NATIONAL MILK PRODUCERS FEDERATION

Regulatory Register

VOLUME 16, ISSUE 1

WINTER 2014

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FDA FOOD SAFETY MODERNIZATION ACT

Food Safety

Update: FSMA Regulations

In recent months, several major elements of the Food Safety Modernization Act (FSMA) were published for public comment, including some with direct impact to dairy producers and cooperatives:

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.

The FSMA Proposed Rule for Preventive Controls in Human Food has potentially far-reaching implications for the dairy industry. In November, NMPF submitted the following comments:

- General comments on the preventive controls for human food as applied to dairy processing facilities. In a joint submission with IDFA, NMPF argued that preventive controls requirements be risk-based and promote food safety, that the Agency's rulemaking stay within FSMA's legislative framework, and that FSMA be enforced consistently and appropriately. Other key areas were discussed as well in greater detail.
- Comments requesting that FDA exempt PMO-compliant facilities or otherwise deem all such facilities as being in compliance with the preventive controls rule and, if needed, use the National Conference on Interstate Milk Shipments to make any beneficial adjustments to the PMO.
- NMPF also submitted comments that, given the high-risk nature of raw milk and in the interest of protecting public health, FDA reconsider the definition of "farm" as it applies to the production of raw milk for human consumption such that these farms would be subject to preventive controls requirements.

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

In November, NMPF also submitted comments on food safety regulations related to produce. The proposed rule included an excessive compliance burden to certain dairy farms with ancillary or incidental sales of fresh produce by including milk sales in the cumulative sales threshold for full and partial exemptions for compliance with the Produce Rule. NMPF submitted comments (with addendum) that FDA not include milk sales toward the threshold for exempting farms from produce regulations. NMPF offered FDA solutions to address this issue with minor changes in the definitions of "food" and "qualified-end user".

In December 2013, FDA announced plans to revise language in four general areas of the proposed rule affecting farms – including that identified by NMPF – and publish it for public comment by early summer. NMPF will review the revised text and provide comment at that time.

Focused Mitigation Strategies to Protect Food Against Intentional Adulteration.

In December, FDA published proposed regulations related to food defense. The proposed rule requires facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm. The proposed rule, which is required by FSMA, would require the largest food businesses to have a written food defense plan that addresses significant vulnerabilities in a food operation. NMPF will be reviewing the rule with a focus on the impact to dairy food processing facilities as well as to dairy farms.

Contact: Beth Briczinski or Jamie Jonker

Environment

USDA to Prepare EIS on Carcass Disposal Options

On October 25, 2013, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) announced its intention to prepare an Environmental Impact Statement (EIS) to examine the potential environmental effects of animal carcass management options used throughout the United States. The Animal Health Protection Act (7 U.S.C. 8301 *et seq.*) authorizes the Secretary of Agriculture to order the destruction or removal of animals to prevent the introduction and spread of livestock pests or diseases. Large numbers of animals and carcasses may need to be disposed of or otherwise managed during or after an animal health emergency. Examples of an animal health emergency include, but are not limited to, an outbreak of a foreign animal disease, a natural disaster, or the introduction of a chemical or radiological agent. As carcasses begin to degrade, bodily fluids, chemical and biological leachate components, and hazardous gases such as methane are released into the environment, potentially impacting the health and safety of surrounding humans, livestock, and wildlife. Therefore, the management of large numbers of carcasses during an animal health emergency must be timely, safe, biosecure, aesthetically acceptable, and environmentally responsible.

The comment period has been extended to January 30, 2014. NMPF will submit comments in support of conducting an EIS as this is a necessary step in ensuring our collective preparedness for such events as an FMD outbreak.

Contact: Jamie Jonker

Animal Health

FARM 2013 Year in Review and 2014 Drug Residue Manual Now Available

In November, NMPF released the Farm Program 2013 Year in Review. Dairy farmers participating in the industry's program to quantify animal care practices are continuing to improve the manner in which they adhere to the program's guidelines. The annual assessment derived from 8,000 second-party evaluations, found universal adoption of many of the best practices from the program.

