



NATIONAL MILK PRODUCERS FEDERATION

# Regulatory Register

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## Food Safety

## Update: Food Safety Modernization Act (FSMA) Regulations

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### Intentional Adulteration (Food Defense).

The Food and Drug Administration’s (FDA) proposed rule on food defense (“[Focused Mitigation Strategies to Protect Food Against Intentional Adulteration](#)”) would require domestic and foreign facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm. As proposed, the rule would require food facilities to have a written food defense plan that addresses significant vulnerabilities in their operation. The *Federal Register* notice also included several questions specific to dairy farms.

In response to the proposed regulations, NMPF argued that milk leaving U.S. dairy farms is an unlikely target for a terrorist attack, and asked the FDA to exempt dairy producers from intentional adulteration regulations.

[In comments filed with FDA](#) on June 30, NMPF said it’s hard to predict where milk from any one dairy farm will go because of constantly changing processing needs

around the country. As a result, milk leaving a dairy farm is unlikely to be a target for intentional adulteration and “activities on dairy farmers should not be addressed through this rule.”

NMPF also pointed out that dairy farms already employ a number of general security strategies that further reduce risks to plant-bound milk and that many anti-terrorist procedures are already being used on these farms.

In addition, [NMPF submitted comments jointly](#) with the International Dairy Foods Association (IDFA) questioning FDA’s proposed regulations focused on preventing intentional adulteration at dairy processing plants. Like dairy farms, the two organizations said, processing facilities have taken an active approach to applying food defense concepts.

Both sets of comments affirmed the industry’s commitment to food safety and encouraged FDA to work in collaboration with the National Conference on Interstate Milk Shipments to determine the best way to apply food defense

requirements to the dairy industry.

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

In February 2014, a [Federal Register notice](#) described FDA’s draft process and methodology to review and evaluate data to define “high-risk foods”. 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.

In [joint comments submitted](#) on May 22<sup>nd</sup> by NMPF and IDFA, the groups pointed out that products that undergo a validated “kill step” – like pasteurization for dairy products – should not be considered high-risk foods. Upon reviewing FDA’s draft approach, other concerns identified included not weighting appropriate preventive controls and processing steps that control the risk of a food being implicated in a foodborne illness outbreak, as well as

*(continued on p 4)*

FDA FOOD SAFETY MODERNIZATION ACT

**Animal Health****OIE Animal Welfare and Dairy Cattle Production Standards**

The [World Animal Health Organization \(OIE\)](#) continues to develop a chapter on animal welfare and dairy cattle production standards. The OIE released a second draft of the proposed standards in March. The initial draft was released in 2013 and comments received were reviewed by the OIE working group.

NMPF has worked in conjunction with the Animal Ag Alliance to coordinate a U.S. animal agriculture industry response. NMPF is submitting a comprehensive list of comments to USDA. Comments will also be submitted to the International Dairy Federation Standing Committee on Animal Health.

The draft standards focus on

on-farm practices that include animal health and animal handling.

The comments from OIE member countries will be reviewed by the working group this fall and a final document is expected to be put forward to the OIE General Assembly in 2015.

Contact: [Betsy Flores](#)

**Environment****Waters of the United States Update**

On April 21, 2014, the U.S. Environmental Protection Agency (EPA) and the U.S. Army Corps of Engineers released a [proposed rule](#) to revise the definition of “waters of the United States” (WOTUS) for all Clean Water Act (CWA) programs. The definitional changes contained in the proposed WOTUS rule may impact permitting and regulatory requirements for dairy farms. On May 30, 2014, NMPF [requested an extension](#) because the EPA and the Army Corps of Engineers have not completed the report providing the scientific

underpinning for the regulation; and many of the key concepts discussed in the draft are unclear or subject to interpretation by government regulators. In response to the NMPF request, EPA extended comment deadline to October 21, 2014.

