National Milk Producers Federation

Regulatory Register

Volume 19, Issue 1 Spring 2017

Food Labeling

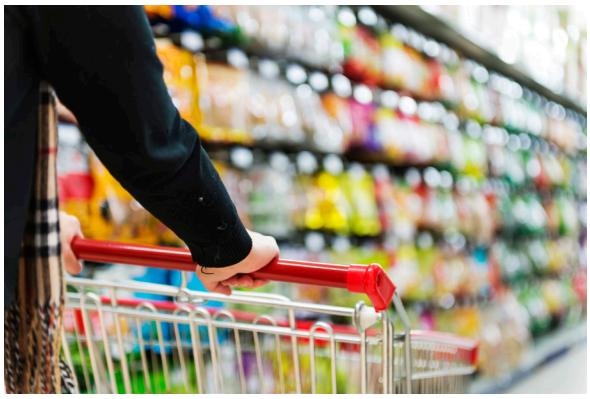
Two Labeling Changes, Two Different Rules, Two Deadlines

NMPF is asking the U.S. Food and Drug Administration (FDA) to combine two labeling regulatory deadlines into one to simplify the process and lower costs for manufacturers.

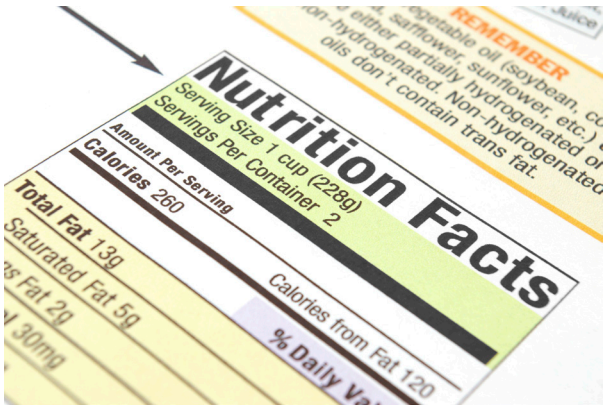
After significant NMPF engagement, a bill establishing a national bioengineered disclosure was signed into law in July 2016 with a compliance date of July 30, 2018. Earlier last spring, FDA issued its rule on changes to the Nutrition Facts panel, with a compliance date of July 26, 2018.

Considering the high cost of labeling changes, and the possibility of companies doing so twice in a short time, NMPF is asking that these two deadlines be harmonized so that there is only one date by which to make changes. FDA said it wants to maintain the current deadlines, but the Trump Administration has asserted that it will push for harmonization. Until the confirmation of Sonny Perdue as Agriculture Secretary, this issue will remain in flux.

Regarding the biotechnology disclosure law, precise labeling methods have yet to be determined, but it is likely that manufacturers will need to use a symbol, QR code or text to disclose any bioengineered material. USDA's Agricultural Marketing Service has not indicated how long regulated entities will then have to comply with new biotechnology labeling requirements, but estimates put the date at July 31, 2019.



For the Nutrition Facts label, changes include bolding and increasing the type size for Calories, Servings per Container and Serving Size. Manufacturers must declare the actual amount, in addition to Percent



Daily Value, of vitamin D, calcium, iron and potassium, among others. Manufacturers must use the new label by July 26, 2018. However, manufacturers with less than $10 million in annual food sales will have an additional year to comply.

To help the food industry prepare for changes in food product nutrition labeling, FDA released two draft guidance documents earlier this year related to final rules on Nutrition Facts labeling and serving sizes:

- A Q&A document focused on compliance, labeling of added sugars, rounding amounts of vitamins and minerals, and label format. In response to comments from NMPF, naturally occurring lactose found in dry dairy ingredients like milk powder and whey (except for lactose as defined in 21 CFR 168.122) will not be labeled as an added sugar.
- Examples of food products that belong to product categories included in the tables of Reference Amounts Customarily Consumed (RACCs) per eating occasion that are established in FDA's serving size regulations.

NMPF is aware that some customers are asking their suppliers to make any labeling changes now. If the product will not be subject to biotechnology labeling, such a request is appropriate. However, if a company feels that its products may be subject to both rules, NMPF advises holding off on making changes until the USDA formally weighs in on the issue. NMPF can assist members in determining whether the biotechnology rule will affect any of their dairy products.