NMPF also released its 2014 safe use manual for antibiotics and other animal drugs. The Milk and Dairy Beef Drug Residue Prevention Manual permits producers to quickly review those antibiotics approved for use with dairy animals. It can also be used to educate farm managers on how to avoid drug residues in milk and meat. The 2014 version has a new section on multidrug testing and updated drug and test kit lists.

Contact: Betsy Flores

Environment

NMPF Submits Comments on EPA Water Quality Standards

On January 2, 2014, NMPF submitted comments with a coalition of agriculture and forestry organizations on the U.S. Environmental Protection Agency (EPA) proposed Water Quality Standards Regulatory Clarifications Rule. The EPA proposed changes to the federal water quality standards (WQS) regulation for implementing the Clean Water Act. The submitted coalition comments raised three primary concerns: (1) the proposed regulatory changes will fail to embrace the fundamental principle under the Clean Water Act that the primary responsibility for establishing and implementing water quality standards rests with States; (2) the proposed regulatory changes will create the opportunity for EPA claim new authorities and encroach on areas that are outside of the scope of the Clean Water Act; and (3) the proposed regulatory changes are likely to lead to increased, not decreased, litigation by creating new litigable duties on states, EPA, and the regulated community.

Contact: Jamie Jonker or Ryan Bennett

Environment

NMPF Comments on EPA Draft Water Report

On November 6, 2013, NMPF submitted comments as part of the Waters Advocacy Coalition to the U.S. Environmental Protection Agency (EPA) Scientific Advisory Board on the draft report *Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence*. The EPA Office of Research and Development (ORD) developed the draft report reviewing and synthesizing the peer-reviewed scientific literature on the connectivity or isolation of streams and wetlands relative to large water bodies such as rivers, lakes, estuaries and oceans. The submitted coalition comments detailed important concerns about the draft report for the EPA Scientific Advisory Board consideration including: the lack of distinctions between significant connections and non-significant connections; not accounting for factors of variability in connectivity, such as climate, stream size, habitat, watershed characteristics, frequency and duration of flow, or proximity to navigable waters; and defining key terms, such as "stream" and "wetland," inconsistently with existing regulatory definitions.

Contact: Jamie Jonker or Ryan Bennett

Animal Health

Final BSE Rule Released by USDA

On November 1, 2013, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) announced a Final Rule that will complete efforts to modernize the Agency's import regulations for bovine spongiform encephalopathy (BSE), demonstrating to the international community that the United States is committed to basing its BSE regulations on internationally accepted scientific literature and standards set by the World Organization for Animal Health (OIE). The final regulation will allow for the safe trade of bovines and bovine products, while still protecting the United States from the introduction of BSE.

In June 2012, NMPF submitted comments in support of this regulatory change. The Final Rule, published in the Federal Register, becomes effective March 4, 2014.

Contact: Jamie Jonker

Nutrition

NMPF Comments on Competitive Foods in Schools, Community Eligibility Provision

On October 28, 2013, NMPF submitted comments to the USDA, urging the agency to make adjustments in a proposed rule affecting how dairy products are made available to school students beyond the lunch line.

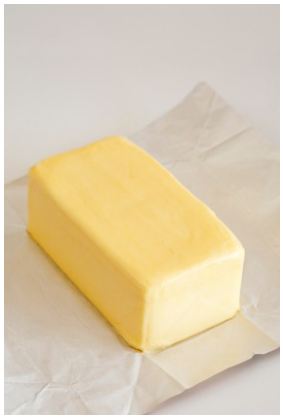
The NMPF comments single out the "favorable treatment afforded to competing beverages – which, in contrast to milk and juice, do not supply significant amounts of nutrients essential to students' diets," and points out that the proposed regulation confers an unfair and inappropriate advantage to these products.

The comments are in response to USDA's interim final rule establishing nutrition standards for foods sold outside of school meal programs. Because dairy products in those settings are competing against other foods and beverages, NMPF urged USDA to limit the time and place that non-dairy, non-juice lower-calorie and calorie-free beverages are available.

