



National Milk Producers Federation

2107 Wilson Blvd., Suite 600, Arlington, VA 22201 | (703) 243-6111 | www.nmpf.org

January 18, 2024

U.S. Food and Drug Administration
Center for Veterinary Medicine
7500 Standish Place
Rockville, MD 20855

Dr. Dr. Flynn,

The National Milk Producers Federation (NMPF) is pleased to provide the following comments to the U.S. Food and Drug Administration's (FDA), Center for Veterinary Medicine (CVM) Environmental Scan (ES). The purpose of the ES is to identify major trends including emerging issues and ongoing challenges in CVM's internal and external environments to support, inform, and improve short-term and long-term strategic planning. 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.

U.S. Dairy Industry Commitment to Animal Health and "One Health"

In 1990, the U.S. dairy began a coordinated dairy farmer education program about judicious and responsible antimicrobial use (AMU) through implementation of standards and best practices to minimize the incidence of drug residue violations in milk and dairy beef. This was the beginning of the U.S. dairy industry's commitment to a One Health approach. In 2009 NMPF, with support from Dairy Management Inc., launched the National Dairy FARM Program: Farmers Assuring Responsible Management™ (FARM Program). The Farm Program is a national on-farm education, evaluation, and verification program designed to help dairy farmers assure high standards in animal care and wellbeing, including antimicrobial stewardship.

The FARM Program details animal care guidelines and best practices in the FARM Animal Care Reference Manual and the FARM Milk & Dairy Beef Residue Prevention Manual that farmers must follow for every calf and cow on the farm – that evolve with the latest research on quality animal care. The manuals and corresponding educational materials detail the highest standards for animal care when it comes to animal health from birth to end of life including veterinary oversight in the development of protocols for the prevention, control, and treatment of common diseases. Protocols developed with veterinarians include a comprehensive herd health plan, judicious and responsible use of antibiotics, and biosecurity.

On-farm evaluations occur at least once every three years to provide dairy farmers feedback on conformance to the FARM Program standards and best practices. Evaluators are veterinarians, extension educators, university personnel, co-op field staff or other qualified persons who have completed intensive training and have passed comprehensive exams. The evaluation provides farmers with the information they need to develop action plans for continuous improvement.

Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards' Creameries
California Dairies, Inc.
Cayuga Marketing
Cooperative Milk Producers Association
Dairy Farmers of America, Inc.
Ellsworth Cooperative Creamery
FarmFirst Dairy Cooperative
First District Association
Foremost Farms USA
Land O'Lakes, Inc.
Lone Star Milk Producers
Maryland & Virginia Milk Producers Cooperative Association
Michigan Milk Producers Association
Mount Joy Farmers Cooperative Association
Northwest Dairy Association
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Scioto Cooperative Milk Producers' Association
Southeast Milk, Inc.
Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.

The integrity of the program is ensured through third-party verification, which is completed by outside experts who inspect a statistically representative percentage of farms each year. When the dairy industry says it's taking great care of its animals with judicious and responsible AMU, third-party verification measures it – providing statistically verified data demonstrating that excellent animal care is an expectation of the dairy industry. The FARM Program has successfully completed ten years of third-party verification.

Today, 145 dairy cooperatives and proprietary processors representing more than 99 percent of the U.S. milk production are enrolled in the FARM Program. More than 95,000 on-farm evaluations have been conducted by the almost 400 certified FARM evaluators. Participation includes the largest organic milk dairy cooperative in the U.S. along with other cooperatives and proprietary processors with organic dairy farm suppliers.

When a dairy farm is found to not meet a standard during either a second-party evaluation or a third-party verification, a plan is put forth to make improvements through a corrective action plan. Based upon a risk-based approach, a varying timeline for implementing correction action plan improvements has been established. An Immediate Action standard requires change within 48 hours to meet the standard with the requirement that the dairy farm has second-party evaluator follow-up at 1 week, 1 month and 3 months interval to ensure standard is met. A Mandatory Corrective Action Plan requires that the standard must be met within nine months. A Continuous Improvement Plan requires that action be taken to meet the standard within a minimum of three years.

