NMPF
NATIONAL MILK
PRODUCERS FEDERATION

# REGULATORY REGISTER

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## Dietary Guidelines Committee Holds Second Meeting

NMPF's newest regulatory expert, Miquela Hanselman, testified at joint U.S. Department of Agriculture and U.S. Department of Health and Human Services meetings soliciting public comment on the upcoming update of the Dietary Guidelines for Americans on July 10th and 11th.

The meetings began with each of the DGAC's six subcommittees and one working group presenting draft protocols or proposed scientific approaches which will be used to examine the scientific evidence. These protocols include analytic frameworks, inclusion and exclusion criteria, and search strategies, all of which are available online. The committee has requested comment on the protocols by July 24th; however, the comment period will be open for the entirety of the dietary guidelines process.

The second part of the meeting focused on comments from members of the public. While some public comments were anti-dairy and not supported by scientific literature, the dairy industry was united in promoting the importance of dairy in healthy diets. NMPF and the National Dairy Council commented on key areas regarding dairy's important place in the dietary guidelines.

Our key priorities for dairy include:

- Maintaining dairy as a separate nutritional group
- Maintaining the recommendation of three dairy servings per day
- Preventing non-dairy beverages from being allowed into the dairy group
- Emphasizing the protein quality of dairy products

You can find the full statement here. NMPF will submit written comments and continue to monitor the dietary guidelines as more information is released.

Contact: Clay Detlefsen

## NMPF Cheers EPA Efforts to Exempt Manure Air Emission Reporting Under EPCRA

NMPF celebrated a successful milestone in a more than two-year effort on June 5 when the Environmental Protection Agency issued a final rule that codified its earlier interpretation that air emissions from manure are not reportable under the Emergency Planning and Community Right-To-Know Act.

The Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 was created to help communities plan for chemical emergencies and requires industry to report on the storage, use and release of hazardous substances to federal, state, and local governments. The extent to which agricultural operations needed to be included has been controversial, with the EPA moving toward fewer burdensome requirements for farmers.

NMPF had been engaged with the effort to codify the manure exemption since April 2017, filing comments as recently as last December supporting EPA's efforts last fall to modify its regulations to eliminate the reporting of ammonia or hydrogen sulfide air emissions from manure.

EPA's final actions with EPCRA is consistent with Congress' recent action to exempt manure emissions reporting requirements under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). NMPF supported that approach and noted that EPCRA's legislative history showed that Congress did not intend for continuous air emissions reports to be filed under EPCRA if they were not required under CERCLA.

**Amended Text of Rule:**
The amended text states "air emissions from animal waste (including decomposing animal waste) at a farm" are exempt. Animal waste was formally defined to mean feces, urine or other excrement, digestive emission, urea, or similar substances emitted by animals (including any form of livestock, poultry, or fish). This term includes animal waste that is mixed or commingled with bedding, compost, feed, soil, or any other material typically found with such waste.

Contact: Clay Detlefsen

## FDA Opens Potassium Chloride Labeling Docket

FDA opened a docket in May to allow for comments regarding its draft guidance for industry entitled "The Use of an Alternate Name for Potassium Chloride in Food Labeling." The guidance was put together in response to the use of potassium chloride in foods in place of traditional salt to decrease the amount of sodium in the food supply.

NMPF will be filing joint comments with the International Dairy Foods Association. These comments will include two key points:

1. Cheese should not be included in the voluntary sodium reduction goals. Sodium is an important part of the cheesemaking process that affects the water content and water activity and influences functional characteristics like body and texture.
2. The FDA should expand any enforcement discretion to facilitate the use of potassium chloride in standardized foods whose definitions call for "salt" but ensure that the amount of substitution is solely in the discretion of the manufacturer.

Currently, the docket closes in September, and the FDA will issue its final guidelines after reviewing the comments. NMPF will keep watch on this topic and work with FDA as necessary.

Contact: Miquela Hanselman or Clay Detlefsen

## NMPF Farmer Leadership Meets with USDA on Important Animal Health Issues

Karen Jordan, DVM, Chair of the NMPF Animal Health and Wellbeing Committee, and NMPF staff met with USDA APHIS Administrator Kevin Shae and other USDA animal health leadership on June 13 to discuss  animal-health issues for U.S. dairy farmers.

