National Milk Producers Federation

Regulatory Register

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Animal Health

NMPF Comments on TB/Brucellosis Eradication Changes

On May 16, NMPF submitted comments to USDA Animal and Plant Health Inspection Service (APHIS) on the proposed changes to the brucellosis and bovine tuberculosis (TB) eradication programs. USDA APHIS proposed to establish standards for disease surveillance, epidemiological investigations and affected herd management. States and tribes will have to develop and implement an Animal Health Plan that outlines how they will meet those standards. States and tribes will be categorized by whether they have an animal health plan, whether APHIS has approved this plan and whether they are following the activities outlined in their plan.

NMPF identified several concerns for the implementation of the proposed rule, and commented that additional revision and stakeholder input are necessary prior to finalization. The major concerns include combining TB and brucellosis into a single standard; technical, workforce and financial resources available for implementation of Animal Health Plans by states; replacing the current disease prevalence rate-based classification system with a system based on compliance with the Animal Health Plan; and implications for trade.

Contact: Jamie Jonker

Animal Health

OIE 84th General Session Review

The 84th General Session of the World Organization for Animal Health (OIE), held in Paris in May, included several actions of note for the U.S. dairy industry. The Terrestrial Health Code chapter on the welfare of dairy cattle had several amendments, including simplification of colostrum feeding recommendations and new pain management recommendations, which now align with the National Dairy FARM Program standards. The OIE reaffirmed its commitment to combatting antimicrobial resistance through a One Health approach with the World Health Organization and Food & Agriculture Organization, including strategies to decrease use, monitor resistance and provide guidance on alternatives.

The U.S. also concluded a series of bilateral animal health agreements on foreign animal disease preparedness and response, including:

- International Animal Health Emergency Reserve with Australia, Canada, Ireland, New Zealand and United Kingdom;
- Foot and Mouth Disease Vaccine Sharing with Australia, Canada, Mexico and New Zealand; and
- Zoning for Foreign Animal Disease Outbreaks with Australia, Canada and New Zealand.

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

Contact: Jamie Jonker

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Animal Health

Presidential Advisory Council on Combating Antimicrobial-Resistant Bacteria

The Presidential Advisory Council on Combating Antimicrobial Resistant Bacteria (PACCARB) met March 30-31 in Washington, D.C., to discuss its activities and its report, "Initial Assessments of the National Action Plan for Combating Antibiotic-Resistant Bacteria." The report contains a wide array of recommended goals and objectives to combat antimicrobial resistance.

In general terms, these goals and recommendations from PACCARB for livestock production focus on four topics: (1) on-farm antibiotic use data collection; (2) increasing antimicrobial stewardship in food and companion animals (including additional veterinary oversight); (3) flow of antimicrobial resistance through the environment (from use in animals to people and use in people to animals); (4) development of new disease detection, prevention, control and treatment options (vaccines, new antibiotics, etc.).

Contact: Jamie Jonker

Animal Health

NMPF Comments on USDA-FSIS National Residue Monitoring Program

The USDA-FSIS maintains a robust residue monitoring system of routinely sampled and tested animal drug and pesticide chemicals in animal carcasses at slaughter through the National Residue Monitoring Program. This includes Tier 2 testing programs (also called exploratory assessment programs) to provide a means to monitor potential chemical hazards and address further action based on data and supported by a risk assessment.

Although carcasses selected for sampling by USDA-FSIS as part of the exploratory assessment program should be permitted to be released into commerce before exploratory results are available, the USDA-FSIS needs to clarify whether products derived from those carcasses would be subject to any regulatory action if violative test results are received.

In comments submitted March 29, NMPF supported using *de minimis* levels (DML) as a guide to determine whether Tier 2 exploratory program activities require follow-up action. The *Federal Register* notice states "the derivation of a DML follows standard and routinely accepted risk assessment approaches."