In tandem with the proposed rule, the agencies have issued an [Interpretive Rule](#) that exempted [56 practices](#) from permitting requirements so long as they are conducted according to Natural Resources Conservation Service (NRCS) conservation practice standards. In [comments submitted](#) on July

7, 2014, NMPF stated that, as written, the Interpretive Rule would adversely affect dairy farmers and have the perverse impact of harming the longstanding trust and cooperative relationship between dairy producers and the USDA NRCS. For a number of reasons, NMPF requested that the Interpretive Rule be withdrawn and that the agencies’ policy on establishing eligibility for the 404 exemption be re-proposed through a normal proposal comment process.

Contact [Jamie Jonker](#) or [Ryan Bennett](#)



**Labeling****NMPF Questions FDA's Ingredient Labeling Focus, Calls Attention to Misbranded Imitators**

In a May 5th letter, [NMPF questioned why the FDA](#) is focused on clarifying the use of terms like “dried cane syrup” or “evaporated cane juice” at the same time it allows soy, rice, nut, and hemp products to repeatedly define themselves as milk in violation of FDA’s own long-standing food standards.

“It seems rather disingenuous for the Agency to utilize its often-referenced ‘limited resources’ to issue additional labeling guidance, while simultaneously not enforcing existing regulations pertaining to the identity of foods” like imitation dairy products,

NMPF wrote. “The Agency has blatantly disregarded the names displayed on the labels of imitation dairy products (e.g., ‘soy milk’, ‘rice yogurt’, etc.) in the current marketplace.

“While the FDA has made its position clear through warning letters to several manufacturers ... these actions have been too infrequent to be effective, essentially creating a labeling landscape free of enforcement,” NMPF said.

The letter was the latest in a long series of NMPF attempts to get the FDA to enforce

requirements for the labeling of these imposters, many of which are not nutritionally equivalent to real dairy products.

“Manufacturers of these imitation products have misled American consumers for far too long – making a mockery of current labeling regulations – by usurping the ‘dairy halo’ associated with wholesome and nutritious milk and dairy products,” the letter said.

Contact: [Beth Briczinski](#)

**Animal Health****ISO Animal Welfare Update**

The [ISO Working Group 16](#) (WG) met in Paris in May to continue work on developing a technical specification (TS) on animal welfare. The meeting followed the official adoption by the ISO Technical Committee 34 of a New Work Item Proposal to create a technical specification on this topic.

The WG meeting focused on how the process was going to move forward. The WG is very large so a drafting group was nominated. The drafting group will work through the summer to create an outline of the TS. The WG will work electronically through the fall and winter to agree on a first

draft. An additional in-person meeting is expected to take place in May/June 2015. Completion of the work is not expected until 2016.

Contact: [Betsy Flores](#)



**Food Safety****Update: FSMA Regulations (continued)**

(continued from page 1)

evaluating all dairy products in a single “Dairy” category. Viewing “Dairy” as a single group ignores the different combinations of product characteristics and processing steps represented by unique dairy foods. It would also inaccurately skew the risk represented by dairy products as foodborne illness data from unpasteurized milk and dairy products would be included under a single “Dairy” classification.

**Sanitary Transportation.**

The 7<sup>th</sup> and final major regulation proposed under the Food Safety Modernization Act (FSMA) is the “[Sanitary Transportation of Human and Animal Food](#)”. The proposed rule applies to all food, raw materials (including packaging) and ingredients, for both human food and animal feed,

transported in the United States.

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 tentatively proposed a waiver for shippers, carriers, and receivers who hold valid permits and are inspected under the NCIMS Grade “A” Milk Safety Program, when engaged in transportation operations involving Grade “A” milk and milk products.

FDA granted requests for an extension of the comment period, and NMPF is currently preparing to submit comments on FDA’s proposal at the end of July.

Contact: [Beth Briczinski](#)

**Animal Health****FMD Preparedness**

The NMPF Animal Health & Wellbeing Committee has established an FMD Preparedness Task Force to assess the state of and future needs for FMD preparedness for the U.S. dairy industry. [FMD](#) is a highly contagious viral disease affecting cattle, pigs, sheep, goats and other cloven-hoofed animals. The [consequences of an FMD outbreak](#) in the U.S. would be

extremely high with direct impacts upon animal health and productivity as well as indirect impacts for personal livelihoods and the loss of trade and economic well-being for our country. The FMD Task Force is examining a variety of topics on FMD preparedness, including the [North American FMD Vaccine Bank](#); vaccine research and technology; USDA [National](#)

[Animal Health Laboratory Network](#); FMD diagnostics; [the Plum Island Animal Disease Center](#) and the future [National Bio and Agro-Defense Facility](#); and the [Secure Milk Supply](#). The FMD Task Force is also developing on-farm biosecurity and FMD educational materials for dairy producers.

