**National Milk Producers Federation**

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November 17, 2022

Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Pl, HFV-1
Rockville, MD 20855

Re: FDA CVM Regulation of Animal Foods with Certain Types of Claims (FDA-2022-N-2015-0001)

To whom it may concern:

The National Milk Producers Federation (**NMPF**) takes great interest in the Food and Drug Administration Center for Veterinary Medicine (**FDA-CVM**) Regulation of Animal Foods with Certain Types of Claims (FDA-2022-N-2015-0001). 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.

The FDA-CVM regulates both food and drugs for animals. Depending on characteristics of the product, how a product for animals is intended to be used, and what the product claims to do, the product could meet the legal definition of a food, a drug, or occasionally, both a food and a drug. FDA-CVM is considering updates to the CVM Policy and Procedures Manual (**PPM**) 1240.3605, Regulating Animal Foods With Drug Claims. Published in 1998, this PPM states that the FDA-CVM will usually regulate nutritional ingredients or products with claims describing an intended effect on the structure or function of an animal's body (structure/function claims) as animal food. The PPM also states that the FDA will usually regulate nutritional ingredients or products with production claims and non-nutritive ingredients or products with structure/function claims as animal drugs. The FDA is currently reviewing this existing policy to evaluate how it could be updated to reflect evolving scientific knowledge and promote innovation. We appreciate the opportunity to comment on this important matter for the U.S. dairy industry.

These comments are in addition to the presentation provided during the FDA-CVM virtual listening session on Oct. 18, 2022. NMPF testified of the need to modernize FDA CVM Program Policy and Procedures Manual Guide 1240.3605 through existing statutory authority where FDA can regulate products with data-backed claims of acting on or in the digestive tract that have environmental benefit and other claims. Our testimony concluded with the hope "that FDA will modernize this process so that our U.S. dairy farmers, which are already exporting 20 percent of their dairy production worldwide, will be able to catch up to the ability of their competitors in such places as a European Union, South America and Oceana." The presentation is appended at the end of these comments.

**General Comments**

*We support using existing statutory authority through the Food, Drug, and Cosmetic Act, where FDA-CVM can regulate products with data-backed claims of acting on/in the digestive tract that have environmental benefit claims, production claims, and claims about effects on the animal well-being and pre-harvest food safety as animal feeds/foods and feed additives.*

Innovative and voluntary solutions are needed to reduce greenhouse gas (GHG) emissions, including methane. In this context, our organization 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 roughly one third of all GHG emissions from dairy farms and present an important area of opportunity for methane reductions.

Feed composition changes can directly or indirectly reduce enteric emissions resulting from livestock. 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, Brazil, Australia, Chile, and most recently, Canada. Growing research indicates that feed additives can reduce enteric methane emissions by 30% or more.

However, FDA has not currently approved any feed additives to meet this need. Current regulatory policy delays market approval and hinders widespread adoption in the U.S. In 1998, the FDA-CVM made a decision, outlined in the Program Policy and Procedures Manual Guide 1240.3605, that utilizes the lengthy, time-consuming, and expensive regulatory approval process for permissible animal food label marketing claims (such as environmental benefits) for animal food ingredients to be the same process as for approval of new animal drugs (including antibiotics and hormones). 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 likely is also affecting U.S. research and development investments in this area.

We support FDA-CVM efforts to revisit how it regulates animal foods which act on/in the digestive tract with certain types of claims and commend FDA-CVM for hosting the October listening session. We believe FDA-CVM has clear authority for an alternate approval process that would still ensure the efficacy and safety of feed additives while avoiding the lengthy and necessary process which animal drugs must follow. As FDA-CVM continues its work, we urge the agency to prioritize consideration of those additives with climate and

digestive efficiency benefits, recognizing those products whose mode of action is solely within the digestive tract of animals. Doing so would better align U.S. policy with those of other major developed countries that currently allow for animal feed additives to decrease the environmental footprint of food production. Streamlining approvals would also send signals to the private sector making key research and development decisions and support further innovation in this area.

**U.S. Dairy Industry Commitment to Sustainable Production**

The U.S. dairy industry's sustainability successes have been intimately tied to the long-standing USDA work in research, education, and economics. Due to the foundational research from and extension outreach by USDA going back many decades, by 2007 producing a gallon of milk used 90 percent less land and 65 percent less water, with a 63 percent smaller carbon footprint than in 1944.[1] In 2009 and reaffirmed in 2013, the U.S. dairy industry and USDA committed to increase sustainability by reducing greenhouse gas (GHG) intensity 25% by 2020.[2] Preliminary analysis shows the goal is within reach with producing a gallon of milk in 2017 requiring 30% less water, 21% less land, a 19% smaller carbon footprint and 20% less manure than it did in 2007.[3]