In addition, NMPF also asked USDA to include low-fat flavored milk as an allowable beverage, extend the saturated fat exemption for reduced-fat cheese to combination foods, and clarify the final rule's saturated fat standard.

NMPF also submitted comments jointly with IDFA supporting implementation of USDA's community eligibility provision, a reimbursement option for eligible agencies and schools that wish to offer free school meals to all children in high poverty schools without collecting household applications. In their January 3, 2014 comments, NMPF and IDFA noted that community eligibility "offers an important opportunity to ensure that children attending schools in high poverty areas will have greater access to school meals and increase the likelihood that children in these communities will meet their recommended dietary recommendations for milk and dairy products."

Contact: Beth Briczinski



Food Safety

FDA Tentative Determination Regarding Partially Hydrogenated Oils

On November 8, 2013, the Food and Drug Administration (FDA) published in the Federal Register its tentative determination that partially hydrogenated oils (PHOs), the primary dietary source of industrially-produced *trans* fats, are not generally recognized as safe (GRAS) for use in food.

Over the past decade, the food industry has drastically reduced the use of PHOs as part of broader health and wellness initiatives, and now FDA is proposing to eliminate them entirely. If finalized, this would mean that food manufacturers would no longer be permitted to sell PHOs, either directly or as ingredients in another food product, without prior FDA approval for use as a food additive.

PHOs are commonly found in snack foods, microwave popcorn, frozen pizza, creamers and vegetable shortenings. FDA's proposal does not apply to the naturally-occurring *trans* fat in dairy products.

NMPF will be submitting comments on the proposed rule, which are due March 8, 2014.

Contact: Beth Briczinski

NMPF Promotes Betsy Flores, Beth Briczinski

NMPF

Effective January 1, 2014, NMPF promoted Betsy Flores to Vice President, Animal Care. Betsy manages the National Dairy FARM Program, which assures consumers that milk and other products from American dairy farms are the end result of responsible animal care practices.

Beth Briczinski was promoted to Vice President, Dairy Foods & Nutrition. Beth's main responsibilities include food safety, standards & labeling, and nutrition.

Flores and Briczinski will report to Tom Balmer, NMPF Executive Vice President.

FDA to Sample Raw Milk Cheeses

Food Safety

In 2014, FDA will launch a year-long sampling assignment to obtain more extensive data on contamination of raw milk cheeses.

FDA plans to collect and test 1,600 raw milk cheese samples for *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7. Approximately 70% of the samples will be collected from imported cheeses.

The data obtained through this sampling assignment will allow FDA to act proactively, to better allocate resources, and to assess and manage risks associated with specific food processes.

Contact: Beth Briczinski

NMPF Comments on 2015 Dietary Guidelines

Nutrition

Preparations for the 2015 Dietary Guidelines, issued jointly by the US Department of Agriculture and Health and Human Services, have begun. Most recently, the Dietary Guidelines Advisory Committee (DGAC) held their second public meeting, which included public testimony.

On January 14, 2014, NMPF urged the scientific advisory panel to keep the recommendation of three daily servings of dairy products for most Americans, since dairy products are the number-one source of nine key nutrients.

"Dairy foods are uniquely nutrient-rich and virtually irreplaceable in the diet if we want to meet nutrient recommendations," stated Beth Briczinski. "We strongly urge the committee to maintain the current recommendation of three daily servings of dairy, and to focus on the serious public health problem of under-consumption of milk and dairy products."

Dairy's unique nutrient profile cannot be matched by other foods and, if other calcium sources are incorporated, nutrient inadequacies still exist in the diet. "There is simply no substitute for dairy," noted NMPF's testimony. "Americans have major shortfalls in recommended milk consumption starting at just four years of age. None of us should find that acceptable."

Based on dairy's role in preventing several chronic diseases and it's cost-effectiveness as a nutrient package, NMPF advocated that the DGAC encourage people who are under-consuming dairy to add at least one more serving a day.

NMPF's full oral testimony is available.

Contact: Beth Briczinski

"There is simply no substitute for dairy."