Dr. Jordan spoke about the importance of industry-government collaboration on preparedness for foreign animal diseases such as Foot and Mouth Disease. She also commented on the need for USDA to modernize the FMD Vaccine Bank, stating, "while there is always the promise for better vaccines in the future, now is the time to build a best-in-class FMD Vaccine Bank with the new funding provided by the 2018 Farm Bill." Dr. Jordan also stressed the need to maintain and enhance the Secure Milk Supply and the FMD Bulk Tank Milk Test.

The meeting also addressed domestic cattle diseases. USDA is currently revising and updating the National Tuberculosis Eradication Program standards to meet contemporary challenges of disease eradication, including disease transmission, lower disease incidence, and changing production systems. Dr. Jordan complimented USDA for its monthly teleconferences with the dairy and beef sectors and identified improving TB diagnostics as a priority for advancing TB eradication. The current diagnostic test (caudal fold test) has outlived its usefulness for the Test and Remove Protocol for dairy herds affected by TB, she said.

Dr. Jordan also said trade is important to U.S. dairy farmers. "Today more than 15 percent of U.S. milk is exported around the world, and APHIS leadership is necessary to maintain and enhance market access for U.S. dairy farmers," she said. The important work that USDA APHIS does with Codex Alimentarius, the World Organization for Animal Health, and animal health certification for export certificates is vital to maintain and expand trade.

Contact: Jamie Jonker

## NMPF Praises Clarity and Certainty in Endorsing EPA WOTUS Proposal

NMPF in April endorsed the Environmental Protection Agency's proposed changes to the Waters of the U.S. rule, a plan meant to provide clarity and certainty about the waterways subject to regulation under the federal Clean Water Act. Released in February 2019, the EPA proposal was a response to the ill-fated 2015 WOTUS rule that has been mired in litigation.

NMPF urged the EPA in 2014 to rethink WOTUS, citing its many ambiguities and uncertainties. A subsequent NMPF analysis showed that the EPA and Army Corps of Engineers' proposal did not meet the requirements of various Supreme Court rulings that were the catalyst for the 2015 regulation.

NMPF expressed strong support for the basic jurisdictional line EPA made around intermittent and more significant waters as being within the regulatory power of the United States. NMPF believes this line accurately reflects the U.S. Constitution, statutes, and court decisions interpreting the law.

"Clean water is essential to milk production, and the dairy industry is very willing to work with EPA to protect U.S. waters," said NMPF President and CEO Jim Mulhern. "EPA's latest draft provides the clarity and certainty we were seeking in 2014 around which waterways fall under the jurisdiction of the Clean Water Act. While it has taken five years, we are grateful EPA has redrafted the WOTUS regulations."

NMPF submitted extensive comments on the EPA regulation to clarify when farmers must seek Clean Water Act permits for a long list of normal farming activities near wetlands. While the WOTUS proposal did address many long-standing concerns, NMPF offered some additional points of clarity in other areas to further improve the proposal.

Contact: Jamie Jonker

# Dairy Foods Labeling Docket Remains Under Review

The dairy-labeling docket closed at the end of January with a total of just over 14,000 comments being filed. The docket, which was opened to "better understand how consumers use these plant-based products and how they understand terms such as, for example, 'milk' or 'yogurt' when included in the names of plant-based products, and if they understand the difference between plant-based products and dairy products including the basic nature, characteristics, ingredients and nutritional content.

The docket contained a wide array of comments ranging from people in support of properly labeling plant-based foods to people who were outraged the docket was even opened.

