

## REGULATORY REGISTER

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### Dr. Stephen Hahn's Confirmed as FDA Commissioner

Dr. Stephen Hahn was confirmed by the Senate as the next FDA Commissioner on December 12. NMPF is pleased with Dr. Hahn's confirmation, as he will provide strong leadership and direction to an agency that, understandably, has been reticent to resolve important issues in the absence of a full-fledged leader.

"Dr. Hahn showed in his confirmation hearing that he understands the public-health need to address the issue of mislabeled plant-based products inappropriately marketed using dairy terms," said NMPF President and CEO Jim Mulhern upon his confirmation. "As this problem grows more acute, consumer deception about nutritional content increases, adding urgency to the need for the FDA to enforce its own rules."

"Dr. Hahn has <u>voiced</u> his support for 'clear, transparent, and understandable labeling for the American people,' and we urge him to act quickly on this issue at FDA, as he pledged during his confirmation hearing."

Contact: Miquela Hanselman

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### NMPF Files Comments Emphasizing the Unintended Consequences of Horizontal Standards of Identity

NMPF filed comments November 12 to the FDA's modernizing standards of identity docket, emphasizing that in many cases so called "horizontal" changes to standards are unnecessary, and have the potential for unintended consequences. NMPF cautioned FDA not to move forward with the proposal.

Horizontal standards, which would be applied to all current standards of identity as a way to modernize them all at once, were proposed at a meeting in September. At this forum, NMPF argued that companies would use it to cheapen their food products, not make them healthier. "When dealing with hundreds of very different standards, and the intention is to improve one, such changes may not be transparent when applied to different foods, and stakeholders could be deprived of a proper opportunity to weigh in," Clay Detlefsen said.

NMPF's comments focused on why maintaining the standards of identity are necessary to meet consumers' expectations of products, noting that innovation in food groups is already happening without horizontal standards. "Creating these horizontal standards would allow companies to cheapen their products under the guise of innovation," NMPF wrote. The full comments can be found <a href="https://example.com/here">here</a>.

Contact: Miguela Hanselman

FDA Announces Extension for Compliance with Nutrition Facts
Panel Requirements

The FDA <u>announced</u> October 23 that it plans to work cooperatively with manufacturers during the first six months following the January 1, 2020, compliance date for the new Nutrition Facts label requirements for manufacturers with \$10 million or more in annual sales. In addition to working cooperatively, FDA won't focus on enforcement during the first six months, giving manufacturers more time to comply. The decision comes after several manufacturers requested more time to meet the new requirements.

Issued May 3, 2018, the final rule includes various changes to nutrition facts panels to promote healthier food choices. These changes included: stating the number of servings in larger and bolder font; more prominently featuring calorie amounts; updating recommended daily values, changing the nutrients required to be listed as well as the actual amounts of nutrients declared; a new footnote explaining percentage daily values; and a line listing the amount of added sugar.

Contact: Clay Detlefsen

#### SIDE-BY-SIDE COMPARISON **Original Label New Label Nutrition Facts Nutrition Facts** Serving Size 2/3 cup (55g) Servings Per Container About 8 8 servings per container **Serving size** 2/3 2/3 cup (55g) Amount Per Serving Calories 230 Calories from Eat 72 Amount per serving 230 Calories % Daily Value % Daily Value Saturated Fat 1g 5% Total Fat 8g 10% Trans Fat 0g Saturated Fat 1g 5% Cholesterol 0mg Sodium 160mg Trans Fat 0q Total Carbohydrate 37g 12% Cholesterol 0mg 0% Dietary Fiber 4g Sodium 160mg 16% Total Carbohydrate 37g 13% Protein 3g Dietary Fiber 4g Total Sugars 12g Vitamin A 10% 20% Includes 10g Added Sugars Protein 3a Calcium Vitamin D 2mcg nt Daily Values are based on a 2,000 of daily value may be higher or lower depe Calcium 260mg Iron 8mg 45% 2,000 2,500 Potassium 235mg 6% The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calorie a day is used for general nutrition advice.

#### FDA Releases More PFAS Test Results and Q&A Document on PFAS

On December 20, the FDA posted results from the second round of testing for 16 types of per- and polyfluoroalkyl substances (PFAS) in foods collected for the <u>Total Diet Study (TDS)</u>. These findings, along with the first round of testing results posted in October 2019, continue to inform FDA about the occurrence of PFAS in the general food supply. TDS foods represent a broad range of foods, including breads, cakes, fruits, dairy vegetables, meats, poultry, fish, and bottled water, that average consumers might eat and that were not specifically collected from areas of known environmental PFAS contamination.