Contact: Jamie Jonker

Animal Health

Biosecurity Posters Now Available

In 2014, the NMPF Animal Health and Wellbeing Committee identified the need for Foot and Mouth Disease (FMD) educational resources for dairy farmers and veterinarians. Through a cooperative agreement from USDA-APHIS, the Center for Food Security and Public Health (Iowa State University) has developed a variety of FMD educational resources. NMPF, the American Association of Bovine Practitioners (AABP) and the National Cattleman's Beef Association also contributed to this effort. An FMD poster and pocket guide were published last September. Three new Biosecurity resources have become available:

- General biosecurity in English and Spanish
- Visitors with animal contact biosecurity in English and Spanish
- Visitors without animal contact biosecurity in English and Spanish

The posters are also available on the Secure Milk Supply website.

Contact: Jamie Jonker

Animal Health

FDA Finalizes BSE Feed Ban Rules

On March 17, FDA issued a rule finalizing three previously issued interim rules related to the feed ban on specified-risk-material to reduce the risk of bovine spongiform encephalopathy (BSE). The final rule provides definitions for prohibited cattle materials and prohibits their use in human food, dietary supplements and cosmetics to address the potential risk of BSE. The rule additionally confirms that milk and milk products, hides and hide-derived products, tallow that contains no more than 0.15 percent insoluble impurities, and tallow derivatives are not prohibited cattle materials. Overall, there are no material changes from the previously issued interim rules from 2004, 2005, and 2008.

Contact: Jamie Jonker

Animal Health

USDA-APHIS Trying to Identify Manufacturers of FMD Vaccine

On March 14, USDA-APHIS issued a "sources-sought notice" to conduct market research to identify interested vaccine manufacturers with the resources to manufacture, store and deliver Foot and Mouth Disease (FMD) vaccines. The result of this market research will contribute to future action by USDA-APHIS for modernization of the FMD vaccine bank, including enough vaccine for use in vaccinate-to-live scenarios. In 2014, the NMPF Board of Directors approved the NMPF Animal Health and Wellbeing Committee recommendations on FMD preparedness, which featured modernization of the FMD vaccine bank, including enough vaccine for use in vaccinate-to-live scenarios.

Contact: Jamie Jonker

Environment

Clean Water Act Litigation Army Corp v. Hawkes

On May 31, the Supreme Court ruled in favor of the defendants on United States Army Corps of Engineers v. Hawkes Company about due process over government-asserted Clean Water Act jurisdiction. The 8-0 decision provides that landowners have a right to seek judicial review when their property is designated as wetlands subject to federal jurisdiction under the Clean Water Act.

The Army Corps issues "jurisdictional determinations" (JDs) under the Clean Water Act to advise landowners whether their property contains "waters of the United States" – that is, waters subject to the act's requirements, including a potentially long and costly permitting process if the landowner wants to fill in a wetland. The issue before the Supreme Court was whether Hawkes could proceed immediately with a lawsuit that challenges the Army Corps' claim to jurisdiction over the land, or whether it must go through a potentially lengthy and expensive permitting process before it could bring a case. In siding with Hawkes, Chief Justice Roberts said landowners shouldn't have to wait until the end of the permitting process, which "can be arduous, expensive and long."

Contact: Jamie Jonker

Environment

EPA Nutrient Recycling Challenge Update

On March 30, the Environmental Protection Agency (EPA) announced the winners of Phase I of the Nutrient Recycling Challenge during the Nutrient Recycling Challenge DC Summit, in Washington, D.C. The summit was a forum for innovators to meet experts and other innovators, as well as to learn about resources to develop their ideas into real-life technologies. The Nutrient Recycling Challenge is seeking ideas for cost-effective technologies that extract nutrients (nitrogen and/or phosphorus) from cow or hog manure to concentrate them into a usable and potentially marketable form. The Nutrient Recycling Challenge is a partnership between EPA and industry and stakeholder partners including NMPF, the Innovation Center for US Dairy and several dairy cooperatives.

Contact: Jamie Jonker

Food Safety

FDA issues Intentional Adulteration Rule

On May 27, FDA issued the last of the seven major rules under the Food Safety Modernization Act, "Mitigation Strategies to Protect Food Against Intentional Adulteration," otherwise known as the Food Defense Rule. The rule will cover approximately 9,800 food facilities and is estimated to cost as much as $930 million to implement in the first year.

