# Regulatory Register

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NATIONAL MILK PRODUCERS FEDERATION

INSIDE...



## Environment Introducing: Newtrient

Newtrient, LLC, was formed this past summer by twelve of the nation's dairy cooperatives, the National Milk Producers Federation and Dairy Management Inc. The company is headed by Steve Rowe, former general counsel at Darigold.

Newtrient's focus is on treating manure as a valuable product. Mr. Rowe has assembled a team of experts to drive the vision of reducing the dairy industry's environmental footprint while improving its economics. Newtrient was formed after years of exploration into how the dairy industry could take advantage of technology to protect or improve the environment and to provide an additional revenue source for producers, thus improving every dairy producer's social license to operate.

Early steps have included collecting information on the nutrient recovery technologies that make it easier for producers to assess their own needs, and to find out which technologies or practices help them the most. One of the biggest challenges will be figuring out which markets handle the outputs from the various nutrient recovery technologies.

The creation of Newtrient has generated quite a buzz in many public and private circles, which will help drive innovation and will result in meaningful improvements in the economics and efficiencies of nutrient recovery and other technologies.

Contact: Clay Detlefsen or Ryan Bennett

## Environment Update on Waters of the U.S. Final Rule

On October 9, the U.S. Court of Appeals for the Sixth Circuit ordered a nationwide "stay" of implementation of the Waters of the U.S. (WOTUS) Final Rule, which became effective August 28. The nationwide stay was granted by a 2-1 vote, with the majority finding "a substantial possibility of success on the merits of their [18 states bringing the suit] claims." The court took issue with both the content of the rule, as well as the lack of notice and comment for significant changes that were added in the final version. Due to both procedural and merits claims, the court ordered that "The Clean Water Rule is hereby STAYED, nationwide, pending further order of the court."

On August 27, an injunction on the compliance and enforcement of the WOTUS Final Rule was issued by the U.S. District Court for North Dakota and applied to only the thirteen states that brought the lawsuit. After EPA and the Army Corps indicated they would proceed with enforcement and compliance in the remaining 37 states, on August 31, NMPF requested that enforcement of the regulations be suspended nationwide due to the preliminary injunction granted to the thirteen states in the North Dakota decision.

Contact: Jamie Jonker or Ryan Bennett

## Food Safety — Preventative Controls Rules for Human Food and Animal Food Finalized

On September 10, the U.S. Food and Drug Administration (FDA) took one of the most significant steps in decades to prevent foodborne illness by finalizing the first two of seven major rules under the Food Safety Modernization Act (FSMA). These preventive controls require human and animal food facilities to develop and implement written food safety plans that indicate the possible problems that could affect the safety of their products, and then outline steps the facility would take to prevent or significantly minimize the likelihood of those problems occurring. Food companies will be accountable for monitoring their facilities, identifying any potential hazards in their products and preventing those hazards from occurring.

The preventive controls final rules are the result of extensive outreach efforts. FDA incorporated thousands of public comments – including valuable input from farmers, consumers, the food industry and academic experts – to create a flexible and targeted approach to ensuring food safety. Though FDA initially envisioned that many facilities would be subject to both preventive controls rules, it modified its position after public comment such that most food processing operations for human food – like dairy – would only be subject to the human food rule even if some product gets diverted to animal food facilities.

Contact: Clay Detlefsen or Beth Briczinski

## Food Safety — Three More Major FSMA Rules Released

On November 13, the U.S. Food and Drug Administration (FDA) released three more major final rules that will help produce farmers and food importers prevent food safety problems before they occur: "Produce Safety, Foreign Supplier Verification and Accredited Third-Party Certification."

The Produce Safety rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables grown for human consumption. The Foreign Supplier Verification rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. The Accredited Third-Party Certification rule establishes a voluntary program for the accreditation of third-party certification bodies, also known as auditors, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce.

Now, with five major rules released, FDA can focus on the last two, the Intentional Adulteration and Sanitary Food Transportation rules. FDA still needs to release a substantial amount of guidance so that industry and stakeholders can better understand the new requirements.