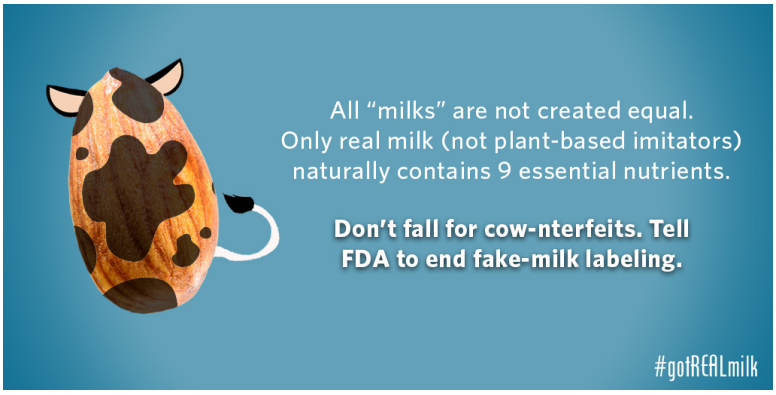
Many of the comments against the proper use of dairy terms were rants from plant-based consumers that appear to have misinterpreted what the docket was asking, with many making statements along the lines that "they are not so stupid they can't understand that soy or almond doesn't come from an animal. Duh," which is not related to the issues of nutritional confusion the FDA is examining.

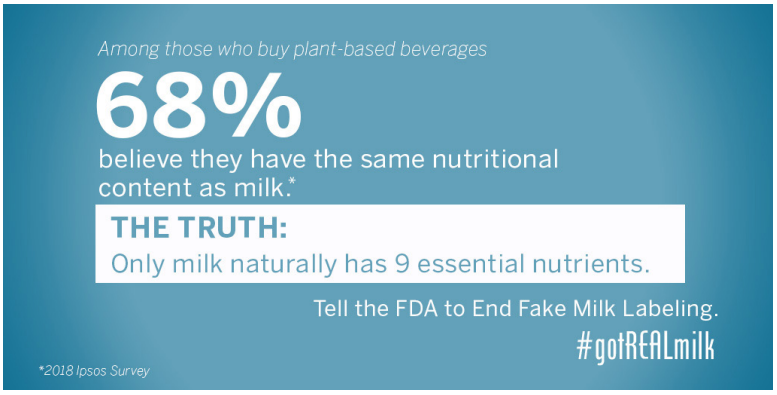
On the other side of comments, a pediatrician from upstate New York with no ties to the dairy industry wrote-in because of her concern with parents not understanding the nutritional difference between cow's milk and plant-based products. Her comment stated: "It is nutritionally different and deceptively marketed to parents trying to be healthy. I was horrified to find one set of parents feeding hemp milk to a small baby. I had another baby with a serious lifelong medical problem being given a wobbly start on a vegan diet." You can find her full comment here.

The American Academy of Pediatrics (AAP) felt similarly and stated: "Pediatricians report using the term 'milk' in the labeling of dairy-free alternatives has caused parental confusion, leading to the purchase of products that they assume contain traditional dairy ingredients and, thereby, unintentionally causing harmful nutritional deficiencies in their children." You can find the full comments from the AAP here.

NMPF would like to thank everyone that submitted a comment. In response to this docket, we have requested a meeting with FDA to emphasize the findings in this docket and the importance of this matter for consumers' health.

Contact: Clay Detlefsen




# NMPF Citizen Petition- File a Comment!

In response to the Citizen Petition on fake milk products filed by NMPF, the FDA has opened a docket for comments to be submitted. NMPF urges stakeholders to submit comments here to ensure that the agency continues to hear why this is such an important issue. This docket closes August 20th and the FDA is suspected to make a ruling regarding plant-based foods labeling by early next year.

**Details of the Petition:**
The petition argues that the use of standardized dairy terms such as "milk," "yogurt," "cheese," "ice cream" and "butter" on non-dairy plant-based substitutes "falsely implies that the non-dairy substitutes are equivalent to and interchangeable with standardized dairy foods." It also lays out a road map for what these plant-based products could be labeled as if they wanted to continue to use dairy terms on their packages, and details why this isn't a first amendment issue.

Contact: Clay Detlefsen

## Organic Trade Association Releases Questionable Study on Milk Residues

The Organic Trade Association in late June released an Emory University study which implausibly found that 60% of 35 conventional milk samples that were tested had antibiotic residues. The alleged antibiotics detected included sulfamethazine and sulfathiazole, which aren't allowed for use in lactating dairy cattle. One sample also allegedly tested positive for amoxicillin levels higher than what is approved by the FDA, despite all milk being tested for amoxicillin (and other Beta lactam drugs) as required by the Pasteurized Milk Ordinance. In addition to the antibiotics, the conventional samples also tested positive for pesticides which is inconsistent with recent USDA data. The organic milk samples tested were found to have no pesticides or antibiotics.