The rule requires covered facilities to create and maintain written food defense plans. The plans must identify vulnerabilities, actionable process steps (places where contamination could occur), mitigation strategies, procedures for food monitoring, corrective actions and verification. Food defense plans must be reanalyzed every three years. In many respects, this rule parallels the Preventive Controls for Human Food rule with the exception that it deals with intentional bad acts.

There are a number of exemptions, including animal food, alcohol, very small businesses and food that is being held, except for food held in liquid storage tanks. Most notably, while Congress specifically stated the rule could be applied to dairy farms, FDA has chosen not to do so at this time – in direct response to comments submitted by NMPF (for the general dairy industry and specific to dairy farms). Instead, it will work with the National Conference on Interstate Milk Shipments (NCIMS) to explore the matter further. Dairy processing facilities, on the other hand, are subject to the rule.

FDA will make a variety of tools available to assist the regulated community with preparation and compliance. This summer, FDA will issue version 2.0 of its popular Food Defense Plan Builder tool, an easy-to-use and innovative software program that helps create robust customizable food defense plans. The software tool was created using knowledge gleaned from the numerous vulnerability assessments conducted collaboratively with industry and government partners. Training materials will be created by the Food Safety Preventive Controls Alliance (FSPCA), which will begin its work later this summer. NMPF's Clay Detlefsen has been asked by FDA to be part of that effort. Given that this rule is the first of its kind, compliance dates are pushed out to three years for most businesses and four years for small businesses.

Contact: Clay Detlefsen

Food Safety

FSMA Update: Time to Start Getting Ready

FDA has now released all major Food Safety Modernization Act rules. The compliance deadline for the most impactful rule on the dairy processing industry, the Preventive Controls for Human Food rule, is September 19, 2016. FDA has yet to issue the substantial guidance that is necessary to understand what is and what is not required – a challenge for interpreting the best way to achieve compliance. While there is considerable uncertainty about how to put together a food safety plan under the Preventive Controls rule without the needed guidance, there are things that dairy plants should be doing.

NMPF recommends each processing plant have at least one trained qualified individual on staff, preferably two or more. Training is broadly available, including via NMPF — both Beth Briczinski and Clay Detlefsen are lead instructors and will be training cooperative staff at their headquarter facilities. After staff are trained, they will have a much better understanding of how a food safety plan will look and function.

One requirement under the rule is to develop a food safety plan for each food in the facility, but grouping foods is permitted – something NMPF recommends as much as possible. Lastly, a flowchart is needed for your facilities' operations. During that exercise, it is important to take advantage, consider and note which nodes on that flowchart might be an entry point for a hazard that will need a preventive control.

This process will get easier with additional guidance from FDA, training and time. NMPF staff are available to help with compliance over the months and years ahead.

Contact: Clay Detlefsen

Food Safety

NMPF to Host Technical Webinars

The NMPF regulatory staff have hosted a number of webinars on a variety of current topics. Most recently, webinars were held on the FSMA rules for "The Sanitary Transportation of Human and Animal Food" and "The Mitigation Strategies to Protect Food Against Intentional Adulteration," specifically highlighting application of these regulations to the dairy industry.

NMPF subject-matter experts will continue to provide technical information to members through webinars or other forums. If you have a suggestion for a regulatory topic that you think bears discussion, please contact either Beth Briczinski or Clay Detlefsen.

Contact: Beth Briczinski or Clay Detlefsen

Food Safety

NMPF Helps Scuttle Raw Milk Bill in Louisiana

A state bill aimed at legalizing the sale of raw milk in Louisiana is dead for the year, thanks in part to NMPF's comments vehemently opposing the legislation.

Senate bill 29 would have allowed the direct sale of raw milk to consumers by removing existing regulations. It passed the Louisiana Senate on April 18, but was voted down May 5 in the House Agriculture committee. Louisiana remains one of the last southern states that does not allow the sale of raw milk.

