

# Regulatory Register

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## FDA FOOD SAFETY MODERNIZATION ACT

## Food Safety Update: FSMA Regulations

### Sanitary Food Transport.

In a January 31, 2014 Federal Register notice, the FDA proposed a rule on the "Sanitary Transportation of Human and Animal Food". The regulations will require shippers, receivers, and carriers who transport food in the US by motor vehicle or rail to comply with established criteria to prevent the contamination of human and animal food during transportation. The regulations establish requirements for the design and maintenance of vehicles and transportation equipment, control of transportation operations, information exchange, training, and recordkeeping.

FDA has proposed a waiver for those engaged in transportation operations involving Grade "A" milk and milk products. Those who hold permits and are inspected through the Grade "A" program are in compliance with practices to ensure that milk products are not transported in an unsanitary manner. The waiver would only apply to transportation operations of Grade "A" milk and milk products.

The comment period is open

through May 31st. NMPF will be preparing comments.

### Draft Methodological Approach to Identifying High-Risk Foods.

On February 3, 2014, a <u>Federal Register notice</u> was published describing FDA's draft process and methodology to review and evaluate data to define "high-risk foods". FDA is seeking comments and scientific data to assist in refining their approach.

Foods that are designated as "high-risk" will be subject to increased frequency of inspection and additional recordkeeping requirements to rapidly and effectively track and trace such foods during a foodborne illness outbreak or other event.

NMPF is reviewing the draft approach and will be preparing comments, which are due May 22, 2014.

### Preventive Controls for Animal Food.

In <u>comments</u> submitted to the FDA in March 2014, NMPF asked for revisions to the proposed regulation on "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals". The draft regulation

incorrectly imposes safety standards on animal feed that are similar to those for human food and incorrectly establishes manufacturing standards that equate animal feed and human food. The proposed regulation also unnecessarily regulates byproducts from brewing when they are used in animal feed, even though there is no public health risk associated with these products.

### In separate comments

submitted jointly with the International Dairy Foods
Association, NMPF also identified unnecessary and duplicative requirements for dairy processing plants which may divert some food production materials such as cheese trim and liquid whey to animal feed as these plants are already subject to FSMA requirements for human food production.

### In an April 24, 2014 blog post,

FDA Deputy Commissioner for Foods and Veterinary Medicine Michael Taylor addressed questions posed about requiring spent brewers grains going into animal feed to comply with FSMA animal feed standards. Taylor acknowledged the minimal risk

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### Animal Health

### Importation of Beef from Brazil



On April 22, 2014, NMPF submitted comments on the draft USDA risk analysis of importation of certain fresh beef products from an FMD-Free with Vaccination Region in Brazil. USDA had concluded in its risk assessment that Brazil had sufficient safeguards in place to allow importation of certain fresh beef products from the World Animal Health Organization (OIE) recognized FMD-Free with Vaccination Region in Brazil. Upon review,

NMPF identified a number of concerns with the draft USDA risk analysis as presented that warrant further analysis prior to finalizing an allowance for importation of beef from a Region of Brazil. While recognizing a qualitative risk assessment is OIE compliant, NMPF urged USDA to follow the precedent of a quantitative risk assessment as used for the importation of the same products from Uruguay. NMPF urged USDA to be

more transparent in the risk assessment so that conformance to OIE requirements can fully be evaluated. Finally, NMPF requested that the risk assessment should clearly address issues with Brazilian compliance with meat export requirements (as identified by USDA-FSIS) and animal disease reporting to OIE.

Contact: <u>Jamie Jonker</u>



#### **Environment**

### Waters of the United States



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On April 21, 2014, the **Environmental Protection** Agency and the US Army Corps of Engineers published for <u>public comment</u> a proposed rule defining the scope of waters protected under the Clean Water Act (CWA), in light of several US Supreme Court cases. The agencies proposed to define "waters of the United States" for all sections of the CWA to mean: traditional navigable waters; interstate waters, including interstate wetlands; the territorial seas; impoundments of traditional navigable waters,

interstate waters, including interstate wetlands, the territorial seas, and tributaries, as defined, of such waters; tributaries, as defined, of traditional navigable waters, interstate waters, or the territorial seas; and adjacent waters, including adjacent wetlands.