The USDA-AMS has determined the FARM Program animal welfare standards (which include AMU stewardship standards) meet the requirements of the International Organization for Standardization (ISO) Animal Welfare Technical Specification. The World Organization for Animal Health (WO-AH) and ISO work together to help farmers and programs like FARM standardize and implement their animal care guidelines. The WO-AH, the World Trade Organization-recognized body for setting animal health and welfare standards affecting international trade, adopted dairy cattle welfare standards in 2015.

FDA CVM Questions and NMPF Response

Below are the NMPF responses to the questions posed by FDA CVM.

- 1. CVM published the Animal Veterinary Innovation Agenda in September 2023. How do the objectives and actions laid out in the agenda impact the sectors your organization represents or engages with? What additional objectives and actions would improve the agenda?***

NMPF supports the general objectives of the FDA CVM [Animal and Veterinary Innovation Agenda](#). The Agenda, which builds on the [2018 Plant and Animal Biotechnology Action Plan](#), provides a succinct basis of FDA CVM's current and intended future efforts to spur and support developments in regulated product areas and, where needed, adopt approaches to regulation that align the need to protect animals, people and the environment, while helping the regulated industries bring safe products to market that meet current and future challenges facing the animal industries and as a society.

NMPF requests the addition of an objective, with associated actions, that specifically calls for inter-agency collaboration and harmonization with co-regulators such as USDA (United States Department of Agriculture) and EPA (Environmental Protection Agency). Innovation and

technology in animal health, welfare, and feeding can be stifled when mixed or conflicting messaging and regulatory processes exist between agencies which should be aligned to advance these areas for stakeholders.

2. *CVM is enhancing its information technology and digital environment. As we advance this initiative, what should we consider that will help us meet your organization and stakeholder needs?*

NMPF comments on this question are specifically information technology and digital environmental for any data collected from or submitted by dairy farms focusing on four areas: (1) confidentiality, (2) voluntary participation, (3) specification and data interoperability, and (4) interagency cooperation.

Any data collection system for on-farm antimicrobial use or animal health data must be able to ensure complete data protection from misuse. Dairy farmers trust for the confidentiality of the data collection system is necessary to gain access to on-farm data. Personal and proprietary information must be protected from inappropriate release with protection against Freedom of Information Act release. NMPF suggests a third-party private data repository concept may offer protection of the confidentiality of personal and proprietary information.

Any collection of on-farm antimicrobial use or animal health data must be voluntary. Mandatory systems would depend on regulatory action and lose sight of the concept of collaborative action between the public and private sectors. If FDA intends to collect on-farm data, NMPF believes that voluntary participation of External Data Providers may be useful to provide anonymous data which could be summarized to establish trends and note changes in antimicrobial use and animal health.

Any data collection system for on-farm antimicrobial use or animal health data must consider specification and data interoperability. For example, the best metrics to assess animal health and antimicrobial use will be different for each species of food-producing animals. When collecting data, each food animal species requires capture and analysis of different data elements. Unlike more vertically integrated production systems of some other food animal species, the dairy industry operates under a supply chain composed of about 28,000 dairy farms with a multitude of different data collection systems currently in use. Data interoperability will be a challenge for collecting antimicrobial use and animal health data for dairy cattle. FDA CVM has funded research efforts to better understand the methodologies in place to collect and record antimicrobial use data for dairy cattle.

NMPF encourages FDA CVM to work cooperatively and collaboratively with other government agencies in any effort there may be to collect antimicrobial use data and animal health data. For example, the USDA APHIS (Animal and Plant Health Inspection Service) collects on-farm data through the National Animal Health Monitoring System survey tools. However disparate governmental data sources for antimicrobial use and animal health data may result in confusing outcomes as comparisons will be made between the various data sources. Interagency cooperation on any data collection will be necessary for success.