NMPF and IDFA submitted comments emphasizing that raw milk is considered a public health risk, a fact that has been well-documented in scientific literature with evidence spanning over 100 years.

"The CDC has reported that nearly 80% of raw milk-associated outbreaks have occurred in states where sale of raw milk was legal," said NMPF. "Easing the regulations around the state-wide sale of raw milk in Louisiana increases the risk to public health, opening up the state's consumers to the inevitable consequence of falling victim to a foodborne illness."

Contact: Beth Briczinski

Labeling

NMPF Submits Comments on "Natural" Definition

On May 10, NMPF submitted comments to the Food and Drug Administration (FDA) on defining the term "natural" in food labeling. Over 7,000 comments were received in response to the *Federal Register* notice from November 2015.

NMPF's comments focused on the following key points:

- Ensuring the dairy industry can continue to use "natural" to differentiate between natural and processed cheeses.
- Ensuring that practices that enhance food safety (e.g., pasteurization) do not prevent use of the term "natural."
- Ensuring that the term "natural" is not limited to raw agricultural commodities.

NMPF urged FDA, should they decide to define the term, to make use of an ample public comment period to receive input on a proposed rule or guidance document.

Contact: Beth Briczinski

Labeling

FDA Updates Serving Sizes, Nutrition Panel; Highlights Sugar Content

On May 27, the Food and Drug Administration (FDA) announced the availability of final regulations for nutrition labeling and serving sizes for foods. While much of the final regulations did not differ from what FDA had proposed, the new label requirements will not include some forms of lactose as an added sugar — reflecting concerns raised by NMPF. This was a significant victory for the dairy industry.

Last fall, NMPF commented to FDA on its proposal for including added sugars on the nutrition facts label. National Milk cautioned that the agency's proposed definition of added sugar would lead to confusion between the natural lactose of dairy ingredients and other sugars such as sucrose.

In the final rule, FDA is requiring a declaration of "includes x g Added Sugars" and adjusted its definition of added sugars so that while lactose alone is considered an added sugar, the lactose in dairy ingredients will not be. This means the naturally occurring lactose present in dry dairy ingredients such as milk powder and whey (except for lactose as defined in 21 CFR 168.122) won't have to be labeled as an added sugar.

The new FDA label places more emphasis on overall calories, and also updates the daily values assessment to help consumers understand the relative nutrient content of certain foods. It also adds vitamin D and potassium as nutrients that must be declared, joining calcium and iron on the label. Vitamins A and C will no longer be required, but can be included on the label on a voluntary basis.

At the same time, FDA also released the final rule updating serving sizes and reference amounts customarily consumed

(RACC) for foods. The final rule requires dual-column labeling for foods that contain at least 200% but no more than 300% of the RACC, indicating nutrition information both "per serving" and "per package."

In August 2014, NMPF submitted comments opposing FDA's proposal to increase the serving size for ice cream from one-half cup to one cup, while supporting a decrease in the serving size for yogurt from 8 ounces to 6 ounces. In the final rule, the RACC for yogurt was decreased to 6 ounces, and the RACC for a serving of ice cream increased to two-thirds of a cup.

Manufacturers will need to use the new label and base nutrient calculations on the new serving sizes by July 26, 2018. However, manufacturers with less than $10 million in annual food sales will have an additional year to comply with the regulation.

Contact: Beth Briczinski

Labeling

FDA Issues Final Guidance on "Evaporated Cane Juice"

On May 25, FDA released its final guidance for industry stating FDA's view that sweeteners derived from sugar cane should not be declared on food labels as "evaporated cane juice."

FDA's view is that the term "evaporated cane juice" is false or misleading because it suggests that the sweetener is fruit or vegetable juice or is made from fruit or vegetable juice, and does not reveal that the ingredient's basic nature and characterizing properties are those of a sugar.

This guidance is the final word from FDA after issuing draft guidance in 2009, which led to uncertainty among the food industry and consumers, causing manufacturers of foods and beverages to be targeted with false advertising lawsuits.