In tandem with the proposed rule, the agencies have issued an <u>interpretive rule</u> that continues existing statutory and regulatory exemptions from CWA Section 404 permitting requirements for normal farming, silviculture and ranching practices where

these activities are part of an ongoing farming, ranching or forestry operation. The interpretive rule is immediately effective and expands the list of existing agricultural exemptions to include an additional 53 activities that are exempt from permitting requirements so long as they are conducted consistent with Natural Resources Conservation Service conservation practice standards.

Contact <u>Jamie Jonker</u> or <u>Ryan</u> <u>Bennett</u>

### Food Safety

### NMPF Weighs in on Raw Milk Bills, Both State and Federal

State legislatures have seen a busy calendar this year, with over 40 bills related to raw milk being introduced in 23 States, the majority of which would legalize or expand intrastate access to direct sales or distribution of raw milk.

On January 28, 2014, Beth Briczinski, NMPF vice president of dairy foods and nutrition, testified before the Maryland House of Delegates Health and Government Operations Committee in opposition to House Bill 3

Operations Committee in opposition to House Bill 3, which would allow the statewide sale of raw milk for direct consumption by the public through cow-shares. "No claim related to the purported health benefits of raw milk has been substantiated in any of the medical literature," she explained. "The only scientific consensus is that raw milk can cause serious illnesses and hospitalizations, and can result in life-long negative health complications and death."

Ultimately, the bill was tabled and withdrawn on March 24<sup>th</sup>, with the formation of a workgroup to study the issue expected in coming months.

Similarly, NMPF weighed in with written testimony, jointly with IDFA, on the issue in other states, including

- SB 126 with the <u>South</u>
   <u>Dakota Senate</u> Health and Human Services
   Committee;
- LD 1786 with the <u>Maine</u> <u>State Senate</u>, State House, and Governor Paul LePage;
- AB 2505 with the <u>California General</u> <u>Assembly</u> Committee on Agriculture; and
- HB 247 with the
   <u>Louisiana House of</u>
   <u>Representatives</u>
   Committee on
   Agriculture, Forestry,
   Aquaculture and Rural
   Development.

On March 25, 2014, NMPF

sent a letter with IDFA in opposition to new federal legislation introduced in Congress that would allow the interstate sales of raw milk, saying that any additional availability of the product will increase the number of sicknesses and deaths of people who consume it.

The "Milk Freedom Act of 2014" and the "Interstate Milk Freedom Act of 2014" were introduced by Rep. Thomas Massie (R-KY), which would repeal a long-standing ban on the sales across state lines of unpasteurized milk.

"Seldom has the science behind public health policy been so clearly one-sided. Pathogenic bacteria can be found on any dairy farm, regardless of its cleanliness or the good intentions of its owner. This legislation is a threat to public health and should not be approved," the organizations said.

Contact: Beth Briczinski



"Seldom has the science behind public health policy been so clearly one-sided..."

### <u>Animal</u> <u>Health</u>

### FARM Train-the-Trainer Workshop In June

A FARM Train-the-Trainer workshop was held in Monticello, FL in April. The workshop covered the revisions to the FARM Program guidelines. Participants successfully completing the two-day course are certified to train FARM evaluators and evaluate

farms for the program.

This provides cooperatives, proprietary processors, veterinarians and university professors the opportunity to conduct in-house training for evaluators.

A second Train-the-Trainer

course will be held in Columbus, OH on June 18th-19th. For more information go to the <u>events page</u> of the FARM website.

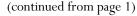
Contact: <u>Betsy Flores</u>



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### **Food Safety**

### Update: FSMA Regulations (continued)



associated with feeding spent grains and indicated the Agency will re-evaluate and revise the language around the regulation.

## Proposal Updates and Timelines.

FDA published proposed regulations related to food defense at the end of 2013. Last month, in response to stakeholder requests, additional time to comment on the proposed rule and the accompanying draft qualitative risk assessment was

announced, with a new deadline of June 30, 2014. The extension follows three public meetings on the proposal, which would require facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm.