3. ***How would you like to see CVM more involved in advancing One Health priorities?***

Because the health of animals, people and the environment are interconnected, the One Health approach is a collaborative effort of the human health, veterinary health, and environmental health communities. Zoonotic pathogens (disease causing organisms) can evolve and move from one organism to another and through the environment. Sometimes they mutate or evolve into more virulent strains, and sometimes they evolve to resist countermeasures such as the application of antibiotics, other bacteria or viruses, and other challenges. Investment in understanding the ecology of zoonoses is necessary to develop strategies to address them.

The FDA CVM [Animal and Veterinary Innovation Agenda](#) appears to be well positioned to help facilitate animal and veterinary product development of more safe, novel products and products for unmet human and animal needs – such as zootechanical food substances, monoclonal antibody therapies, gene therapies, intentional genomic alterations in animals.

As noted in response to **Question 1**, NMPF requests FDA CVM be engaged in close inter-agency collaboration and harmonization with co-regulators such as USDA and EPA for these new and novel products. Additionally, FDA CVM should be a partner in the broader executive branch One Health collaborations including but not limited to other partners such as the U.S. Fish and Wildlife Service, the Centers for Disease Control and Prevention, the National Institutes of Health (NIH), and tribal Nations, to maintain or reduce health risks to animals, humans, and the environment.

4. ***Based on your organization's mission, what changes, challenges, or opportunities can you identify, from the human, animal or environmental health sectors, will potentially have an impact on your organization's work and on CVM in the next five years? What can CVM do now to prepare our Center and help your organization and its stakeholders, to meet those changes, challenges, or opportunities?***

In the next five years, the U.S. dairy industry will need innovative technology solutions to address animal health, antimicrobial use, and environmental issues due to both regulatory and customer needs. For example, this September there will be a United Nations General Assembly High Level meeting on Antimicrobial Resistance. This meeting will result in a Political Declaration which may be used by domestic and international regulatory authorities and dairy customers to make changes as to how, when, and what antimicrobials are used for therapeutic purposes in dairy cattle. New animal health interventions through innovative technology may be needed to meet these challenges.

Innovative and voluntary solutions are also needed to reduce greenhouse gas (GHG) emissions, including methane. In this context, NMPF seeks enacted policy solutions that will help reduce methane emissions resulting from enteric fermentation in dairy cattle. Enteric emissions directly from cows currently account for one third of all GHG emissions from dairy farms and present a key area of opportunity for methane reductions. Feed additives can significantly improve digestibility and redirect production pathways of enteric methane emissions. Some of these additives are already approved for use in the European Union, United Kingdom, Brazil, Australia, Chile, Canada, and elsewhere. Growing research indicates that feed additives can reduce enteric methane emissions by 30% or more. As detailed in **Question 5**, FDA CVM currently lacks the

authority to regulate feed additives that have non-nutritive benefits, including environmental benefit claims, through the Feed Additive Petition process. This means that feed additive manufacturers are bypassing the U.S. market approval process in favor of processes in other countries which have a more streamlined approval process. This approval lag is also affecting U.S. research and development investments in this area.

5. *What are some of the strengths and weaknesses of CVM's legal authorities?*

A significant weakness in FDA CVM's current legal authority relates to the Feed Additive Petition (FAP) process. The current FAP process is for feed additives that are intended to provide nutrition only. This dates to the 1998 FDA *Policy and Procedures Manual Guide 1240.3605* which has prevented animal food ingredient manufacturers from utilizing the FAP process to approve their products that have non-nutritive benefits, including environmental benefit claims, production claims, and claims about effects on the animal well-being and pre-harvest food safety. To date, such products must be reviewed via FDA's cumbersome New Animal Drug Application process, which is primarily targeted toward products intended toward diagnosing, curing, mitigating, or treating diseases. NMPF supports providing FDA CVM legal authority to regulate animal feed additives with non-nutritive benefits through the FAP process.