However, when lab experts began to analyze the methodology of the study, many questions were raised including the size of the study, the standards used for the testing, and the four-year lag period between sample collection and the published analysis. Furthermore, as part of the National Milk Drug Residue Monitoring Program which is conducted by the Food and Drug Administration (FDA), a report in 2018 found that out of the 60,000 milk samples tested for sulfonamide drugs, none of the samples tested positive. This fact is reinforced when looking at the 10-year historical data which found sulfonamide antibiotics present in only 99 samples of the 884,455 tested.

NMPF released a joint statement with the International Dairy Foods Association and the National Dairy Council stating that, "Milk is one of the safest foods you can buy. Regarding this new study, it is very important to note that information about the methodology used is so scant that serious flaws are likely to exist. Many of the key results raise red flags and leave more questions than answers, including a sample size that is not statistically valid, a four-year lag between data collection and published analysis, and results that are so far out of line with federal government data that they seem implausible. Given these facts, combined with the historical testing data using FDA-approved methodology that clearly demonstrates the occurrence of residues for several of the antibiotics in question is extremely rare, the data underlying this recent study must be considered highly questionable and not a true reflection of the U.S. milk supply."

The article, originally picked up by USA Today, was amended to include a piece on "reasons for skepticism" highlighting the potential flaws of this study, and other media pickup was virtually nonexistent.

Contact: Jamie Jonker or Clay Detlefsen

# FDA Launches New PFAS Webpage; Senate and House Pass Bills; Dairy Encouraged to Learn More

NMPF is encouraging its members to familiarize themselves with the Per- and Polyfluoralkyl (PFAS) issue, the subject of a website launched by the Food and Drug Administration at the beginning of the month. With two U.S. dairies among publicly reported examples of PFAS-contaminated areas, the dairy community will need to be better-educated on PFAS, as well as their real and perceived risks, as the substances gain government and media attention in the coming months.

PFAS contamination has become a rising concern among municipalities, military installations and businesses that may have high levels of the substances in their drinking water and soil. The FDA site explains what the substances are and the issues surrounding it. PFAS encompasses nearly 5,000 synthetic chemicals that stay in the environment for potentially thousands of years – they're sometimes referred to as "forever chemicals." Typically used in non-stick products because of their impermeability to grease, water and oil, PFAS chemicals are also found in stain and water-resistant fabrics and carpeting, cleaning products, paints, and fire-fighting foams.

PFAS can be found in food primarily through environmental contamination, including the use of contaminated water and soil to grow food for human or animal consumption. While health impacts have not been substantiated, the FDA is working to better understand the potential dietary exposures by sampling for contamination and reviewing the current authorized uses of PFAS in food contact applications.

Amounts of PFAS exceeding the Environmental Protection Agency health advisory limit have been found on two U.S. dairies. One of the farms, located in New Mexico, was contaminated because of the use of firefighting foams containing PFAS on the Air Force base nearby. Water samples from the surrounding area were found to be 35 times greater than the advised limit. The second farm, located in Maine, was spreading sewage sludge which contained PFAS on to their fields. Neither farm is currently able to ship their milk, and further testing on dairy farms suggests the presence of exceedingly high PFAS levels may be isolated instances.

The Senate was the first to pass PFAS legislation as part of the National Defense Authorization Act which includes provisions regarding PFAS contamination. These include 1) authorizing the U.S. Geological Survey to develop advanced testing methods to detect and catalog PFAS in the environment, 2) allowing the Department of Defense to acquire PFAS-contaminated land surrounding airbases and to provide compensation to the land owners, 3) authorizing the Department of Defense to engage in remediation to clean-up ground water and 4) to provide water to the agricultural operations impacted.

The House legislation passed as well and includes giving the Department of Defense the ability to provide water to impacted agricultural operations, adds funding for the Centers for Disease Control's nationwide PFAS health survey and similarly to the Senate bill, adds funding for the U.S. Geological Survey to conduct sampling for PFAS contamination. NMPF will be working hard to make sure all provisions from the Senate legislation are included in the final Bill.