The Federal Register notice of the proposed regulations includes several questions that are specific to dairy farms. NMPF has formed a small working group to review the rule with a focus on the impact to both dairy farms and dairy processing facilities.

FDA plans to publish revised language for the proposed rules on preventive controls for human food, preventive controls for animal food, and produce safety. The extension was granted after public input led FDA to believe that "significant changes" were needed in the proposed regulations.

Key provisions of the rules will be revised (only key components, not the full rules) and are expected to be published in Summer 2014.

Contact: <u>Beth Briczinski</u> or <u>Jamie Jonker</u>





### Animal Health

### **Animal Disease Traceability**



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On March 4, 2014, the USDA Animal and Plant Health Inspection Service announced it will "begin making sure that all animals moved interstate have the proper identification." Animal identification with an Interstate Certificate of Veterinary Inspection has been a requirement for animals moving in interstate commerce (exception for animals bound for slaughter) for a long time.

This announcement, rather, is USDA's notice that it will begin more vigorous enforcement of those requirements. The announcement contains two important points on this enforcement: (1) As a standard practice, USDA will continue to notify first time offenders when they do not meet the regulatory requirements for interstate movement of livestock; and (2) USDA will

now pursue appropriate penalties in situations where an individual repeatedly fails to comply with the regulatory requirements. The animal traceability Final Rule was originally published in the <u>Federal Register</u> on January 9, 2013 and became effective on March 11, 2013.

Contact: <u>Jamie Jonker</u>

### Nutrition

## NMPF Comments to FDA on PHO GRAS Determination

On March 8, 2014, NMPF <u>submitted comments</u> to FDA on their <u>preliminary determination</u> that partially hydrogenated oils (PHOs), the primary dietary source of artificial *trans* fat in processed foods, are not "generally recognized as safe" (GRAS) for use in food.

NMPF urged the agency, should it decide to withdraw the GRAS designation, to distinguish between industrialproduced *trans* fats, which do

not occur in nature, and ruminant trans fats, which occur naturally in meat and milk and are unavoidable in ordinary diets. NMPF recommended a number of steps the agency take if the GRAS status is withdrawn, including clearly stating in the preamble that the trans fatty acids that occur naturally are not affected by the agency's determination and addressing the meat and dairy issue in an accompanying Q&A to ensure consumers are not confused

about the topic.

In the absence of such clarification, NMPF further noted that Americans attempting to reduce consumption of ruminant *trans* fats could result in undesirable dietary effects, such as lower intakes of the nine essential nutrients in milk and milk products.

Contact: Beth Briczinski









### **Food Safety**

### FDA Drug Residue Report

Only one out of 7,200 milk tankers tested positive for antibiotic residues last year, according to the National Milk Drug Residue Database 2013 report released last month by the FDA. The new report showed that the decade-long decline in bulk milk samples testing positive for residues is continuing. Of the approximately 3.2 million

milk pickup tankers tested, only 445 (or 0.014%) yielded a positive – down from 0.017% in 2012. This is the seventh year in a row that the percentage of positive tankers has declined.

Additionally, not a single sample of the 40,435 consumer-packaged pasteurized milk products tested positive for animal drug residues. Data from four of the last five years have not yielded a single positive result for pasteurized products.

Meanwhile, NMPF continues to monitor the progress of the FDA-CVM raw milk sampling assignment. A final report is expected soon.

Contact: Beth Briczinski



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#### **Nutrition**

### FDA Proposes Changes to Nutrition Label

Nu	trition Facts
	vings per container
	per 2/3 cup ories 230
% DV*	
12%	Total Fat 8g
5%	Saturated Fat 1g
	Trans Fat 0g
0%	Cholesterol 0mg
7%	Sodium 160mg
12%	Total Carbs 37g
14%	Dietary Fiber 4g
	Sugars 1g
	Added Sugars 0g
	Protein 3g
10%	Vitamin D 2mcg
20%	Calcium 260 mg
45%	Iron 8mg
5%	Potassium 235 mg
	e on Daily Values (DV) and calories ce to be inserted here.

On March 3, 2014, two longawaited FDA proposals were published in the Federal Register: "Food Labeling: Revision of the Nutrition and Supplement Facts Labels", and "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing **Certain Reference Amounts** Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments".