Contact: Clay Detlefsen or Beth Briczinski

## Food Safety — NMPF Webinar on FSMA Preventative Controls for Human Food Rule

On November 20, NMPF staff conducted the first Food Safety Modernization Act (FSMA) webinar, which was well received by those who participated. This complimentary webinar focused on the Preventive Controls for Human Food (PCHF) rule – the most significant of the seven major FSMA rules – and was presented by Clay Detlefsen and Beth Briczinski.

During the webinar, staff outlined the rule's requirements and provided some background on how it was developed. Staff members also emphasized that, while the final PCHF rule was released, there is still considerable uncertainty about how effective and burdensome this rule will be. A much better assessment will be made when FDA releases numerous guidance documents on hazard analysis, preventive controls, allergen control and environmental monitoring, among other issues.

NMPF staff plan to routinely utilize similar webinars for other FSMA rules and guidance documents in the months ahead to ensure that the regulated community has reliable information with which to plan and make decisions.

Contact: Clay Detlefsen or Beth Briczinski

## Food Safety NMPF Comments on FDA's Raw Milk Cheese Assessment

On November 2, NMPF submitted comments in response to FDA's request for information on the assessment "Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk."

NMPF did not support finished product testing as a control measure, but did support the concept of a performance objective or performance standard for cheeses made from unpasteurized milk, and suggested criteria to evaluate intervention strategies or process controls. NMPF also supported clear labeling of cheeses made from unpasteurized milk, which could also include any specific technologies or intervention strategies (thermal or non-thermal) employed.

FDA's goal was to identify intervention measures that might affect the presence of bacterial pathogens in cheese manufactured from unpasteurized milk. The request was in response to scientific data on potential health risks associated with consumption of cheese made from unpasteurized milk.

Contact: Beth Briczinski

## Food Safety FDA Issues NCIMS Concur/Non-Concur Letter

The U.S. Food and Drug Administration (FDA) initially concurred with all of the passed proposals from the 2015 National Conference on Interstate Milk Shipments (NCIMS), with the exception of four (#219, #226, #227 and #246).

Three of these proposals (#219, #226, #227) were non-concurred with based on language adjustments and/or timing changes:

- #219: Allowing lab personnel approved by the Milk Lab Control Agency to do the averaging of sample results;
- #226: Changing the PMO bacteriological water standards to address EPA elimination of the Maximum Contaminate Level for Total Coliform and implementation of an *E. coli* MCL;
- #227: Changing the annual tank inspection frequency.

The NCIMS Board met on October 7-8, 2015, to review the FDA Concur/Non-Concur Letter. The NCIMS Board accepted the suggested wording and/or timing changes to the three proposals above, after which FDA then concurred. The fourth proposal (#246: Extending the time for transportation of water samples from 30 to 48 hours) was non-concurred with by FDA based on a lack of scientific data. The NCIMS Board directed the NCIMS Lab Committee to work on developing data necessary to address FDA's concerns before the 2017 conference.

All proposals with which FDA concurred will be incorporated into the PMO and related documents. All changes will take place one year from the electronic publication of those documents, unless otherwise specified.

The current estimated timeline is:

- November 2015: Electronic publication of PMO and related documents by FDA
- November 2016: Changes in PMO and related documents become effective.

Contact: Beth Briczinski

## Food Labeling FDA Requests Comments on "Natural," "Gluten-Free"

On November 12, the *Federal Register* included a request from the U.S. Food and Drug Administration (FDA) for information and comments on "Use of the Term "Natural" in the Labeling of Human Food Products." FDA is taking this action after receiving three citizen petitions asking that the term "natural" be defined for use in food labeling, and one citizen petition asking that FDA prohibit the term "natural" on some food labels.

NMPF will be submitting comments (due February 10) discussing the implications such a definition would have on dairy products. Please contact Beth Briczinski to assist in preparing or reviewing comments.