Contact: Clay Detlefsen or Beth Briczinski

In this issue

Food Labeling

House, Senate Bills Would Enforce Dairy Labeling Standards

NMPF expressed ardent support in January and February for two bills introduced in the Senate and House that would direct FDA to police the misuse of dairy-specific terms.

NMPF has pushed FDA for many years to take action against plant-based imitators that are mislabeling their packages, and worked with leaders in both congressional chambers to formulate the new legislation.

Sen. Tammy Baldwin's (D-WI) DAIRY PRIDE Act, introduced in mid-January, would protect the integrity of dairy standards by requiring FDA to develop a 90-day timetable for enforcement actions against vegetable-based milk imitators made from non-dairy ingredients like almonds, rice and soy. Her bill also would require that the FDA report to Congress two years after the bill's enactment to explain its enforcement actions.

Meanwhile, an identical, bipartisan bill was introduced on Jan. 31 in the House by Reps. Peter Welch (D-VT), Sean Duffy (R-WI), Mike Simpson (R-ID), Joe Courtney (D-CT), David Valadao (R-CA) and Suzan DelBene (D-WA). NMPF President and CEO Jim Mulhern praised the lawmakers for their work on this important issue.

Current regulations (CFR 131.110) define milk as a product of a cow. Though existing federal policy is clear on this subject,

FDA has not challenged the labeling practices of imitators made out of nuts, beans, seeds and grains. NMPF has noted how the United States' lack of enforcement efforts differs greatly from those in similar nations, which actively enforce standards of identify. For example, while the term "almond milk" is seen on products sold in the United States, it is absent from the same brand of almond beverage sold in Canada and the United Kingdom.

Contact: John Hollay

Food Safety

NMPF Continues to Battle Against State Raw Milk Bills

With a changing political landscape and new legislative calendar, several bills to relax food-safety regulations on raw milk are being considered in state legislatures this year. NMPF has continued to weigh in with lawmakers across the country, urging them to reject these measures that threaten consumers' health.

NMPF has jointly submitted letters with the International Dairy Foods Association calling for the rejection of these bills "due to the significant public health risks associated with the consumption of raw milk," in response to the following bills:

- New Jersey A696, establishing a raw milk permit program, in the Agriculture and Natural Resources Committee;
- Virginia HB 2368, exempting small producers, in the House Agriculture, Chesapeake and Natural Resources Committee;
- Virginia HB 2030, exempting raw milk sold at farms and farmers markets, in the House Agriculture, Chesapeake and Natural Resources Committee;
- North Dakota HB 1433, exempting raw milk sold direct to consumers, passed the House 69-21;
- Massachusetts S442, an ag omnibus bill that would legalize herd shares and allow raw milk delivery, in the Joint Committee on Environment, Natural Resources and Agriculture;

- Illinois HB 2466, expand raw milk sales, in the Consumer Protection Committee;
- Montana HB 352, exempts raw milk from state regulations, in the House Agriculture Committee, and;
- Montana HB 325, exempting small producers, in the House Agriculture Committee.

NMPF has been an industry leader and vocal opponent to making raw milk more accessible to consumers.

Contact: Beth Briczinski

NMPF Challenges FDA's Hazard Analysis Guidance

In late February, NMPF challenged a number of flaws in FDA's Hazard Analysis and Risk-Based Preventive Control for Human Food Draft Guidance for Industry, also known as the Preventive Control for Human Food rule, under the Food Safety Modernization Act (FSMA).

In the guidance, FDA identified hazards that the dairy industry should consider when developing food safety plans, as required by the rule. NMPF replied that FDA's definition of a "hazard" includes consideration of the severity of a potential injury or illness, as well as the probability that one will occur. FDA listed many hazards that NMPF argued would not result in an injury or illness or had little to no probability of occurring.

FDA identified drug residues in dairy products as a chemical hazard that should be considered when conducting a hazard analysis. NMPF challenged this concern, pointing out that the dairy industry tests approximately 99 percent of the raw milk supply for beta-lactam residues. Last year's national survey of milk tankers found that only 0.011% tested positive, while the testing of retail-ready dairy products found zero residues. In addition, a review of the scientific literature failed to identify any allergic reaction to drug residues in milk. FDA also identified lactose as a potential hazard, and suggested allergen labeling as a form of preventive control. However, lactose is not an allergen and therefore would not trigger an allergic reaction. NMPF asked for that section of the guidance to be redrafted to avoid confusing consumers about the distinction between milk protein allergies and lactose intolerance.