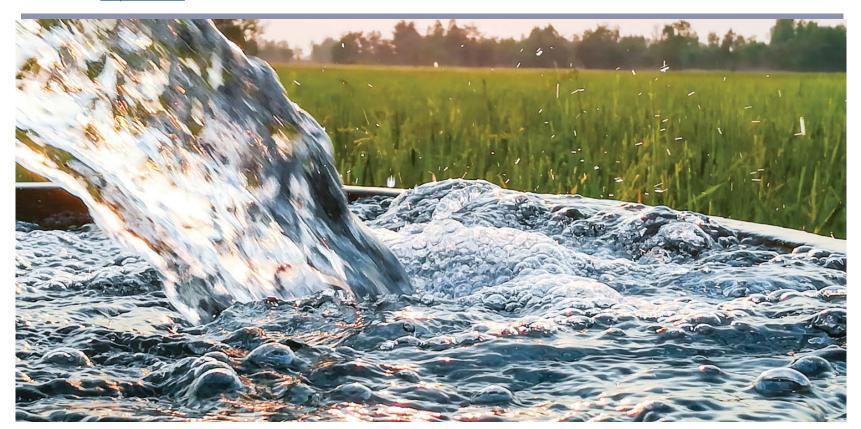
The results show that out of 88 foods, one sample—tilapia— had a detectable level of perfluorooctane sulfonate (PFOS), which is a type of PFAS. This is the same PFAS that was detected in the two samples with detectable levels—ground turkey and tilapia— reported in the first round of testing in foods collected for the TDS. Both sample sizes are limited and cannot be used to draw definitive conclusions. Based on the best available current science, the FDA has no indication that PFOS levels found in the limited sampling from these TDS data sets present a human health concern.

The TDS is conducted on an on-going basis and serves as the FDA's primary method of monitoring levels of various pesticide residues, contaminants, and nutrients in foods. PFAS are not currently part of the TDS. Results from FDA's testing for PFAS in TDS foods will be used to determine how the FDA will monitor PFAS in foods going forward, including whether steps should be taken to include it in the TDS, and/or if targeted sampling assignments are necessary for certain foods.

While two samples of tilapia have detectable levels of PFOS, these levels are very low and are not likely a health concern. Therefore, there is no scientific evidence that supports recommending consumers avoid a particular food, including tilapia or other seafood. As part of a healthy eating pattern, fish and other protein-rich foods have nutrients that may offer health benefits for children and adults. Importantly PFAS was not detected in any dairy food in the second round and the previously reported positive in chocolate milk was determined to be a false positive triggered by the presence of chocolate.

The results to date show that the 16 PFAS chemicals - for which we have a validated method - were not detected in most of the foods analyzed from Total Diet Study. The FDA is committed to continuing their surveillance of the food supply and research in this area, and to informing the public as new information becomes available.

Contact: Clay Detlefsen



### PFAS Continues to Make a Stir; NDAA Passed

Per- and polyfluoroalkyl substances (PFAS) continue to be a hot topic of discussion among members of Congress and the media. The National Defense Authorization Act (NDAA), which has been passed by both the House and Senate, includes key PFAS provisions, which will assist people who have been negatively impacted by the use of firefighting foam containing PFAS on military bases.

#### Key PFAS provisions include:

- Allowing the Department of Defense (DoD) to provide non-contaminated water for agricultural purposes;
- Providing the DoD with clear authority to acquire contaminated farmland that is adjacent to military bases and pay for relocation expenses;
- Prohibiting DoD from using PFAS-containing aqueous film forming foams during training exercises at military installations;
- Requiring DoD to phase out the use of PFAS-containing aqueous film forming foams at military installations by 2024;
- Adding some of the PFAS chemicals to the Toxic Release Inventory;
- Adding PFAS to the unregulated contaminant monitoring rule system; and
- Requiring the U.S. Geological Survey to do monitoring of surface and ground water, soils, and wells.

Aside from the NDAA bill, the EPA has started to move forward with its PFAS Action Plan. They have issued advanced notice of proposed rulemaking to add PFAS to the Toxic Release Inventory toxic chemical list. In addition, PFOA and PFOS, two PFAS chemicals, have been proposed to be listed on the Contaminant Candidate List. This list identifies unregulated chemicals that are known or anticipated to occur in public water systems and are not currently subject to EPA drinking water regulations.