The guidance recommends that ingredients currently labeled as "evaporated cane juice" be relabeled to use the term "sugar," optionally accompanied by a truthful, non-misleading descriptor to distinguish the ingredient from other cane-based sweeteners.

Contact: Beth Briczinski

Nutrition

FDA Proposes Sodium Advice on Foods

The Food and Drug Administration (FDA) issued voluntary guidance for reducing sodium content in foods, including dairy products. The guidance aims to reduce Americans' sodium consumption from the current 3,400 milligrams per day to 3,000 over two years, and to 2,300 over 10 years. That long-term goal is already recommended by the Dietary Guidelines for Americans (DGA). Some recent studies have suggested that there are also dangers in very low-sodium diets, though these would represent reductions even below the 2,300-milligram level. Americans find it hard to cut sodium intake on their own since most of what is consumed doesn't come from the salt shaker, but is already in food when it is purchased.

FDA proposes targets for 13 types of cheese. The short-term targets would require around a 5-10 percent reduction. For example, Cheddar and Colby cheeses have a baseline (current content) of 649 milligrams and the two-year target is 615, a 5-percent cut. However, 10-year targets are around 15 percent below current levels, a more challenging goal. Butter's 10-year target is about 30 percent below current levels. And for frozen pizza without meat, FDA hopes to see a 10-year reduction in sodium of nearly 49 percent, with similar cuts for other types of frozen and fresh pizza.

NMPF will be submitting comments, which are due August 31, 2016.

Contact: Beth Briczinski

Animal Health

New FARM Program Materials Released

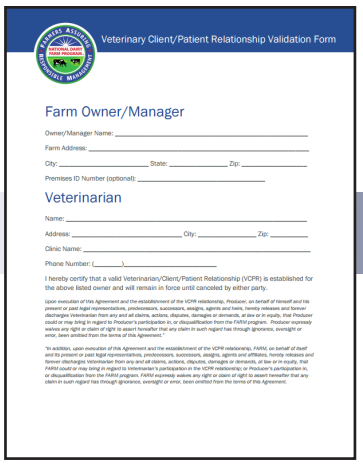
In anticipation of Version 3.0 of the FARM Program, new materials are continuously being developed to assist program participants. Some of the most recent materials that are now available for order from the FARM website include:

Veterinarian-Client-Patient Relationship (VCPR) Form
VCPRs should be reviewed and signed on an annual basis by the farm owner/manager and the Veterinarian of Record. Any farm that does not have a current, signed VCPR form will be subject to a Mandatory Action Plan after January 1, 2017 (when version 3.0 of the FARM Program takes effect).

Dairy Cattle Care Ethics and Training (DCCET) Agreement
Formerly known as the 'Cow Care Agreement,' the DCCET Agreement affirms that employees maintain the highest standard of animal care, pledge to never abuse, neglect, harm or mishandle animals and to report any signs of deliberate animal abuse, neglect, harm or mishandling. Additionally, this agreement confirms that all employees have received training at least in basic stockmanship and their assigned area of responsibility on an annual basis. Farm owners are encouraged to document all training that occurs by listing a brief description of the training and the date. This document must be signed and dated by the employee and farm owner/manager on an annual basis.

Emergency Contact Poster and Magnet
The poster and magnet are formatted so that a full emergency contact list can be posted in a prominent location on the farm in both English and Spanish. Both include space to add contact information for: farm owner/manager, veterinarian, feed dealer, milk handler/field representative, milk hauler, equipment dealer, machinery dealer and any other critical contacts. Both poster and magnet are dry erase marker-friendly and can be updated as needed.

Contact: Emily Yeiser Stepp


Veterinary Client/Patient Relationship Validation Form

Farm Owner/Manager

Owner/Manager Name: _____

Farm Address: _____

City: _____ State: _____ Zip: _____

Premises ID Number (optional): _____

Veterinarian

Name: _____

Address: _____ City: _____ Zip: _____

Clinic Name: _____

Phone Number: (_____) _____

I hereby certify that a valid Veterinarian/Client/Patient Relationship (VCPR) is established for the above listed owner and will remain in force until canceled by either party.

