

Regulatory Register

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Food Safety Modernization Act (FSMA)

Preventive Controls Comments Filed

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NMPF staff filed its thirty-first set of comments regarding rulemaking under the Food Safety Modernization Act (FSMA). These comments addressed issues raised in FDA's supplemental proposed rule on <u>Current Good Manufacturing</u> <u>Practice and Hazard Analysis</u> and Risk Based Preventive Controls for Human Food.

In many respects the supplemental proposal, which modified and supplemented an earlier proposal, was strong evidence that advocacy and engagement during the rulemaking process pays off. A great deal of the supplemental proposal addressed issues that NMPF and the International Dairy Foods Association (IDFA) had raised in comments and in numerous meetings. For example, NMPF strongly advocated against mandatory finished product pathogen testing and pointed out how costly and ineffective a strategy this would be. Despite strong support for such a testing protocol from many groups, FDA saw the common sense in the approach, and they will not require finished product pathogen testing.

NMPF also advocated against FDA's very rigid supplier verification proposed requirements and the reproposal does in fact provide considerable additional flexibility. In addition, FDA has clarified that if a facility is subject to the Preventive Controls for Human Food rule, it will not have to follow the Preventive Controls rule for Animal Feed even if that facility diverts outdated or off-spec food to animal feeding operations. In earlier comments, NMPF had advocated for that precise outcome.

FDA FOOD SAFETY MODERNIZATION ACT

NMPF also used this comment period to once again request that Grade "A" milk facilities be exempted from the Preventive Controls rule and continue to be regulated under the Pasteurized Milk Ordinance as has successfully been done for decades.

With respect to FDA's supplemental proposal on the <u>Produce Rule</u>, NMPF supported FDA's decision to apply its produce safety regulation to farms based on produce sales only. As originally drafted, the regulation applied to mixed-type facilities with total *food* sales of more than \$25,000. This would have affected more than 2,000 dairy farms with

incidental fresh produce sales.

Under a federal court directive, FDA must issue a final preventive controls rule by August 30, 2015. Very small businesses will have three years to become complaint, small businesses two years and all others must be compliant within one year. For dairy processors, this is the single most important of all the new rules under FSMA.

The comments in response to the supplemental proposed <u>Preventive Controls rule</u> and the <u>Produce rule</u> were filed on December 15, 2014.

Contact: <u>Beth Briczinski</u> or <u>Clay Detlefsen.</u>



REGULATORY REGISTER



Food Safety

FDA's Intentional Adulteration; Food Defense Rule Applies to Dairy Farms

In January 2011, the President signed the Food Safety Modernization Act into law. Among the numerous provisions is a requirement for FDA to develop a regulation to protect against the intentional adulteration of food. Congress instructed FDA that they shall specify how a person will assess whether to implement mitigation strategies to prevent adulteration and to specify science-based mitigation strategies to protect the food supply at specific vulnerability points. Congress also instructed FDA that the regulation shall only apply to food for which there is a high risk of intentional contamination. Congress exempted all farms from the regulation with the exception being dairy farms.

On December 24, 2013, FDA issued a proposed rule to address the Congressional mandates. They did so under court order, in contrast to original plans to proceed with a fact finding mission. In comments submitted to FDA on the proposed rule on June 30, 2014, NMPF strongly argued that on-farm milk for pasteurization is not a high-risk food and, therefore, dairy farms should not be addressed through this rule.

NMPF staff have worked closely with FDA on food defense matters since shortly after 9/11 and play a key role in the leadership of the Food and Ag Sector, one of sixteen critical infrastructure partnerships created under the auspices of Homeland Security Presidential Directives 7 & 9. However, NMPF disagrees with FDA's



finding in the proposed rule that dairy farms are at high risk of being intentionally contaminated. FDA in its declaration of high risk, has in essence, determined that if farm milk were intentionally contaminated, the consequences would be significant. But, high consequence is not the same thing as high risk.

FDA must issue a final rule by May 31, 2016. NMPF believes a revised proposal will be issued this year, hopefully with significant revision reflective of our earlier comments. NMPF will continue to advocate for a sensible regulation for dairy food processors and strive to minimize or eliminate any dairy farm regulatory burdens. Hopefully, industry and FDA together can find a regulatory solution that will make sense in such a novel area.