However, NMPF did concur with FDA that pathogens in raw milk are a hazard that should be addressed, which is why milk and dairy products are pasteurized and raw milk sales should be restricted.

In a second set of comments on the guidance, NMPF pointed out that the product categories were inappropriately named. NMPF argued that for the sake of consistency, clarity, and to avoid consumer confusion, the names of non-dairy alternatives should reflect federal standards of identity. NMPF requested the names for some products to be changed to rice or soy "beverage" and "soy-based frozen dessert," or else include the word "imitation." NMPF will continue to argue for proper use of standardized dairy terms.

Contact: Beth Briczinski or Clay Detlefsen

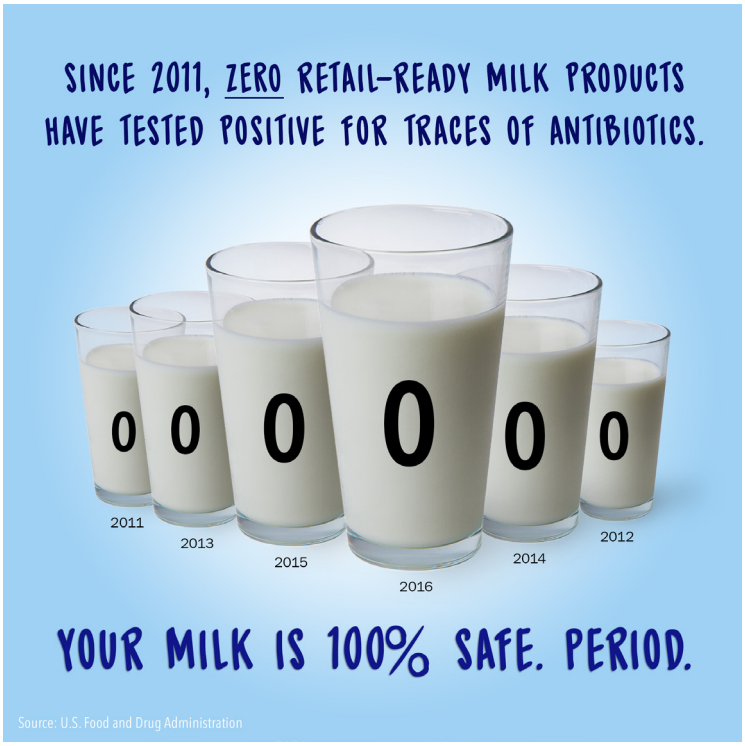
Food Safety

Annual FDA Drug Residue Report Finds Continued Progress

Only 1 out of 8,800 milk tankers tested positive for antibiotic residues in 2016, according to the 2016 National Milk Drug Residue Database report released last month by the U.S. Food and Drug Administration – continuing a long-term national pattern of improvements in milk quality practices on the farm. Of the approximately 3.1 million milk pick-up tankers tested in the past year, only 350 (0.011%) yielded a positive – down from 0.012% in 2015.

Additionally, not a single sample of the 38,329 consumer-packaged pasteurized milk products tested positive for animal drug residues. Data from the last seven years have not yielded a single positive drug test result for pasteurized Grade A products.

Contact: Beth Briczinski



Sanitary Food Transportation Rule Takes Effect in April; NMPF-Requested PMO Waiver Under Review

The Sanitary Food Transportation Act, part of the Food Safety Modernization Act (FSMA), will go into effect April 7, 2017, for all businesses except small ones. This rule allows FDA to waive the requirements of this rule if it has determined that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health. NMPF has asked for a waiver on several occasions and. in early March, FDA said a waiver for Pasteurized Milk Ordinance-regulated activities has been drafted and is under review prior to being published the *Federal Register*. Specifically, FDA stated the waiver 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."

NMPF is pleased about this update, but remains skeptical over whether the waiver will apply to outbound, finished Grade "A" products, and whether shipping non-Grade "A" with Grade "A" products will alter the waiver. NMPF has argued that the waiver should apply to outbound shipments, and the inclusion on non-Grade "A" with Grade "A" products should not alter the waiver. NMPF anticipates this waiver will be published prior to the April 7 compliance date.