These moves come as media attention to PFAS has grown following the release of the film "Dark Waters," which tells the story of corporate attorney Robert Bilott exposing DuPont for knowingly dumping PFAS waste into local water systems and covering up the health impacts of PFAS in the commonly-used product, Teflon.

NMPF is pleased with the PFAS provisions put into the NDAA, as they address the most pressing matters for dairy farmers and will continue to monitor the situation.



# FDA Releases 2019 Report on Antimicrobials Used in Food-Producing Animals

On December 10, the FDA released the 2018 report on antimicrobials sold and distributed for use in food-producing animals. While there was a nine percent rise in antibiotic usage in 2018, it was still the second-lowest year on record.

The report, which was first released in 2009, aims to monitor market changes related to antimicrobial drug products for food-producing animals and slow the development of antimicrobial resistance. Use has dropped 38 percent since 2015, the peak year of antimicrobial sales. The <u>full report</u> breaks down antimicrobial drug sales by class and medical importance, noting that that antimicrobials sold doesn't equate to antimicrobials used.

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



### NMPF Signs on to ANPC, Newtrient Water Quality Trading Comments

NMPF signed on to comments with the <u>Agriculture Nutrient Policy Coalition</u> and wrote a letter of support for Newtrient's <u>comments</u>, which were submitted to the water quality trading docket December 18. The comments detailed support for Water Quality Trading as an important tool for water quality improvement in the United States.

NMPF has a long history of supporting water-quality trading, serving on the steering committee of the National Network on Water Quality Trading that published "Building a Water Quality Trading Program: Options and Considerations" and "Breaking Down Barriers: Priority Actions for Advancing Water Quality Trading." NMPF has also been involved with Maryland's effort to launch a water quality trading program and Pennsylvania's water-quality procurement legislation.

In November, Clay Detlefsen, NMPF's senior vice president for regulatory affairs, provided oral comments stating its strong support for the Environmental Protection Agency's (EPA) efforts to promote water quality improvements at a lower cost than traditional regulatory approaches, agreeing with EPA that the Clean Water Act allows for pollutant reductions from water quality trading to achieve compliance with regulatory requirements.

Detlefsen also said NMPF appreciated EPA's efforts this year to update its water quality trading policy to encourage technologies and practices that reduce nonpoint source pollution. NMPF also concurred with the six principles laid out in the 2019 Memorandum, namely:

- States, tribes and stakeholders should consider implementing water quality trading and other market-based programs on a watershed scale.
- EPA encourages the use of adaptive strategies for implementing market-based programs;
- Water quality credits and offsets may be banked for future use;
- A single project may generate credits for multiple markets;
- Financing opportunities exist to assist with deployment of nonpoint land use practices; and
- Encouraging simplicity and flexibility in implementing baseline concepts

Contact: Clay Detlefsen

#### NMPF Files Comments to FDA Over the Counter Antimicrobials Docket

NMPF filed <u>comments</u> to FDA's draft guidance, "Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter" on December 24, emphasizing the dairy industry's commitment to prudent and responsible antibiotic use and general support for the guidance.

NMPF has recognized that the availability of over-the-counter (OTC) antimicrobials has decreased over the years and has made the Veterinarian Client Patient Relationship a cornerstone of the FARM Animal Care Program.

FDA's intent with GFI #263 is for animal drug pharmaceutical manufacturers to voluntarily change the marketing status of the remaining approved animal drugs containing antimicrobials of human medical importance from OTC to prescription (Rx) under the oversight of licensed veterinarians. This draft guidance comes as part of FDA's five-year plan for supporting antimicrobial stewardship in veterinary settings as part of a strategy to address antimicrobial resistance associated with the

use of antimicrobial drugs in animal agriculture.

GFI #213 was FDA's first step to increase oversight of antimicrobial use through voluntary industry action to change marketing status of medically important antimicrobials used in feed or drinking water for food-producing animals from OTC to VFD/Rx. This also resulted in the elimination of the use of these antimicrobials for production practices. While GFI #263 will be voluntary, NMPF anticipates that pharmaceutical manufacturers will change the marketing status of the limited number of dosage forms of medically important antimicrobials still available from OTC to Rx for both food-producing and companion animals.

NMPF recognizes that there may be geographic and farm size challenges for some dairy farmers to have access to large-animal veterinarians. These concerns were outlined in our comments.