In addition, NMPF has been working closely with the FDA, EPA, state officials, and IDFA to stay on top of the issue, emphasizing that it is a drinking water issue and to advocate on behalf of dairy farmers.

Contact: Clay Detlefsen

# NMPF Pleased with NCIMS Results

The 2019 National Conference on Interstate Milk Shipments meeting that ran from April 26-May 1 in St. Louis was a win for U.S. dairy producers, as NMPF staff, members and state and federal agencies successfully debated and secured modifications that help the industry.

The widely attended biennial conference included more than 400 federal, state and industry leaders. NMPF had submitted several proposals, three of which were considered "must-pass":

- A proposal for streamlining the information required on a shipping statement for milk and milk products;
- A proposal on antibiotic testing that provides clarity on confirmation testing for antibiotic residues;
- And a proposal recognizing the importance of drug residue testing by making the ad-hoc committee on drug residue testing a permanent full standing committee.

Through collaboration with our members, the processing industry and our state and federal partners, all three proposals successfully made it through the complex NCIMS process. For more detailed information on the outcomes of the proposals, please see our special NCIMS edition of the Regulatory Register, which can be found on the NMPF website.

Contact: Clay Detlefsen

## Dairy Groups Participate in World Organization for Animal Health General Sessions


In May, Jamie Jonker (NMPF) and Nick Gardner (USDEC) joined the U.S. delegation to the 87th World Assembly of the World Organization of Animal Health (OIE) held in Paris. The OIE is recognized by the World Trade Organization for setting science-based standards to help manage animal diseases and improve animal health and welfare. These standards can be adopted by countries into national regulations.

NMPF is closely monitoring several issues of interest raised at the meeting. Among them are the formation of a new antimicrobial resistance (AMR) working group that will begin working over the next year and updates on global outbreaks of animal diseases that could impact U.S. dairy exports, including foot and mouth disease, African swine fever and lumpy skin disease. Animal welfare was also discussed, although sections specific to dairy production were completed with NMPF input several years ago.

NMPF worked closely with other U.S. animal organizations and international partners including the International Dairy Federation (IDF) during the meeting to ensure visibility of the potential impacts of OIE policies on AMR and the state of these disease outbreaks on trade in dairy products. The 87th World Assembly of the World Organization of Animal Health Final Report is available online. This work was made possible through support of the U.S. Dairy Export Council.

Contact: Jamie Jonker

## NMPF Submits Comments on Codex Antimicrobial Resistance Documents

In May, NMPF and the U.S. Dairy Export Council (USDEC) jointly submitted comments to the U.S. Department of Agriculture and U.S. Food and Drug Administration on the Codex Task Force on Antimicrobial Resistance (TFAMR) documents, "Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance" and "Proposed Draft Guidelines for the Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance." NMPF and USDEC have been engaging the U.S. government for over two-years to ensure the Codex TFAMR documents support the responsible and prudent use of antibiotics without endorsing unscientific and unfair barriers to U.S. dairy exports (see previous Regulatory Registers for more information). Additionally, NMPF and USDEC have provided leadership to the International Dairy Federation efforts to develop global dairy consensus on responsible and prudent use of antibiotics.

The comments focused on the need for antimicrobial use for animal health and welfare, which counters some proposals that restrict antibiotic use in animals without reducing the risk of AMR. Additional comments sought to maintain the Codex mandate on food safety for risk mitigation of the potential spread of AMR through the food chain – some countries wish to expand these documents beyond the Codex mandate of food safety into animal health, which is already covered by the World Organization of Animal Health. All comments on these documents will be considered at the next Codex TFAMR meeting to be held in December in South Korea. The CODEX TFAMR work is anticipated to be completed in 2020.

This work was made possible through support of the U.S. Dairy Export Council.

Contact: Jamie Jonker

## NMPF CEO Discuss Bovine TB Eradication Program Modernization with USDA Undersecretary Ibach

NMPF President & CEO Jim Mulhern met on June 27 with USDA Undersecretary Greg Ibach and other USDA staff to discuss modernization of the National Tuberculosis Eradication Program. The TB eradication program, started in 1917, was last updated 2005, making its rules less applicable to current TB risks or the transformation of the U.S. dairy industry over the last 15 years.

