the Organic Livestock and Poultry Practices Final Rule, published in the *Federal Register* on Jan. 19, 2017, which changed animal production standards by imposing a variety of new animal care and housing standards. NMPF initially commented on the proposed animal production standards in July 2016, saying the changes fall short of standards already employed by the National Dairy FARM Animal Care Program.

USDA specifically requested comments on implementing, delaying, suspending or withdrawing the final rule. In <a href="these-comments">these-comments</a>, NMPF stated that the <a href="FARM Animal Care Program">FARM Animal Care Program</a> assures animal care and wellbeing throughout the U.S. dairy industry, and thus the requirements in USDA's final rule are unnecessary and duplicative for dairy cattle. Further, the basis of the FARM Animal Care Program is sound science, and standards are updated every three years to accommodate the latest research around animal health and wellbeing. As such,



NMPF recommended suspending the final rule indefinitely, and said USDA should consider whether to implement, modify or withdraw the final rule.

Contact: Jamie Jonker

### **Animal Health**

## **NMPF Meets with APHIS Admin on Dairy Cattle Health Priorities**

In April, NMPF staff, joined by Karen Jordan, NMPF Animal Health & Wellbeing Committee chair, met with Kevin Shea, administrator of USDA's Animal and Plant Health Inspection Services, and other key <u>USDA animal health</u> staff to discuss animal health priorities for the U.S. dairy industry.

NMPF discussed seven current animal health priorities to ensure a healthy and productive domestic dairy herd and thus maintain U.S. consumer confidence and enhance global competitiveness of U.S. dairy exports: (1) Foot and Mouth Disease preparedness, including modernizing the vaccine bank, continued development of the Secure Milk Supply, improved diagnostics and agreements on trade during an outbreak; (2) Bovine Tuberculosis and Brucellosis eradication

programs; (3) Animal identification and disease traceability; (4) Transboundary and emerging animal diseases such as Schmallenberg virus, pathogenic Salmonella heidelberg and anaplasmosis; (5) National Animal Health Laboratory Network; (6) transition of the Plum Island Animal Disease Center to the National Bio- and Agro-Defense Facility in Manhattan, Kan.; and (7) antibiotic use data collection through the National Animal Health Monitoring System. NMPF will continue to work with USDA animal health staff to monitor and implement these priorities for the U.S. dairy industry.

Contact: Jamie Jonker







## **NMPF Says Regulatory Process Should Permit Gene Editing**

NMPF submitted comments on June 19 to FDA on draft <u>Guidance for Industry #187</u>, "Regulation of Intentionally Altered Genomic DNA in Animals."

FDA revised the previous Guidance for Industry #187 to expand the scope of the guidance to address animals intentionally altered through gene-editing techniques. In the draft guidance, FDA proposed regulating animals that result from gene-editing techniques (which, in most cases, is within the genome of the species) in the same manner as animals resulting from transgenic techniques (adding genes from a different species) through the <a href="New Animal Drug Application">New Animal Drug Application</a> (NADA) process. There is unique potential in gene-editing techniques for the dairy industry to address animal health issues, as well as assisting the industry in continuously improving areas such as animal welfare, responsible antibiotic use and sustainability.

NMPF <u>commented to FDA</u> that the NADA process is unnecessary for most gene-editing applications in livestock. NMPF suggested that FDA should use the regulatory

framework suggested by the recent 2017 National Academies of Sciences, Engineering and Medicine report, "Preparing for the Future Products of Biotechnology." The report offers a clear pathway FDA can utilize to determine what approval should be required for gene-edited animals not intended to produce biopharmaceuticals or medical devices. This regulatory approach would utilize the report's clear and concise classification system of new biotechnology products as "familiar and noncomplex", "unfamiliar or complex" and "unfamiliar and complex".

NMPF also proposed that FDA institute a notification process in which the developers of gene-edited animals inform FDA of the technical nature of the genetic edit (quantitative and qualitative descriptors of factors such as the source, size and method of the edit) so that FDA can expeditiously and predictably categorize and take appropriate action. NMPF noted that FDA's draft guidance may be appropriate for animals intended to produce biopharmaceuticals or medical devices.

Contact: Jamie Jonker



### **NMPF** News

## **NMPF Announces 2017 Scholarship Winners**

At NMPF's June board meeting, the NMPF Scholarship Committee selected two graduate students to receive scholarships as part of the 2017 NMPF National Dairy Leadership Scholarship Program. These students are conducting research in areas that will benefit dairy cooperatives and producers.

The 2017 Hintz Memorial Scholarship, given to the top scholarship candidate, was awarded to Sarah Adcock (left), a Ph. D candidate in animal behavior at the University of California-Davis, who is studying the long-term welfare implications of hot-iron disbudding in dairy calves.

A scholarship was also awarded to Carlyn Peterson (right), a Ph. D candidate in animal biology, also at the University of





California-Davis, who is studying the use of a novel methane inhibitor to improve the environmental footprint of dairy cattle.

Contact: Beth Briczinski

## **Upcoming Dates**

**Annual Conference of the <u>American Association of Bovine Practitioners</u>** 

Omaha, Neb. Sept. 14-16, 2017

**World Dairy Expo** 

Madison, Wisc. Oct. 3-7, 2017

**U.S. Animal Health Association Annual Meeting** 

San Diego, Calif. Oct. 12-18, 2017

NDB/NMPF/UDIA Joint Annual Meeting

Anaheim, Calif. Oct. 30 – Nov. 1, 2017





2107 Wilson Blvd., Suite 600, Arlington, VA 22201 (703) 243-6111 www.nmpf.org The National Milk Producers Federation, based in Arlington, Va., develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies.

### **NMPF Regulatory Staff**

Dr. Beth Briczinski Vice President, Dairy Foods & Nutrition beth@nmpf.org

Clay Detlefsen Senior Vice President, Regulatory & Environmental Affairs & Staff Counsel cdetlefsen@nmpf.org Dr. Jamie Jonker Vice President, Sustainability & Scientific Affairs jjonker@nmpf.org