The Innovative FEED Act pending before Congress would provide FDA CVM legal authority to regulate non-nutritive feed additives using the FAP process. NMPF strongly believes that this is the right approach because none of these products are medical in nature, and all of them operate solely within the animal's digestive tract, as foods. Other countries have updated their regulatory frameworks to review products like these as foods, rather than drugs. Current U.S. policy puts U.S. farmers and ranchers at a competitive disadvantage with their global counterparts, as it does not enable products to quickly come to market for producers to use. The FAP process still requires rigorous safety and efficacy reviews, but in a manner that will help get products into farmers' hands more quickly and on par with their global competitors.

6. *In what ways could CVM improve communication with your organization?*

In late 2022, NMPF received a call from a state dairy organization informing us that FDA inspectors had shown up at several dairy farms and asked to take samples of corn grain, corn silage and alfalfa so that the samples could be tested for PFAS chemicals. The state dairy organization asked if we were aware of any FDA surveillance assignment that would require such actions, we told them we were not and that it was an anomalous action by an FDA inspector. We then inquired with FDA-CFSAN and were told that there was no such surveillance assignment. A week or so later, NMPF was on a call and was informed that an FDA inspector had visited another dairy farm and insisted on taking samples of corn grain, corn silage and alfalfa. The farmer was displeased with the lack of information being shared.

NMPF was surprised to hear this as it was in a different region of the US from the other visits, which indicated to us that the earlier visits were not anomalies by one inspector. We contacted FDA-CFSAN again to ask if there was a surveillance assignment for dairy feed, explaining why we thought there was. A short while later we were told that yes, in fact, FDA-CVM was conducting a sampling assignment. FDA-CFSAN then scheduled a call with CVM and NMPF to

discuss the assignment where we learned the parameters and rationale for what was being done. We were informed that the collection of samples was voluntary and that the dairy producers could get the test results after the FDA completed testing. NMPF told CVM that we would encourage dairy producers to allow sampling and let CVM know that producers getting timely test results back was imperative. NMPF did let producers know about the assignment and we encouraged producers' cooperation.

Weeks and months passed without the second producer receiving test results from the FDA. Several more months and inquiries to the FDA yielded nothing. Finally, we were told the samples were non-detect for PFAS. It is also important to note that the assignment was supposed to have been concluded in late 2023 and yet progress reports have not occurred and to the best of our knowledge the assignment may or may not have been completed or was abandoned.

Communications on this issue could have been significantly better. FDA-CVM should have informed NMPF of the assignment in advance of going into the field so that we could support FDA efforts and explain to dairy producers what was going on. FDA-CVM should have promptly provided producers with information about test results and should have provided NMPF with periodic progress updates. As of January 17, 2024, we do still do not have any information beyond the initial readout of the sampling and the non-detect results at the second producer's location. Unless NMPF is informed and is provided with information that we can use to inform our members, NMPF cannot collaborate with FDA and will not support FDA's efforts. While NMPF has not always been consulted in advance about sampling assignments, when we have been involved, the assignments have been less invasive and more palatable for producers involved, making it a win for everyone.

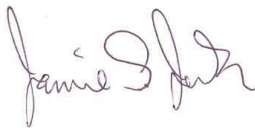
- 7. Please provide any additional feedback that you would like to share with respect to the topics included in this questionnaire or on other matters impacting your organization.***

NMPF has no additional comments currently.

Conclusion

We thank FDA CVM for the opportunity to provide feedback on the Environmental Scan and including the U.S. dairy industry as a stakeholder in this and other FDA CVM activities. We hope to continue to engage with the agency in future direction for the benefit discussions concerning this important action for dairy cattle health and wellbeing.

Sincerely,



Jamie Jonker, Ph.D.
Chief Science Officer
Vice President, Scientific & Regulatory Affairs