In a wide-ranging discussion, Mulhern and Ibach touched upon several areas that will influence and necessitate modernization of the TB eradication program, including the white tail deer reservoir in Michigan, worker to animal TB transmission, and TB diagnostics. Traditionally, the TB eradication program has focused on whole-herd buyouts when TB has been discovered, however due to producer interest, more complex animal movements, and increasing average herd size, an effective Test and Remove Protocol which is easy to implement is needed as part of the modernization of the TB eradication.

Mulhern reiterated to USDA the dairy industry's commitment to continue to be partner in the TB eradication program. The NMPF Animal Health and Wellbeing Committee has established a TB Task Force to identify dairy industry priorities and to work with USDA on modernizing the TB eradication program.

Contact: Jamie Jonker

## 2019 FARM Drug Residue Prevention Manual Now Available

For more than 30 years, the U.S. dairy industry has focused educational efforts on the judicious use of antibiotics through the annual publication of a best practices manual. The 2019 National Dairy FARM Milk & Dairy Beef Residue Prevention Reference Manual is the primary educational tool for dairy farm managers throughout the country on the judicious and responsible use of antibiotics, including avoidance of drug residues in milk and meat.

The manual is a quick resource to review those antibiotics approved for dairy animals and can also be used as an educational tool and resource for farm managers as they develop on-farm best management practices necessary to avoid milk and meat residues. For ease of use, the most recent update includes a reorganization of the manual into eight chapters. Antibiotic use and treatment forms are also available on the National Dairy FARM website.

Contact: Jamie Jonker

## National Bio and Agro-Defense Facility Advances

Last month, U.S. Department of Agriculture (USDA) and the Department of Homeland Security signed a Memorandum of Agreement that formally outlines how the departments will transfer ownership and operational responsibility for the National Bio and Agro-Defense Facility (NBAF) from DHS' Science and Technology Directorate to USDA. When completed, NBAF will be a biosafety level-4 laboratory in Manhattan, Kansas – the only large-animal BSL 4 lab in the United States' mainland- for the study of diseases that threaten both U.S. agriculture and public health. The state-of-the-art NBAF facility will replace the aging Plum Island Animal Disease Center in New York. USDA also released a document outlining USDA's strategic vision for NBAF summarizing how NBAF will serve as a national biosecurity asset to protect human and animal health, food safety and the ag economy.

Under the terms of the memorandum, DHS retains responsibility for completing construction and commissioning of the $1.25 billion facility, while USDA will assume responsibility for all operational planning and eventual operation of the facility. DHS' efforts are on schedule and on budget to complete construction in December 2020 and to complete commissioning in May 2021, when ownership of NBAF will be formally transferred to USDA. USDA does not currently have an operational and maintenance budget for the NBAF facility, so new funds will need to be authorized and budgeted to ensure it becomes the world-class animal disease research center that has been envisioned.

Contact: Jamie Jonker

## NMPF Regulatory Staff

**Clay Detlefsen, Esq.**
**Senior Vice President, Regulatory & Environmental Affairs**
cdetlefsen@nmpf.org
Clay deals with initiatives related to food safety and defense, product labeling, and environmental issues.

**Jamie Jonker, Ph.D.**
**Vice President, Sustainability & Scientific Affairs**
jjonker@nmpf.org
Jamie's work in sustainability and scientific affairs includes animal health, biotechnology, biosecurity, air and water quality issues, sustainability, and technical service issues.

**Miquela Hanselman**
**Manager, Regulatory Affairs**
mhanselman@nmpf.org
Miquela works on NMPF's regulatory efforts, focusing on issues related to interstate shipments of milk, food safety, labeling, nutrition, and the environment.

**National Milk Producers Federation**
2107 Wilson Blvd., Suite 600
Arlington, VA 22201
(703) 243-6111
www.nmpf.org

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance dairy producers and the cooperatives they own. NMPF's member cooperatives produce more than two-thirds of all U.S. milk, making NMPF the voice of dairy producers in Washington. For more, visit www.nmpf.org.