Contact: Clay Detlefsen

Food Safety

NMPF Preparing Comments for FDA Guidance on *Listeria* in RTE Foods

NMPF is preparing comments on FDA guidance on the "Control of *Listeria monocytogenes* in Ready-To-Eat Foods," issued in January of this year. The guidance, an update of the 2008 original, reflects the modernized current good manufacturing practice (CGMP) and preventive controls regulation issued under the Food Safety Modernization Act (FSMA), as well as recommendations made by FDA's Food Advisory Committee in December 2015.

This guidance is intended to help the dairy industry and other food sectors comply with the CGMP and preventive controls requirements of Part 117 addressing measures that can significantly minimize or prevent the contamination of ready-to-eat (RTE) food with *Listeria monocytogenes* (Lm). The guidance specifically focuses on the possibility of contamination whenever a RTE food is exposed to the environment prior to packaging, and the packaged food does not receive a treatment or include a control measure (such as a formulation lethal to Lm) that would significantly minimize the pathogen.

Listeria monocytogenes (Lm) is a pathogen that can grow in cold, refrigerated environments, is particularly harmful to the elderly, pregnant women and/or their pregnancy, and those who are immunocompromised. Lm contamination accounts for a significant percentage of Reportable Food Registry incidents and has been responsible for several high-profile recalls and investigations.

NMPF will submit its comments by July 17, 2017.

Contact: Beth Briczinski

Food Safety

NMPF Continues Work on Harmonization of PMO and FSMA

At the National Conference on Interstate Milk Shipments (NCIMS) two years ago, several changes were made to the Pasteurized Milk Ordinance (PMO) to harmonize it with the FSMA Preventive Controls for Human Food (PCHF) rule. Those changes were made based on a proposed version of the rule, not the final version. With a final rule in place, NMPF, as a member of the NCIMS Liaison Committee, has been working with FDA to address further changes to the PMO that will need to be made to reflect additional aspects of the final rule.

National Milk has asserted that the additional changes, which relate to hazards not addressed in the traditional PMO, should be addressed in a new Appendix to preserve the integrity and success of the PMO and the agreement that has worked so well for decades. This should make it much clearer to the regulated community and inspectors, and NMPF can coordinate the inspection frequency on non-traditional PMO items to coincide with the inspection schedule laid out by FSMA.

The changes will be discussed and voted on at this year's conference in Grand Rapids, Mich., from May 12 -17, 2017. NMPF will attend the conference to advocate positions of interest to dairy cooperatives and their producer members. NMPF has already submitted 12 proposals to the conference, and authored or reviewed others.

NCIMS is a non-profit organization whose goal is to "assure the safest possible milk supply for all the people." Conference registration information can be found online. NCIMS meets biennially in odd-numbered years.

Contact: Clay Detlefsen or Beth Briczinski

Food Safety

NCIMS Residue Testing Pilot Program to Begin; NMPF Offers Webinar

NMPF will host a members-only webinar in April to provide an update on the development and implementation of an NCIMS Appendix N Pilot Program that will expand regulatory testing of raw milk to veterinary drugs beyond beta-lactams.

In March 2017, the NCIMS Appendix N Modification Committee accepted the Charm ROSA Tetracycline-SL test (with dilution confirmation) for use in the Pilot Program. The committee proposed a start date of July 1, 2017, for testing under the Pilot Program (the start of Q3), pending confirmation by the NCIMS Executive Board.

During the webinar, NMPF will review the status of the Pilot Program and testing requirements. Please contact Beth Briczinski for information to join the webinar.

Contact: Beth Briczinski

Nutrition

NMPF Opposes Proposed WIC Changes

NMPF has objected to suggestions released in January by the National Academy of Sciences (NAS) calling for a reduction in the amount of dairy foods offered through the federal feeding program for low-income Americans.

Responding to a request from Congress, the NAS reviewed the Women, Infants, and Children (WIC) program's food offerings to provide support for aligning the WIC with foods recommended by the Dietary Guidelines for Americans.