Contact: [Jamie Jonker](#)



**Food Safety****Infant Formula Standards Finalized**

In a June 10<sup>th</sup> *Federal Register* notice, FDA issued [final manufacturing standards](#) for infant formula. While FDA does not approve infant formulas, FDA does conduct annual inspections of facilities that manufacture infant formula. The final rule does not change nutritional requirements, but does include:

- Current good manufacturing practices

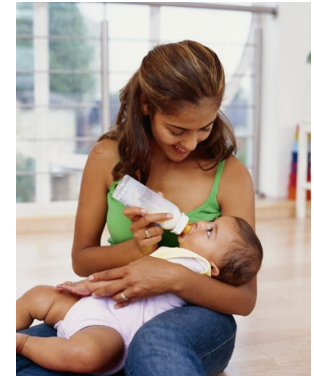
(CGMPs) and quality control procedures specifically for infant formula, including required testing for *Salmonella* and *Cronobacter*.

- A requirement that manufacturers demonstrate that the infant formulas they produce support normal physical growth.
- A requirement that

infant formulas be tested for nutrient content in the final product stage, before entering the market, and at the end of the products' shelf life.

Additional guidance documents and regulatory information are available on [FDA's Infant Formula webpage](#).

Contact: [Beth Briczinski](#)

**Labeling****Dairy Farmer Testifies on Benefits of Biotechnology**

On Wednesday, July 9, the House Agriculture Subcommittee on Horticulture, Research, Biotechnology and Foreign Agriculture held a hearing to consider the benefits of biotechnology. Among the witnesses testifying was a dairy farmer from Vermont, [Joanna Ludwick](#).

Mrs. Ludwick spoke about how biotechnology has helped her family farm. In particular, Mrs. Ludwick cited how

genetically modified feed has lowered costs for feed for their small dairy farm. Without access to such feed, the Ludwicks would have incurred nearly \$75,000 in additional feed costs for their 45 cow dairy.

Mrs. Ludwick also spoke about being both a consumer and a mother and how that has impacted her views on genetically modified foods. As she testified, "I feel secure in the steps that have been taken

to the food produced and available for sale in the grocery store to ensure it is safe to feed my family."

The Subcommittee focused on the need for farmers and proponents of GMO products to share their story and their views as Mrs. Ludwick did and how that would help change the current narrative about GMO products.

Contact: [John Hollay](#)



**Food Safety****NMPF Weighs in on Raw Milk at Both State, Federal Levels****Raw Milk in Louisiana.**

NMPF weighed in on another state-level raw milk bill in April, urging Louisiana lawmakers to reject HB 247 two days before it was scheduled for a hearing. The bill would lift the state's ban on selling unpasteurized milk to consumers.

In a joint letter, NMPF and IDFA cited the government statistics on illnesses and deaths from raw milk consumption and noted that raw milk is a vehicle for transmitting pathogens including *E. coli* 0157:H7, *Campylobacter*, *Listeria monocytogenes*, and *Salmonella*.

The groups also debunked advocates' claims that consuming raw milk has health benefits and that testing and regulation can protect consumers. "No

claim related to the health benefits of consuming raw milk has been substantiated in any of the medical literature," they said, adding that "product testing ... cannot ensure the same level of safety as pasteurization."

HB 247 passed the Louisiana House, but died in the Senate Committee on Health and Welfare, due to safety concerns about unpasteurized milk.

**Interstate Sale of Raw Milk.**

Raw milk, until now mostly an issue in state legislatures, migrated to Congress, where freshman Rep. Thomas Massie (R-KY) introduced the "Interstate Milk Freedom Act" to repeal the long-standing ban on selling unpasteurized milk across

state lines.