On November 18, FDA published a proposed rule in the *Federal Register*, "Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods," to establish requirements for fermented, hydrolyzed and distilled foods or ingredients that are labeled as "gluten-free." While the proposed rule would not require any "gluten-free" labeling, a manufacturer may voluntarily label its product as "gluten-free" if the food meets the applicable requirements.

Hydrolyzed, fermented or distilled foods (like cheese and yogurts) voluntarily bearing the "gluten-free" claim will still have to meet the requirements of the gluten-free food labeling final rule, including record-keeping requirements for manufacturers.

NMPF will be submitting comments (due February 16). Please contact Beth Briczinski to assist in preparing or reviewing comments.

Contact: Beth Briczinski

## Nutrition NMPF Comments on FDA's "Added Sugars" Proposal

On October 13, NMPF submitted comments in response to FDA's proposed rule "Food Labeling: Revision of the Nutrition and Supplement Facts Labels."

In addition to the March 3, 2014, proposal on changes to the Nutrition Facts Panel (NFP), the supplemental rule would require that the NFP for packaged foods include the percent daily value (%DV) for added sugars to be declared.

In summary, NMPF did not support the proposal, disagreeing with FDA that a mandatory declaration of "added sugars" would assist consumers in maintaining healthy dietary practices. More specifically, it cited numerous reasons why FDA's definition of "added sugars" would result in consumer confusion, especially with respect to dried and concentrated dairy ingredients. This is similar to comments NMPF submitted last year on FDA's original proposal to revise the Nutrition Facts Panel.

NMPF stated: "…the FDA's proposed definition of 'added sugars' falls woefully short… and leaves our industry confused and ill-served with respect to comprehending the proposed regulation."

Contact: Beth Briczinski

## Animal Health 2015 FARM Program Year-in-Review

The National Dairy FARM (Farmers Assuring Responsible Management) Program last month released its annual 2015 Year-in-Review report, detailing accomplishments and successes from the sixth year of the program. Included in the report are statistics on the FARM Program animal observation benchmarks, such as Locomotion, Hock and Knee Lesions, Body Condition Score and Hygiene. Data collected over the past year shows that more than 90 percent of farms nationwide meet or exceed the benchmarks on all animal observation criteria.

The report also contains details about the FARM review process, which is currently underway and will be completed in 2017, as well as information about the new FARM program website and social media accounts on Facebook, Twitter and Instagram.

Contact: Emily Meredith

## Animal Health NMPF Staff Attend IDF World Dairy Summit

In September, NMPF staff journeyed to the 2015 International Dairy Federation (IDF) World Dairy Summit (WDS) in Vilnius, Lithuania. Before the summit started, NMPF staff were active participants in the IDF business meetings, discussing important topics like international trade, standards for processed cheese, farm management issues, antimicrobial stewardship and animal care. Due in large part to NMPF's contributions during these meetings, several staff were asked to take leadership roles on several of IDF's standing committees. Specifically, Dr. Jamie Jonker, Vice President of Scientific Affairs, was elected Chair of IDF's Farm Management Committee, Emily Meredith, Vice President of Animal Care, was elected Deputy Chair of the Standing Committee on Residues and Chemical Contaminants, and Shawna Morris, Vice President Trade Policy, will remain as Vice-Chair for US-IDF for another term.

NMPF also spotlighted the U.S. dairy industry successes. Jonker presented during the Animal Health and Welfare session on the "Antibiotic Stewardship in the United States Dairy Industry," showcasing the efforts underway to ensure the judicious use of antibiotics in the dairy industry. During the same session, Meredith discussed the National Dairy FARM (Farmers Assuring Responsible Management) Program in a presentation titled "Addressing Animal Care Concerns and Building Consumer Trust Through 'Responsible Sourcing' Guidelines for Dairy Producers."

During a panel discussion moderated by Jonker about risk management on dairy farms, Morris discussed the Margin Protection Program.