Contact: Jamie Jonker

## CDC Releases Antibiotic Threats Report; NMPF Represents at USDA CDC Pre-Harvest Assessment Meeting



The Centers for Disease Control and Prevention (CDC) released the 2019 Antibiotic Threats Report in November, which includes the latest national death and infection estimates that underscore antibiotic resistance in the United States. The report, last updated in 2013, estimates that 2.8 million antibiotic-resistant infections occur in the United States each year and more than 35,000 people die from them. The report, while largely focused on antibiotic resistance infections in the medical field, also discusses the animal health side to this issue and what veterinarians can do to help slow the growth of these dangerous bacteria.

Dairy farmers Karen Jordan, DVM and Bill Wavrin, DVM, along with NMPF staff, represented U.S. dairy production perspectives at a U.S. Department of Agriculture (USDA)-CDC AMR Meeting in November. The meeting focused on antimicrobial resistance traceability in meat, a key piece to being able to understand the threats released in the report.

New technologies like Whole Genome Sequencing (WGS) can be part of an epidemiological investigation to help determine the origins of a foodborne outbreak. The CDC routinely works with USDA during foodborne outbreak investigations, tracing suspected bacterial-contaminated meat from the point of consumption back to the processing plant of origin. The meeting explored regulatory and business issues related to further traceback to an individual farm.



### NMPF Staff Represents Dairy Industry at Codex Taskforce Meeting

The year ended with a big success for NMPF and U.S. dairy exporters as Codex advanced an important Code of Practice on the use of antimicrobials that is science-based and ensures U.S. dairy farmers will continue to be able to use safe and effective antimicrobials.

Despite a last-minute push by Europe to impose significant unjustified restrictions on antimicrobials commonly used in dairy production, the Taskforce rejected these non-scientific, protectionist arguments thanks to the steadfast insistence of dairy's Codex allies. The Code of Practice advanced in the Codex process with important language that permits preventive uses of antibiotics, defines "medically important antibiotics" in a science-based manner and establishes additional principles that are risk-based and do not restrict ionophores—antibiotics not important to and/or not used in human medicine.

Jamie Jonker, NMPF's vice president of sustainability and scientific affairs, worked with the U.S. Dairy Export Council's Nick Gardner throughout the year to ensure alignment of Codex standards with the FARM Program's commitment to judicious and responsible use of antibiotics, and while much headway was made, more work needs to be done. NMPF continues to try to ensure the Taskforce supports the responsible use of antibiotics with guidelines grounded in science.

Contact: Jamie Jonker

## Joint Agriculture Effort Supports APHIS Plan for Animal Disease Prevention Management

NMPF participated October 1 in a joint press conference with the National Pork Producers Council, National Corn Growers Association and Iowa State University to urge the USDA to quickly spend mandatory funding included in the 2018 Farm Bill to buy enough vaccines to effectively contain and eradicate a Foot and Mouth Disease (FMD) outbreak.

USDA's Animal and Plant Health Inspection Service announced in August initial plans to carry out new animal health activities using resources provided by the 2018 Farm Bill. Section 12101 of the law established a three-part program to comprehensively support animal disease prevention and management. The bill included funding to create two new programs: The National Animal Vaccine and Veterinary Countermeasures Bank (vaccine bank) and the National Animal Disease Preparedness and Response Program (NADPRP). It also expanded funding

opportunities for the existing National Animal Health Laboratory Network (NAHLN).

These 2018 FARM Bill programs were initially identified in 2014 as priorities for FMD preparedness by the NMPF Animal Health and Wellbeing Committee. NMPF worked with a coalition of other stakeholders to obtain new funding in the 2018 FARM Bill for FMD preparedness.

"The time to build a best-in-class FMD Vaccine Bank is now," said Jamie Jonker at the news conference. "NMPF has been active in informing our members and the dairy community of the importance of preparation, and a vaccine bank is a crucial element of protection for the entire livestock industry."

## NMPF Files Comments to Origin of Livestock Docket, Using Plant-Based Analogy

NMPF filed comments to a USDA organic origin of livestock docket on December 2 and used a novel analogy to connect the plant-based foods debate and remind regulators of their responsibilities.

The dairy-centered portion of the docket, which was the focus on NMPF's comments, sought input on two key issues: how a one-time transition requirement is implemented, and how non-organic breeder stock can properly be integrated into the organic program.

On the transition issue, NMPF emphasized the transition from conventional to organic shouldn't be tied to the producer, but instead to the certified dairy operation, arguing that eliminating a farmer's ability to transition a second or a third farm from conventional to organic, which is being proposed by organic advocates seeking to raise barriers of entry to their business, is overly restrictive and unnecessary.