With support from the Food and Nutrition Service of the U.S. Department of Agriculture, NAS convened an expert committee to review and assess the nutritional status as well as the food and nutritional needs of the WIC-eligible population, and provide specific recommendations based on its review and the most recently-available science.

In criticizing the recommendation, NMPF noted that dairy – an irreplaceable source of nutrition for Americans – is already widely under-consumed among WIC recipients. NMPF noted that milk, cheese and yogurt are "the No. 1 source of nine essential nutrients in children's diets: protein, calcium, phosphorus, magnesium, potassium, vitamins A, B12, D and riboflavin."

The NAS report did contain some pro-dairy provisions, such as that yogurt should be easier for women to obtain through the WIC program. The NAS recommendations will now be reviewed by USDA. NMPF will make sure to highlight the value of dairy foods to all Americans and challenge the notion that reductions in the WIC dairy offerings are a prudent change in nutritional policy.

Contact: Beth Briczinski

Nutrition

National Academies Releases DGAC Report

When the newest edition of the Dietary Guidelines for Americans (DGA) was released in early 2016, some of the nutrition recommendations received criticism from stakeholders, leading to questions about the advisory committee's composition and membership selection processes. In response, Congress mandated an evaluation of the process by which the DGA are created. NMPF provided oral testimony on the review of the DGA process before the National Academies in October 2016.

The resulting report was released last month by the National Academies of Sciences Engineering and Medicine Health and Medicine Division and titled "Optimizing the Process for Establishing the Dietary Guidelines for Americans: The Selection Process."

This is the first report in a larger comprehensive review of the DGA process, examining how the DGA Committee selection process can be improved to provide more transparency, eliminate bias and include committee members with a range of viewpoints. NMPF will continue to participate in the review process.

Key recommendations ask the secretaries of the Agriculture and Health and Human Services departments to do the following:

1. Employ a third party to review and narrow the DGA committee candidate pool to a list of primary and alternate nominees. Criteria against which nominees are screened should be developed by USDA and HHS for use by the third party.
2. Create a list of provisional DGA committee appointees available for public comment — including short biographies and any known conflicts — for a reasonable period prior to appointment.
3. Disclose how provisional nominees' biases and conflicts of interest are identified and managed.
4. Adopt a system for continuous process improvement to enhance outcomes and performance of the DGA committee selection process.

Contact: Beth Briczinski

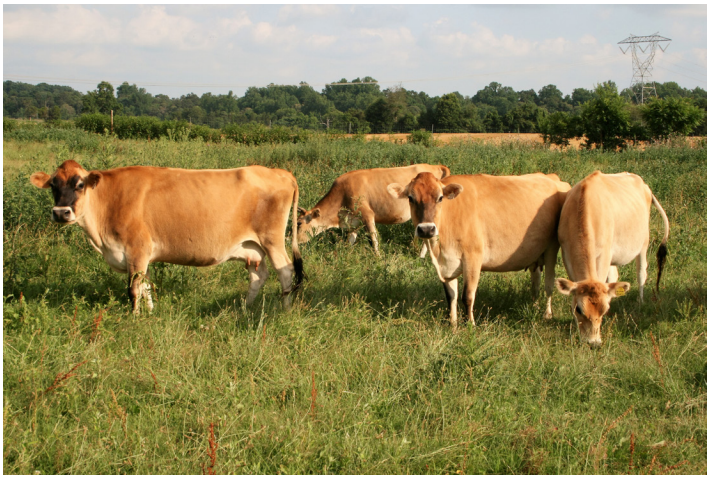
Animal Health

NMPF: More Data Needed on Duration of Antibiotic Treatment for Certain Cattle Diseases

As FDA gathers and reviews evidence on the use of livestock antibiotics, NMPF told the agency this month that in the case of certain veterinary treatments, the agency needs to collect more data before changing currently approved treatment durations.

On March 10, NMPF submitted joint comments with the National Cattleman's Beef Association, the Academy of Veterinary Consultants, and the American Association of Bovine Practitioners in response to an FDA request regarding the Judicious Use of Establishing Appropriate Durations of Therapeutic Administration of Medically Important Antimicrobial Drugs in Food-Producing Animals. FDA solicited comments from NMPF and other industry groups about establishing targeted treatment durations when using medically important antimicrobial drugs for therapeutic purposes. This includes medications administered in the feed or water of food-producing animals.