In addition to highlighting the great things happening on U.S. dairy farms, the WDS provided an excellent opportunity for NMPF staff to network and engage with experts from numerous countries. Staff in attendance brought back ideas that will help inform and improve many NMPF programs.

Staff attendance at this critical industry meeting was made possible by Dairy Management Inc. and the U.S. Dairy Export Council.

Contact: Emily Meredith or Jamie Jonker

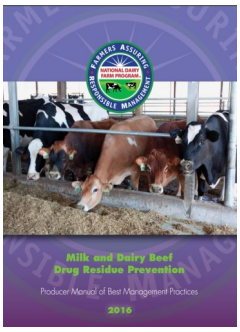
## Animal Health FMD Preparedness: Namibia Meat Export Equivalency

On November 17, NMPF commented on the U.S. Department of Agriculture Food Safety Inspection Service (USDA-FSIS) proposed rule on the "Eligibility of Namibia to Export Meat Products to the United States." The proposed rule, if implemented, would allow the importation of beef and beef products from Namibia based on an equivalency audit of its food safety system.

In comments, NMPF supported the USDA-FSIS equivalency process, but opposed opening the United States to imports of meat from Namibia because the USDA Animal and Plant Health Inspection Service (APHIS) had not conducted a review of the disease status of Namibia, and therefore had not published a formal risk assessment for comment. This type of assessment is warranted because Namibia has had 29 outbreaks of Foot and Mouth Disease (FMD) in cattle from a focal occurrence since June 2015. Safeguarding animal health by preventing the introduction of trade-limiting foreign animal diseases such as FMD is the primary way to protect animal agriculture from financial ruin. Every effort to ensure there is negligible risk from the importation of meat and meat products from FMD-positive countries should be taken before these products are approved for import into the United States.

Contact: Jamie Jonker

## Animal Health FARM Program Releases Residue Prevention Manual

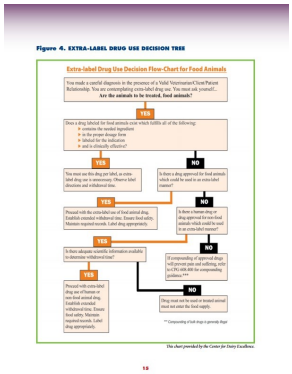


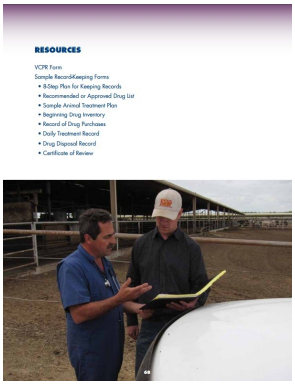

In October, the National Dairy FARM (Farmers Assuring Responsible Management) Program released its 2016 Milk and Dairy Beef Drug Residue Prevention Manual. For more than 25 years, the U.S. dairy industry has focused educational efforts on the judicious use of antibiotics through the annual publication of a Best Practices Manual. The 2016 edition of the residue prevention 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 the antibiotics approved for dairy animals, and can also be used as a resource for farm managers as they develop the best on-farm management practices necessary to avoid milk and meat residues. In addition to the most current information on withdrawal times and routes of administration for all compounds, this year's manual also contains critical information on antimicrobial stewardship.

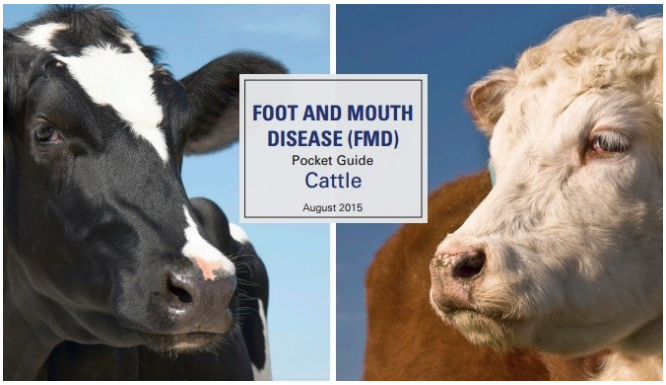
Sponsors of the 2016 manual include Charm Sciences, Inc., Elanco, Idexx Laboratories, Zoetis, Boehringer Ingelheim and Merck Animal Health.