The proposed changes to the Nutrition Facts panel (left) reflect new dietary recommendations, consensus reports and national survey data, including the 2010
Dietary Guidelines for
Americans, recommendations
from the Institute of Medicine,
and intake data from the
National Health and Nutrition
Examination Survey. The new
label also features a fresh
design to highlight key
nutritional concepts that are
important in addressing public
health problems like obesity
and heart disease.

NMPF applauded the added label focus on two key nutrients in milk, potassium and vitamin D, saying they "will help consumers better understand the important role that dairy plays in a healthy diet."

Other proposed changes would

update serving-size requirements to better align with how much people really eat and present calorie and nutrition information for some products for the whole package, in addition to per serving. Serving sizes for ice cream will increase from one-half cup to one cup, but will decrease for yogurt from 8 ounces to 6 ounces.

NMPF will be submitting comments to FDA on both proposed regulations, which are due June  $2^{nd}$ .

Contact: Beth Briczinski

### **Nutrition**

## NMPF Applauds USDA WIC Decision on Yogurt



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NMPF thanked USDA for allowing states to substitute some yogurt for milk in the federal government's Women, Infants and Children (WIC) nutrition program. The dairy industry had pushed for the change for those who are lactose intolerant or who might not drink milk for other reasons. Only low-fat and nonfat yogurt will be allowed, except for very young children.

USDA initially rejected that recommendation, citing concerns over cost. However,

USDA reversed that decision when <u>issuing their final</u> regulations on March 4, 2014. States will now be allowed to authorize WIC recipients to purchase up to a quart of yogurt monthly as a substitute for one quart of milk.

"This is a common-sense decision that gives states more flexibility to meet the needs of WIC participants," Beth Briczinski, NMPF VP of dairy foods and nutrition said.
"Yogurt is convenient, popular and comparable to milk nutritionally. WIC participants

should have the option to purchase yogurt instead of milk, especially if they have difficulty digesting milk."

The Special Supplemental Nutrition Program for Women, Infants and Children is designed to improve the health of low-income pregnant women, new mothers, infants and young children. Milk and other dairy products figure prominently in the WIC food packages and account for nearly a third of all purchases under the program.

Contact: Beth Briczinski

Animal Health

# FSIS Issues Notice on Euthanasia at Slaughter Facilities

The USDA Food Safety and Inspection Service (FSIS) has <u>issued a notice</u> which provides clarification to inspection program personnel and Public Health Veterinarians (PHVs) regarding the procedures that they are to follow when the slaughter facility presents non-ambulatory disabled cattle for ante-mortem inspection, including cattle that are

temporarily down (i.e., nonambulatory disabled) because of a reversible condition.

PHVs are to condemn nonambulatory disabled cattle after ante-mortem inspection and to verify that the slaughter facility promptly euthanizes these cattle. For humane handling reasons, all nonambulatory disabled cattle, except for veal calves that are non-ambulatory because they are tired or cold, are to be promptly euthanized rather than being set aside for treatment.

Contact: Betsy Flores



### **NMPF**

### **Upcoming Events**

- May 27-30, 2014 27th ADSA Discover Conference Strategies for Improving US Dairy Cattle Welfare, Eaglewood Resort and Spa, Itasca, Il <a href="http://adsa.org/Meetings/DiscoverConferences/27thDiscoverConference.aspx">http://adsa.org/Meetings/DiscoverConferences/27thDiscoverConference.aspx</a>
- July 20-24, 2014 ADSA-ASAS Joint Annual Meeting 2014, Kansas City, MO https://asas.org/meetings/jam2014/home
- Sept 17-19, 2014 American Association of Bovine Practitioners Annual Conference, New Orleans, LA <a href="http://aabp.org/meeting/">http://aabp.org/meeting/</a>
- Sept 30-Oct 4, 2014 World Dairy Expo, Madison, WI http://www.worlddairyexpo.com/
- October 27-29, 2014, NDB/NMPF/UDIA Joint Annual Meeting, Grapevine, TX



### **About NMPF**

The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the wellbeing of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the US milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

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