NMPF and others cited numerous examples of how this could be problematic. For example, should a farmer transition a farm to organic, then decide to relocate to a different part of the country, that farmer could not transition another farm to organic. NMPF questioned whether such a restriction could meet constitutional scrutiny and is hopeful that USDA will revise its proposal on this issue and not deprive a farmer's right to transition whatever farms they want to.

The second, more controversial issue, involves the use of non-organic breeding stock to produce organic heifers. When Congress passed the Organic Food Production Act as part of the 1990 Farm Bill, it specifically stated that breeding stock from any source, organic or non-organic, could be used to produce organic heifers if that breeding stock were organically managed for at least the last third of gestation. NMPF believes this is appropriate, arguing that advocates who want only organic breeding stock to produce an organic heifer – again, reducing competition in the organic sector — are taking a position inconsistent with current law.

NMPF's comments to USDA suggests that the agency either work with Congress to change the law or make it abundantly clear that when the rules are followed (e.g. currently a bred non-organic cow must be raised organically for at least its last trimester), non-organic breeding stock can produce organic heifers. NMPF's comments also note that from the time a

heifer, whose mother consumed an organic diet to when that heifer is milked, would have spent at least 27 months managed as organic — much more time than the 12 months used for a one-time herd conversion, leaving no scientific basis for such a restriction.

Finally, the comments point out that there is no violation of the one-time transition rule when using non-organic breeding stock, as that breeding stock never transitioned – tying the two issues in the main comments.

NMPF also supplemented its comments with an additional filing to the docket, noting that whatever agencies may or may not want to do, their discretion to enforce or not to enforce their own rules is increasingly limited, as shown in a separate issue, with NMPF's urging the FDA to enforce its rules on plant-based beverages.

In the case of the transition allowance, NMPF argued that, rather than create a stricter standard that may not comply with law, a simple clarification that the Act is correct would ensure consistency. On the organic breeder stock, NMPF also pointed out that agencies don't have discretion to enforce or change Congressional Acts.

Pointing out that a court recently ruled the FDA doesn't have unfettered discretion not to enforce provisions that Congress put in place, NMPF argued that the USDA doesn't have this right either. Therefore, it shouldn't entertain a rule that contradicts the Organic Food Production Act.

"We cannot support FDA not enforcing the standards of identity for labeling food products, nor can we support FDA rewriting the Congressionally-enacted Butter Act," NMPF wrote in its comments. "By analogy, NMPF cannot support a USDA rewrite of the Congressional expression that non-organic breeder stock can produce organic heifers when those heifers are raised and managed under the organic program requirements. USDA must finalize this part of the proposed rule as proposed, which allows for non-organic breeder stock's ability to produce organic heifers under rigorously-mandated National Organic Program conditions."

The full comments can be found here.

Contact: Clay Detlefsen

### National Dairy FARM Workforce Development Evaluation Tool Available for Comment

The National Dairy Farmers Assuring Responsible Management (FARM) Program, the dairy industry's on-farm quality assurance program, released a proposed Workforce Development evaluation tool for input from industry stakeholders with comments accepted through January 20.

<u>FARM Workforce Development (WFD)</u> is the FARM Program's newest initiative. It focuses on human resources and safety management and has brought together stakeholders from the entire dairy value chain to create educational materials for U.S. dairy owners and managers.



FARM WFD is developing an on-farm evaluation tool that FARM Participants can choose to implement with their dairy producers. The tool is meant to help farms:

- learn about HR and safety management best practices;
- identify which best practices will be most useful to implement on their farm; and
- track improvement over time.

By performing on-farm evaluations, FARM Participants can provide important assurances to supply chain customers: our dairy buyers and retailers.

The evaluation tool was developed in consultation with the <u>FARM WFD Task Force and Working Group</u> members, along with subject matter expert input.

FARM is also getting direct feedback from dairy producers through a pilot program that runs through the end this year. Nine cooperatives have volunteered to test the evaluation tool to solicit feedback. About 60 dairy producers are participating from across the cooperatives. Public comment will complement the pilot.

After the comment period ends, FARM staff, the WFD Task Force and the NMPF Executive Committee will review and consider revisions based upon the comments, then present a final proposed evaluation tool for approval by the NMPF Board of Directors in March. The FARM Program encourages all those involved in the dairy supply chain to participate. To review the draft evaluation tool and provide feedback, please visit this link.





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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 <a href="www.nmpf.org">www.nmpf.org</a>.