Upon execution of this Agreement and the establishment of the VCPR relationship, Producer, on behalf of himself and his present or past legal representatives, predecessors, successors, assigns, agents and heirs, hereby releases and forever discharges Veterinarian from any and all claims, actions, disputes, damages or demands, at law or in equity, that Producer could or may bring in regard to Producer's participation in, or disqualification from the FARM program. Producer expressly waives any right or claim of right to assert hereafter that any claim in such regard has through ignorance, oversight or error, been omitted from the terms of this Agreement."

"In addition, upon execution of this Agreement and the establishment of the VCPR relationship, FARM, on behalf of itself and its present or past legal representatives, predecessors, successors, assigns, agents and affiliates, hereby releases and forever discharges Veterinarian from any and all claims, actions, disputes, damages or demands, at law or in equity, that FARM could or may bring in regard to Veterinarian's participation in the VCPR relationship, or Producer's participation in, or disqualification from the FARM program. FARM expressly waives any right or claim of right to assert hereafter that any claim in such regard has through ignorance, oversight or error, been omitted from the terms of this Agreement.


Dairy Cattle Care Ethics and Training Agreement

Employee Name: _____

Farm Name: _____

Farm Owner/Manager: _____

Farm Owner/Manager Phone Number: _____

Dairy Cattle Care Ethics Agreement

I confirm my commitment to the highest standards of animal care by hereby agreeing that proper animal care is the responsibility of every individual who is around animals, including me. I understand that animal abuse, neglect, harm and mishandling are unacceptable and will not be tolerated. I will immediately report any signs of deliberate animal abuse, neglect, harm or mishandling to a supervisor or other individual(s) responsible for enforcement of proper animal care.

2016 Signature: _____

Date: _____

2017 Signature: _____

Date: _____

2018 Signature: _____

Date: _____


EMERGENCY CONTACTS

Posting the names and telephone numbers of emergency contacts in a prominent place in the animal facility in employees' native languages is necessary to speed up communications in an emergency.

FARM NAME

FARM ADDRESS

OWNER/ MANAGER PHONE:

FOR GENERAL EMERGENCY SERVICES, CALL 9-1-1

LOCAL HERD VETERINARIAN
NAME: PHONE:

FEED DEALER
NAME: PHONE:

MILK HANDLER/FIELD REPRESENTATIVE
NAME: PHONE:

MILK HAULER
NAME: PHONE:

MILK EQUIPMENT DEALER
NAME: PHONE:

MACHINERY DEALER
NAME: PHONE:

OTHER CONTACTS
NAME: PHONE:
NAME: PHONE:

Animal Care

FARM Program to Host Session at AABP Annual Conference

The National Dairy FARM Program has been given the opportunity to host a session during the 2016 American Association of Bovine Practitioners (AABP) annual conference in Charlotte, N.C., on September 15-17, 2016. AABP membership comprises distinguished veterinarians serving society as leaders in cattle health, welfare and productivity.

The focus of this session is to first help AABP veterinarians understand current customer/consumer perceptions of dairy animal care and the pressures dairy cooperatives and processors face in meeting their expectations. Additionally, the session will aim to aid veterinarians in deepening their understanding of the FARM Program while recognizing the critical role that veterinarians play in ensuring the program's continued success.

Contact: Emily Yeiser Stepp

Upcoming Events

National Association of Dairy Regulatory Officials (NADRO) Annual Meeting
Grand Rapids, Michigan — July 10-13, 2016

American Dairy Science Association (ADSA) Annual Meeting
Salt Lake City, Utah — July 19-23, 2016

International Association for Food Protection (IAFP) Annual Meeting
St. Louis, Missouri — July 31-August 3, 2016

International Dairy Federation (IDF) Annual Meeting
Nantes, France — September 7-9, 2016

NMPF Joint Annual Meeting
Nashville, Tennessee — October 31-November 2, 2016

About NMPF

NMPF
NATIONAL MILK
PRODUCERS FEDERATION

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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.

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