NMPF and the other groups conducted a thorough scientific review on currently approved antibiotic treatments for cattle diseases, including anaplasmosis, enteritis, liver abscesses and pneumonia. The scientific review revealed that current data supports the therapeutic use of antimicrobials with defined FDA treatment durations for several reasons: there is evidence



of the efficacy of their use in cattle; the use is consistent with accepted veterinary practice; the use addresses a specific pathogen; and there are currently no available or effective alternatives to antibiotics. Additionally, only a veterinarian of record who is familiar with a specific cattle operation is positioned to determine the most appropriate duration of antimicrobial therapy for a specific group of animals, based on an assessment of disease risk.

Contact: Jamie Jonker

Animal Health

NMPF Assesses Science-Based Tactics for Protection of U.S. Ag

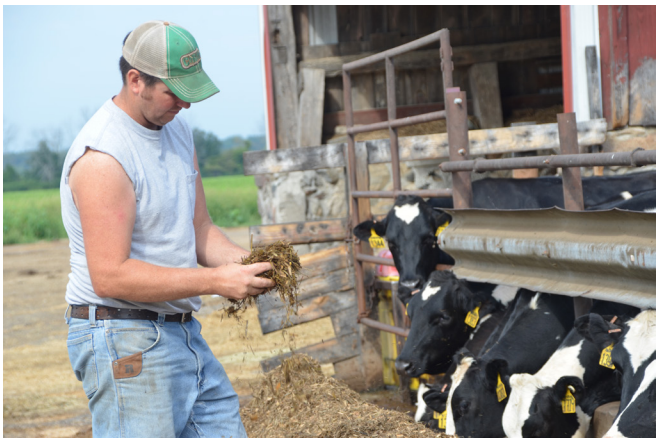
NMPF presented the dairy industry's food defense priorities during a workshop in mid-February focused on "Tactical Sciences for the Protection of the U.S. Agricultural Enterprise." Tactical sciences are the scientific assets that protect the integrity, reliability and sustainability of the U.S. food and agriculture system against known and potential threats from plant, animal and human pests and diseases.

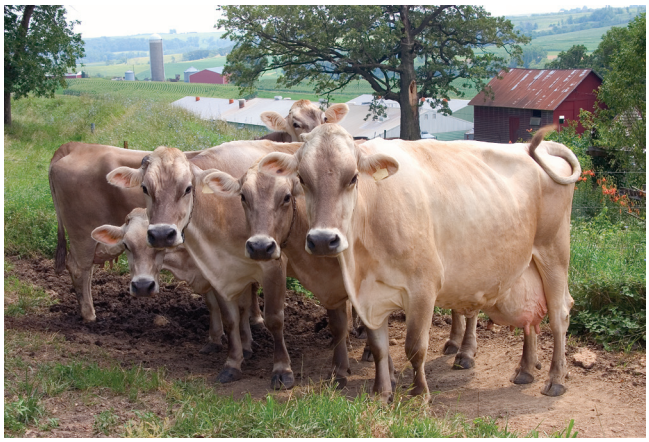
With increasing threats to our food systems as a result of the impacts of globalization, climate change, and other factors affecting the variety of pests and diseases seen today in agriculture, the government is working with academic and industry groups, including NMPF, to review where additional scientific resources are needed to protect our nation's food and agricultural systems.

The workshop was hosted by the University of Maryland in conjunction with USDA National Institute of Food and Agriculture (NIFA). NIFA's current tactical science investments are focused in three areas: detection and diagnostics, regulatory systems support, and the deployment of new crop/animal production and protection technologies and management systems.

The event included academic, industry, state and federal stakeholders that discussed current and anticipated pest and disease challenges facing the U.S. agricultural enterprise. They also touched on the programmatic and organizational infrastructure needed to effectively address these challenges, and possible strategies for re-aligning or re-inventing the current NIFA tactical sciences portfolio. Among the potential disease challenges, NMPF discussed the importance of focusing research and infrastructure needs for Foot and Mouth disease to protect the U.S. dairy industry.