In a [March 25 letter](#), NMPF and IDFA joined forces to oppose the legislation, arguing it would greatly increase the production and consumption of a known health hazard. "Raw milk skips the pasteurization safety process, and this is playing Russian roulette with the health of too many Americans – including many of our children," the letter said.

NMPF President and CEO Jim Mulhern said, if the Massie bill passes, children will be the ones who suffer the most. "The benefits of consuming raw milk are illusory, but the painful costs of illness and death are very real," he said.

Contact: [Beth Briczinski](#)

**Environment****USDA Announces Regional Conservation Partnership**

On May 27, 2014, Secretary of Agriculture Tom Vilsack announced the launch of the new [Regional Conservation Partnership Program](#) (RCPP) including \$400 million in funding available in the first year. Established in the recent Farm Bill, RCPP streamlines conservation efforts by combining four programs (the Agricultural Water Enhancement Program, Cooperative Conservation

Partnership Initiative, the Chesapeake Bay Watershed Initiative, and the Great Lakes Basin Program for Soil Erosion) into one. RCPP promotes coordination between the USDA Natural Resources Conservation Service (NRCS) and its partners to deliver conservation assistance to producers and landowners. NRCS provides assistance to producers through partnership agreements and through

program contracts or easement agreements. Assistance is delivered in accordance with the rules of EQIP, CSP, ACEP and HFRP; and in certain areas the Watershed Operations and Flood Prevention Program.

Contact [Jamie Jonker](#)



**NMPF****NMPF Announces 2014 Scholarship Winners**

At their June meeting, the NMPF Scholarship Committee selected two graduate students to receive scholarships as part of the 2014 NMPF National Dairy Leadership Scholarship Program. These students are conducting research in areas that will benefit dairy cooperatives and producers.

The 2014 Hintz Memorial Scholarship, given to the top scholarship candidate, was awarded to Curtis Park, a PhD candidate in Food Science at North Carolina State University. His research project is the effect of processing on the quality of skim milk powder and sources of off-flavors in whey protein concentrate.

A scholarship was also awarded to Robb Bender, PhD candidate in Dairy Science at the University of Wisconsin-Madison, for his research on using statistical process control to integrate nutritional data in real-time analysis on commercial dairy farms.

Contact: [Beth Briczinski](#)

**Animal Health****U.S.-Canada Draft Framework for Foreign Animal Disease Zoning Arrangement**

On May 13, 2014, USDA Animal and Plant Health Inspection Service (APHIS) released for comment the draft *Framework for Implementing and Maintaining the Arrangement between the CFIA and the USDA for the Recognition of Foreign Animal Disease Control and Eradication Zones* for implementing and maintaining a foreign animal disease (FAD) zoning arrangement between the United States and Canada. The intent of the arrangement is to facilitate recognition by

APHIS and the Canadian Food Inspection Agency (CFIA) of each other's decisions to establish, maintain, and release an area of control in the event of a highly contagious FAD outbreak. The draft Framework details an operational plan for implementation and establishes processes for maintaining the arrangement over time and outlines an approach to engage governmental and non-governmental stakeholders in developing the strategy and

resources to effectively implement the arrangement during an FAD outbreak. [NMPF submitted comments](#) in support of the draft Framework as an important measure for Foot and Mouth Disease. Canada is currently the second-largest export market for U.S. dairy products valued at \$800 million in the last twelve months (June 2013 – May 2014).

Contact [Jamie Jonker](#)

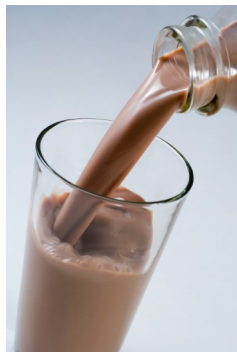


## Nutrition

## Update: Recent Nutrition News

**Flavored Milk in Connecticut.**

On June 12, Connecticut Governor Dan Malloy vetoed legislation passed by the Connecticut General Assembly that would have banned the sale of flavored milk in schools. The General Assembly had unanimously passed the legislation which included the ban on such sales as part of a larger education policy bill. However, legislators admitted that the flavored milk ban was never intended and resulted from an error in drafting due to a misinterpretation of the federal Healthy, Hunger-Free Kids Act. That act sought to lower the sodium content of foods sold in schools but the bill in Connecticut would have eliminated any beverage that had even a small amount of added sodium including flavored milk. Governor Malloy cited the nutritional benefits of flavored milk in announcing his veto and chided the General Assembly for the mistaken interpretation of the federal law.