FOOD

SAFETY



Preparation for NCIMS Underway

Food Safety

Preparations for the National Conference on Interstate Milk Shipments (NCIMS) are currently underway. NCIMS is a non-profit organization whose goal is to "Assure the Safest Possible Milk Supply for All the People." The <u>2015 Conference</u> will be held April 24-29, 2015 at the DoubleTree by Hilton Hotel in Portland, Oregon. NMPF will be reviewing conference proposals and preparing positions.

NCIMS meets biennially in odd -numbered years. For more information on NCIMS, please contact <u>Beth Brizinski</u>.



Animal **Health**

Update: Foot and Mouth Disease

Citing concerns over the risk of a Foot and Mouth Disease (FMD) outbreak in the United States, NMPF opposed a proposal by USDA's Animal and Plant Health Inspection Service (APHIS) to allow chilled or frozen beef imports from Northern Argentina.

In comments filed December 29, NMPF noted that, while Northern Argentina is recognized as FMDfree with vaccination, some of its neighbors are not, and some of its border areas have few natural

barriers. The U.S. has been FMDfree since 1929 due to stringent import controls of animals and animal products from FMD affected



areas of the world. NMPF said APHIS audits of Argentina's inspection system identified deficiencies in meat import

procedures, and European Union audits highlighted concerns over Argentina's border controls, vaccination controls, FMD surveillance measures and wildlife management.

In addition, NMPF said a qualitative, or descriptive, Foot and Mouth Disease risk assessment of imported Argentine beef should have been data-based, as a 2002 FMD risk assessment involving neighboring Uruguay was.

Contact: Jamie Jonker



Animal Health

In November, NMPF released the Farm Program 2014 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 more than 10,000 secondparty evaluations, found universal adoption of many of the best

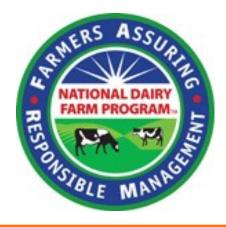
FARM 2014 Year in Review and 2015 Drug **Residue Manual Now Available**

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 2015 version has a new section on multidrug testing and updated drug and test kit lists.

Contact: Emily Meredith



Animal International Dairy Federation Recap

In December, NMPF staff participated in meetings of the International Dairy Federation (IDF), held in Paris, France. Various staff members participated in several standing committees in the areas of animal health and wellbeing, farm management, nutrition, the environment and hygiene and safety.

Health

Specifically, NMPF works closely with our partners at IDF to monitor international animal welfare efforts including those of ISO and World Organization for Animal Health (OIE), works to ensure a scientific approach to Codex resolutions, including those on rBST, and collaborates to support studies on emerging global animal diseases affecting dairy cattle.

Additionally, NMPF staff members Jamie Jonker and Emily Meredith, will chair a sub-committee to facilitate an international dairy farmer forum to occur at the annual International Dairy Federation World Dairy Summit to be held September 20–24, 2015 in Vilnius, Lithuania. The farmer forum, though in early planning stages, will include farm tours and a dairy farmer roundtable meant to foster discussion on the industry's most pressing issues. The forum will be the opportunity for farmers to interact with farmers, share ideas and experiences.

Support for these efforts is provided by the U.S. Dairy Export Council.

Contact: <u>Emily Meredith</u> or <u>Jamie Jonker</u>



Welfare Guidelines

NMPF Submits Comments on ISO and OIE

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

In December, NMPF submitted the third round of comments on the World Organization for Animal Health (OIE) Welfare and Dairy Cattle Production Systems Chapter. These guidelines were distributed as part of OIE's initiative to develop international farm animal welfare guidelines for its 180 member countries, including the U.S. OIE also has sought comment on chapters affecting other species including Introduction to the Recommendations for Animal Welfare and Animal Welfare and Broiler Chicken Production Systems. NMPF's comments will

be collated and submitted by the U.S. delegation to OIE and reviewed by the drafting committee. The final draft of the dairy welfare chapter will be debated at a May meeting of OIE in Paris, France.

Additionally, NMPF also submitted comments to USDA on ISO's governing outline. ISO is the international body tasked with developing standards interpreting and implementing the OIE welfare guidelines.

NMPF's comments will be reviewed and combined with those of other stakeholder groups and utilized as the drafting of these species-specific welfare standards progresses.