Contact: Jamie Jonker





Animal Health

NMPF Offers Dairy Perspective at Government Workshop on Protecting U.S. Cattle Herd

Members of NMPF's Animal Health and Wellbeing Committee provided the dairy industry perspective during a government workshop March 13-15 focused on protecting the U.S. cattle herd from emerging diseases. The event was conducted by the Institute for Infectious Animal Diseases, in conjunction with the Department of Homeland Security and U.S. Department of Agriculture (USDA). The session identified ways to enhance risk-based prevention, preparedness and response to priority diseases affecting the beef and dairy sectors.

The workshop expanded on the USDA August 2016 draft of the Emerging Animal Disease Preparedness and Response Plan in three areas: Improved knowledge of the risk for emerging and re-emerging priority cattle diseases, enabling improved U.S. analysis for prevention and preparedness; identification of needs, gaps and barriers to improve early warning and detection of emerging diseases of cattle in the U.S. and North America; and initiating discussions toward defining appropriate, effective and risk-based priority disease surveillance needs for protecting the U.S. cattle industry.

Contact: Jamie Jonker

Environment

Trump Signs Order to Begin Rollback of Waters of the U.S. Rule

NMPF praised the Trump Administration in late February for its decision to begin rolling back the controversial Waters of the U.S. (WOTUS) rule, which expanded federal authority over certain waters and led to widespread concern from farmers about its ambiguity and potential for serious regulatory overreach.

The original WOTUS regulation, proposed in April 2014 by the U.S. Environmental Protection Agency (EPA) and the U.S. Army Corps of Engineers, included "navigable" waters, but was later expanded to include upstream waters and streams, which farmers often use for drainage and irrigation.

NMPF submitted comments in 2014 stressing that dairy farmers need certainty on which waterways fall under Clean Water Act jurisdiction and which do not. NMPF stressed that either its recommendations be included in the final version, or else the rule be withdrawn and rewritten. NMPF's recommendations were ultimately not included.

WOTUS has been tangled up in litigation, with numerous lawsuits filed against the EPA by states and industry stakeholder groups. On Oct. 9, 2015, the U.S. Court of Appeals for the Sixth Circuit ordered a nationwide stay of implementation, and earlier this year, the U.S. Supreme

Court halted it indefinitely to determine which courts have jurisdiction over the matter.

President Trump's executive order provides the opportunity to rewrite the regulation. NMPF and the dairy industry will work with EPA and Army Corps of Engineers to find a solution that maintains a healthy ecosystem while protecting farmers from regulatory confusion.

Contact: Jamie Jonker

NMPF News

NMPF Accepting 2017 Scholarship Applications

NMPF is now accepting applications for its 2016-2017 scholarship program. Each year, the National Milk offers scholarships to qualified graduate students (enrolled in master's or Ph.D. programs) who are actively pursuing dairy-related fields of research that are of immediate interest to NMPF member cooperatives.

Graduate students pursuing research of direct benefit to the dairy industry are encouraged to apply. Applicants do not need to be members of NMPF to qualify. Materials must be received no later than April 7, 2017.

To qualify for the NMPF scholarship program, applicants must be currently enrolled in a graduate degree program in the United States and must follow all instructions in the application form. Completed applications consist of an application package (an information form, a brief research summary and a current resume) and two letters of recommendation. All application materials should be emailed to Beth Briczinski.

Scholarship recipients will be selected by the NMPF Board of Directors in June 2016 and will be notified soon afterward. Payment will be made to coincide with the start of the 2016-17 academic year.

Contact: Beth Briczinski

Upcoming Dates

Animal Ag Alliance Summit Kansas City, MO	May 3-4, 2017
NCIMS 2017 Conference Grand Rapids, MI	May 12-17, 2017
Northeast U.S. Animal Health Association Atlantic City, N.J.	May 21-24, 2017
NMPF Board of Directors/YC Meeting Washington, D.C.	June 12-14, 2017
American Dairy Science Association (ADSA) Annual Meeting Pittsburgh, PA	June 25-28, 2017
National Association of Dairy Regulatory Officials (NADRO) Annual Meeting Jupiter, FL	July 9-12, 2017

NMPF
NATIONAL MILK PRODUCERS FEDERATION

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

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

Clay Detlefsen
Senior Vice President, Regulatory &
Environmental Affairs & Staff Counsel
cdetlefsen@nmpf.org

Jamie Jonker
Vice President, Sustainability & Scientific Affairs
jjonker@nmpf.org