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Animal Health

FDA Issues Final Guidance 213 and VDF Proposed Rule Change

On December 11, 2013, the U.S. Food and Drug Administration (FDA) finalized Guidance for Industry #213 establishing the procedures for voluntarily phasing out growth promotion indications for medically important antibiotics in alignment with Guidance for Industry #209. In the final guidance, animal pharmaceutical companies will voluntarily revise the FDA-approved use conditions for these products to remove production indications. Additionally, the current over-the-counter status will be changed to bring the remaining appropriate therapeutic uses under veterinary oversight. Importantly, animal health companies have supported this policy since it was first advanced in 2012.

The FDA also announced the intent to amend the Veterinary Feed Directive (VFD) to improve efficiency of the program. The VFD regulation mandates the rules and responsibilities of licensed veterinarians in prescribing and administering medically important antibiotics in feed. The 90-day comment period for the Proposed Rule published via the Federal Register will conclude on March 12, 2014. Ionophores, like monensin, are not affected by the guidance, since they have no human medical relevance. Thus the proposed actions should have no effect on the use of ionophore additives in lactating & dry cows or coccidiostats in growing heifers.

Contact: Jamie Jonker or Betsy Flores

Environment

Water Quality Trading Lawsuit Dismissed

On December 13, 2013, the U.S. District Court of the District of Columbia granted the U.S. Environmental Protection Agency (EPA) motion to dismiss a lawsuit brought by Food and Water Watch (FWW) and Friends of the Earth (FOE) alleging EPA overstepped its bounds by allowing water quality trading as a means of complying with Total Maximum Daily Load's (TMDL's) set by the agency. The plaintiffs alleged that EPA gave "authorization" for water quality trading in their 2010 TMDL's and that this action was contrary to the Clean Water Act (CWA). They also alleged that such "authorization" would violate the Administrative Procedures Act (APA) because the agency did not allow for a Notice of Comment and Rulemaking as required by APA. The judge granted a motion to dismiss by EPA which said that the plaintiffs did not have standing because of lack of subject matter in the case and because the plaintiffs were not challenging any final action by the agency. The judge ruled that the suit was premature as the groups could not show actual harm or an imminent threat from trading programs.

Contact: Ryan Bennett

2014 NMPF Scholarship Program

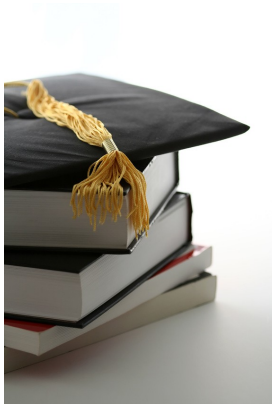
NMPF

NMPF is now accepting applications for its National Dairy Leadership Scholarship Program for academic year 2014-2015. Each year, NMPF awards scholarships to outstanding graduate students who are actively pursuing dairy-related fields of research that are of immediate interest to NMPF member cooperatives and the US dairy industry.

Graduate students pursuing research of direct benefit to milk marketing cooperatives and dairy producers are encouraged to submit an application (applicants do not need to be members of NMPF to qualify). Recommended fields of study include but are not limited to Animal Health, Animal and/or Human Nutrition, Dairy Products Processing, Dairy Science, Economics, Food Science, and Food Safety.

Applicants must follow all instructions in the application form. Materials must be received **no later than April 4, 2014**.

Contact: Beth Briczinski



Upcoming Events

NMPF

- March 3-7, 2014, IDF Symposium on Microstructure of Dairy Products and IDF Symposium on Science and Technology of Fermented Milk, Melbourne, Australia
  http://dairyscienceconf.com/
- March 31-April 3, 2014, National Institute for Animal Health Annual Meeting, Omaha, NE
  http://www.animalagriculture.org/
- May 7-8, 2014, Animal Ag Alliance Summit, Crystal City, VA
  http://www.animalagalliance.org/current/index.cfm
- May 27-30, 2014, ADSA Discover Conference - Strategies for Improving US Dairy Cattle Welfare, Itasca, IL
  http://www.adsa.org/Meetings/DiscoverConferences/

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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