Contact: <u>Emily Meredith</u> or <u>Jamie Jonker</u>





World Organisation for Animal Health

Environment

NMPF Asks EPA to Further Clarify Waters of the United States Regulation

NMPF has recommended a series of changes to the Environmental Protection Agency's (EPA) controversial Waters of the U.S. regulation (WOTUS) a proposal that could greatly expand the waterways subject to regulation under the federal Clean Water Act (CWA).

In more than 23 pages of <u>comments</u>, NMPF stressed that, above all, agriculture needs certainty on which waterways fall under the jurisdiction of the CWA, and which do not. The draft regulation doesn't provide that clarity. NMPF also submitted additional <u>comments</u> on EPA

guidance for when farmers must seek CWA permits for a long list of normal farming activities near wetlands.

NMPF asked EPA to clarify numerous terms in the draft, including "other waters," "upland ditches," "floodplain," "tributary," and "significant nexus." In addition, it urged that any final regulation exclude from federal jurisdiction intermittent streams and wetlands adjacent to excluded streams. NMPF also asked EPA to publish maps clearly indicating the features that make a waterway covered under the CWA.

The draft WOTUS regulation, issued in March, expanded the

EPA Withdraws Water Guidance as Result of

waterways covered under the CWA to nearly all those connected to U.S. navigable waters. Many opponents argued the draft would have a devastating impact, particularly on agriculture.

NMPF first <u>urged</u> the EPA to rethink the regulation last spring, citing its many ambiguities and uncertainties. A subsequent NMPF analysis demonstrated that the EPA and Army Corps of Engineers' proposal does not meet the requirements of various Supreme Court rulings that were the catalyst for the development of the regulation.

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

Environment

As the result of objections raised by the National Milk Producers Federation, the U.S. Environmental Protection Agency (EPA) has withdrawn a regulatory guidance issued last year concerning when farmers must seek Clean Water Act permits for a long list of normal farming activities near wetlands.

On Friday, January 29, the EPA and the U.S. Department of Army <u>signed a</u> <u>memorandum</u> withdrawing the "Interpretive Rule Regarding the Applicability of Clean Water Act Section 404(f)(1)(A)." Last summer, <u>NMPF requested</u> that the Interpretive Rule be withdrawn because it could have actually discouraged water conservation and environmental best practices.

NMPF Objections

The EPA guidance, officially called an Interpretive Rule, was issued in March 2014. It said farmers are only exempt from needing Clean Water Act permits for more than 50 routine farming practices if they comply with detailed NRCS technical conservation standards. Historically, these standards have been voluntary, and the farming practices exempt from the permit process.

In comments filed last July, NMPF said the guidance changes NRCS's role from that of a conservation partner to that of an enforcer of the Clean Water Act, on EPA's behalf.

The now-withdrawn Interpretive Rule was intended to be part of the larger Waters of the U.S. proposal issued last year by the EPA. The larger proposal is still under review by both EPA and the Army Corps of Engineers, and is also being scrutinized by Congress.

Contact: Jamie Jonker



NMPF News 2015 NMPF Scholarship Program

NMPF is now accepting applications for its National Dairy Leadership Scholarship Program for the 2015-2016 academic year. Each year, NMPF awards scholarships to outstanding graduate students who are actively pursuing dairyrelated 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 on the NMPF website. Materials must be received <u>no later than March</u> <u>27, 2015</u>.

Contact: Beth Briczinski



NMPF News

Upcoming Events

- March 9-11, 2015, NMPF Board Meeting, Arlington, VA <u>http://nmpf.org/events/nmpf-spring-2015-board-directors-meeting</u>
- March 24-26, 2015, National Institute for Animal Health Annual Meeting, Indianapolis, IN <u>http://www.animalagriculture.org/</u>
- March 24-25, 2015, FARM Program Train the Trainer, Phoenix, AZ
- April 7-8, 2015, FARM Program Train the Trainer, Albany, NY
- April 23-30, 2015, NCIMS Meeting, Portland, OR <u>http://ncims.org/</u> <u>Conference2015FINAL.html</u>
- April 27-May 5, 2015, Codex Committee on Residues of Veterinary Drugs in Food
- April 26-28, 2015, ADPI & ABI annual meetings, Hyatt Regency Chicago, IL <u>https://www.adpi.org/</u>

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 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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