Contact: Emily Meredith or Jamie Jonker


## Animal Health Food and Mouth Disease (FMD) Pocket Guide and Poster




In 2014, the NMPF Animal Health and Well Being Committee identified the need for FMD educational resources for dairy farmers and veterinarians. With contributions from NMPF, the American Association of Bovine Practitioners and the National Cattleman's Beef Association, as well as through a cooperative agreement from the USDA's Animal and Plant Health Inspection Service (APHIS) to the Center for Food Security and Public Health at Iowa State University, several resources have been developed.

- The Foot and Mouth Disease (FMD) Pocket Guide is an easy-to-use resource illustrating the progression of FMD lesions in cattle. The photos in the guide follow the development of lesions over 18 days and can be used in vesicular disease surveillance programs. The photos were taken by personnel at the Plum Island Animal Disease Center following exposure to animals experimentally inoculated with the FMD virus.
- The Foot and Mouth Disease (FMD) Wall Chart is a corresponding poster to the Pocket Guide.

Contact: Jamie Jonker

## Animal Health Codex Circular Letter on Antimicrobial Resistance

The Codex Alimentarius Commission (CAC) has requested input via a Circular Letter on Codex Work in Antimicrobial Resistance (AMR), in part due to recent adoptions by the World Health Organization of the Global Action Plan to Combat Antimicrobial Resistance and by the Food and Agriculture Organization of the Resolution of Antimicrobial Resistance.

The Codex Code of Practice to Minimise and Contain Antimicrobial Resistance defines the respective responsibilities of authorities and groups involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry, veterinarians, distributors and producers of food-producing animals. The Codex Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance assesses the risk to human health associated with the presence in food and animal feed, including aquaculture, and the transmission through food and animal feed of AMR microorganisms and determinants to provide advice on appropriate risk management activities to reduce such risk.

The World Organization for Animal Health (OIE) through the Terrestrial Animal Health Code, the Aquatic Animal Health Code, and the Manual for Diagnostic Tests and Vaccines for Terrestrial Animals has intergovernmental standards that promote the responsible and prudent use of antimicrobial agents in terrestrial animals so as to preserve their therapeutic efficacy and prolong their use in both animals and humans. Additionally, the OIE has developed intergovernmental standards on antimicrobial resistance and on the monitoring of the quantities of antimicrobial agents used.

In light of the extensive CODEX and OIE codes on AMR, NMPF submitted comments to the U.S. Codex Office on the Circular Letter opposing new work while the U.S. is currently implementing these international codes.

Contact: Jamie Jonker or Emily Meredith

CODEX ALIMENTARIUS

World Health Organization

Food and Agriculture Organization of the United Nations

## Animal Health On-Farm Antimicrobial Use and Resistance Data Collection

On November 30, NMPF submitted comments to the FDA request for input on potential on-farm antimicrobial use and resistance data collection. NMPF commended the efforts of the FDA, the U.S. Department of Agriculture (USDA) and the Centers for Disease Control and Prevention (CDC) to engage stakeholders for feedback on the best approaches for data collection about antimicrobial use and potential resistance in food-producing animals. NMPF further commented that the relationship between antibiotic use and resistance is highly complex, with multiple factors extending beyond antibiotic use in food-producing animals, and that associated data has strong potential to be misinterpreted to portray responsible husbandry practices as harmful, especially if bacterial resistance were not to decrease. Compounding this challenge is the reality that collecting meaningful representative data would be highly resource intensive. Finally, NMPF expressed concerns that collecting on-farm antimicrobial use data without first outlining science-based goals and objectives may lead to less robust and less useful results.