**2015 Dietary Guidelines.**

The fourth meeting of the [2015 Dietary Guidelines Advisory Committee](#) (DGAC) is scheduled for July 17-18, 2014. The DGAC will review work recently completed by the subcommittees and establish a plan of work for the future. Topics include dietary patterns, nutrient intakes and human health, physical activity and behavior, sustainability and food safety. Attendees may [register online](#) to view a webcast of the meeting.

The scientific report from the DGAC is expected at the end of 2014, and the *8<sup>th</sup> Dietary Guidelines for Americans* is expected to be jointly published by HHS and USDA by the end of 2015.

**Proposed Regulations on Nutrition Facts and Serving Size.**

In May, FDA granted stakeholder requests to extend the comment period on two significant nutrition labeling regulations: [“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”.**

Nutrition Facts	
Serving Size 2/3 cup (65g)	
Servings Per Container About 8	
Amount Per Serving	% Daily Value*
<b>Calories 230</b>	Calories from Fat 72
<b>Total Fat</b> 8g	<b>12%</b>
Saturated Fat 1g	<b>5%</b>
Trans Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 160mg	<b>7%</b>
<b>Total Carbohydrate</b> 37g	<b>12%</b>
Dietary Fiber 4g	<b>16%</b>
Sugars 1g	
<b>Protein</b> 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%
* Percent Daily Values are based on a diet of other people's misdeeds.	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Sat Fat	Less than 20g 25g
Cholesterol	Less than 300mg 300mg
Sodium	Less than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g

FDA is proposing to update the Nutrition Facts label for packaged foods to reflect the most recent public health and scientific information, including information about the link between diet and chronic diseases such as obesity and heart disease.

The proposed label would also update out-of-date serving size requirements to better align with how much people really eat, and it features a fresh design to highlight key parts of the label such as calories and serving sizes. Specifically for dairy foods, 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 is preparing to submit comments to FDA on both proposed regulations, which are now due August 1<sup>st</sup>.

Contact: [Beth Briczinski](#)



## Animal Health

### OIE General Session Recap

Each year the [World Animal Health Organization](#) (OIE) meets to update international animal health standards through the [Terrestrial Animal Health Code](#) and report on animal health status of countries around the world. This year, for the first time, the OIE granted disease-free status for [peste des petits ruminants](#) (PPR) including

recognition of disease-free status for the U.S.

The OIE will be convening an *ad-hoc* technical group to examine atypical [Bovine Spongiform Encephalopathy](#). The OIE is also developing a chapter for the *Terrestrial Animal Health Code* on animal welfare in dairy cattle production

systems. The full OIE General Sessions meeting summary is available [online](#).

Contact [Jamie Jonker](#)



## NMPF

### Upcoming Events

- September 16-18, 2014, BIO Livestock Summit, Sioux Falls, SD  
<http://www.bio.org/events/conferences/livestock-biotech-summit>
- September 18-20, 2014, American Association of Bovine Practitioners Annual Conference, Albuquerque, NM <http://aabp.org/meeting/>
- September 30-October 4, 2014, World Dairy Expo, Madison, WI  
<http://www.worlddairyexpo.com/>
- October 16-17, 2014, AMI Animal Care and Handling Conference for the Food Industry, Kansas City, MO <http://www.meatami.com/ht/d/sp/i/101361/pid/101361>
- October 27-29, 2014, NDB/NMPF/UDIA Joint Annual Meeting, Grapevine, TX  
<http://www.nmpf.org/nmpf-joint-annual-meeting>
- October 27-31, 2014, IDF World Dairy Summit, Tel Aviv, Israel  
<http://www.idfwds2014.com/>



## 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 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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