Contact: Jamie Jonker

## Animal Health — Requirements for the Disposition of Non-Ambulatory Disabled Veal Calves

On August 12, NMPF submitted comments on the USDA-FSIS proposed regulation that would remove the ability for slaughterhouses to allow tired or cold animals to have a period of time to rest upon arrival at a slaughter plant. Therefore, any veal calf that arrives to a slaughter plant that is unable to immediately stand would be considered non-ambulatory, condemned and immediately euthanized. Current USDA-FSIS regulations give slaughter plants the option to allow cold or fatigued animals an opportunity to rest. After the rest period, if it is unable to stand the animal is then considered non-ambulatory, condemned and euthanized.

NMPF commented in opposition to the proposal due to the lack of data to justify the change. USDA-FSIS data indicates the success with which current inspectors ensure the implementation of the resting period with proper inspection to ensure non-ambulatory cattle do not enter slaughter.

Contact: Jamie Jonker

## Animal Health — Antimicrobial Animal Drug Sales and Distribution Reporting

On August 18, NMPF submitted comments on the FDA proposed regulation for pharmaceutical companies to report drug sales and distribution data for livestock. Currently, pharmaceutical companies are required by law to report aggregate drug sales and distribution data for livestock by type of drug. FDA proposed that the pharmaceutical companies should report estimates by species (cattle, swine, horse, sheep, goat, poultry). NMPF commented in opposition to the FDA proposal for several reasons, mainly around accuracy of estimations and lack of usefulness of estimate data in context of the larger federal government initiatives on antimicrobial resistance.

Contact: Jamie Jonker

## NMPF News — Winners of the NMPF Annual Cheese Competition


Each year, in conjunction with the Joint NDB/NMPF/UDIA Annual Meeting, NMPF hosts an Annual Cheese Competition. This year, 157 entries were received from 40 dairy plants from 14 dairy cooperatives during the meeting in Orlando, Fla. The cheeses were evaluated on a 100-point scale in 19 classes by the following judges: Ms. Noreen Ratzlaff, USDA; Dr. Mark Johnson, University of Wisconsin-Madison; Mr. Timothy Meyers, College of DuPage; Ms. Allison Reynolds, USDA; and Dr. Marianne Smukowski, University of Wisconsin-Madison.

The AmaBlu cheese entered by Swiss Valley Farms received the prestigious Chairman's Plaque for the Most Outstanding Cheese of the competition. This cheese, produced by the Caves of Faribault in Minnesota, was also awarded Best Italian Cheese. Best Cheddar Cheese was awarded to Tillamook County Creamery Association for an Extra Sharp Cheddar produced in Tillamook, Oregon. The Best Cottage Cheese was awarded to Upstate Niagara Cooperative, Inc. for a 4% Small Curd Pineapple Cottage Cheese produced in West Seneca, New York. Complete results are available on the NMPF website.

Contact: Jamie Jonker

NMPF News

## Briczinski Receives Penn State Honor

Dr. Beth Briczinski, NMPF's vice president for dairy foods and nutrition, was recently named the 2015 Outstanding Recent Alumna by the College of Agricultural Sciences at The Pennsylvania State University.

The Outstanding Alumna award recognizes alumni who have graduated in the past 10 years and provides opportunities for recipients to interact with the college's faculty, students and other alumni.

"We're thrilled that Beth is being recognized for her dedication to the food and dairy industries," said President and CEO Jim Mulhern. "This award further solidifies her vital role in ensuring consumer confidence in the country's milk supply."

Briczinski received her bachelor's, master's and doctoral degrees at Penn State, all in food science. Since becoming an NMPF employee, she has continued her connection with Penn State by guest-lecturing at the undergraduate course on dairy foods.

NMPF News

## Upcoming Events

- National Ice Cream Mix Association Annual Meeting — January 17-20, 2016, Fort Lauderdale, FL
- 55th National Mastitis Council Annual Meeting — January 31-February 2, 2016, Glendale, AZ

## About NMPF

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 more than 32,000 dairy producers on Capitol Hill and with government agencies.

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