In 2010, the U.S. dairy industry launched the National Dairy FARM Program: Farmers Assuring Responsible Management™ "*to show customers and consumers that the dairy industry is taking the very best care of cows and the environment, producing safe, wholesome milk and adhering to the highest standards of workforce development.*"[4] Created by NMPF in partnership with Dairy Management Inc., the FARM Program helps ensure the success of the entire industry by demonstrating that U.S. dairy farmers are committed to producing the best milk with integrity. The FARM Environmental Stewardship platform provides a comprehensive estimate of GHG emissions and energy use on dairy farms with a suite of tools and resources for farmers to measure and improve their footprint.[5] Organizations representing 99 percent of U.S. milk volume participate in FARM, and more than 80 percent by milk volume participate in the FARM Environmental Stewardship area.

In 2018, the Innovation Center for U.S. Dairy convened leadership from across the industry to establish the U.S. Dairy Stewardship Commitment to document and demonstrate collective social responsibility progress in important areas including animal care, environmental stewardship, product quality and safety, workforce development and

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[1] Capper,J.L., R.A. Cady, D.E. Bauman The environmental impact of dairy production: 1944 compared with 2007.
2009. Journal of Animal Science. 87:6 Pp 2160–2167. https://doi.org/10.2527/jas.2009-178 1

[2] Memorandum of Understanding Between United States Department of Agriculture and The Innovation Center for U.S. Dairy. April 2013. https://www.usda.gov/sites/default/files/documents/usda-mou-innovation-center-usdairy.pdf

[3] Capper, J.L., and R.A. Cady. 2020. The effects of improved performance in the U.S. dairy cattle industry on environmental impacts between 2007 and 2017. Journal of Animal Science. 98:1. Pp.1-14. https://doi.org/10.1093/jas/skz291

[4] National Dairy FARM Program. 2020. https://nationaldairyfarm.com/

[5] FARM Environmental Stewardship. 2020. https://nationaldairyfarm.com/dairy-farm-standards/environmentalstewardship/

community contributions.[6] As part of its collective commitment to provide the world responsibly-produced dairy foods that nourish people, strengthen communities and foster a sustainable future, in 2020 the U.S. dairy industry set aggressive new environmental sustainability goals to become carbon neutral or better, optimize water usage and improve water quality by 2050.[7]

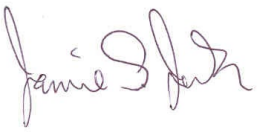
To reach these 2050 goals, the U.S. dairy industry will need to identify technological and other advancements that can accelerate improvements, enabling nimble adaptation and focusing on technology and practices that can be scaled for maximum impact. To meet these challenges, we have mobilized through the Net Zero Initiative a partnership of the U.S. dairy community that seeks to unite collaboratively the assets and expertise of trade, professional and industry organizations to create a path and growing portfolio of strategies and programs to achieve carbon neutrality, as well as significant improvements in water quality, through adoption of economically viable technologies and practices.

**Conclusion**

One of the greatest opportunities that exists for U.S. dairy farmers is their ability to provide real solutions to many of today's biggest environmental challenges like GHG emissions. Embracing new practices and technologies is key to making America's dairy farmers an environmental solution while providing wholesome and nutritious dairy products to the U.S. and the world.

We look forward to continued advancement, including the FDA-CVM intention to provide the public with additional opportunities to share input on other animal food-related topics, such as the FDA role in the America Association of Feed Control Officials ingredient definition process. Thank you for your consideration of our comments. We look forward to continuing to work with you on this important environmental stewardship and GHG reduction priority.

Sincerely,



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

[6] Innovation Center for U.S. Dairy. 2018. The U.S. Dairy Stewardship Commitment. http://commitment.usdairy.com/

[7] 7Innovation Center for U.S. Dairy. 2020. New Environmental Goals Including Carbon Neutrality and Cleaner Water with Maximized Recycling by 2050. https://www.usdairy.com/sustainability/environmental-sustainability

# FDA Listening Session on the Regulation of Animal Foods with Certain Types of Claims


**Jamie Jonker, Ph.D.**

**Chief Science Officer**

**National Milk Producers Federation**

# U.S. Dairy: By the Numbers

**9,448,000**
dairy cows in the U.S.

**29,858**
dairy farms in the U.S.

**94%**
of farms are family owned

**226.2 billion**
pounds of milk/milk production

**316**
average farm/herd size

Sources :USDA Milk Production Report 2022; USDA Ag Census 2017 analysis

# U.S. dairy is an environmental solution

**By 2050, U.S. dairy collectively commits to:**

- Achieve **greenhouse gas (GHG) neutrality**
- **Optimize water use** while maximizing recycling
- **Improve water quality** by optimizing utilization of manure and nutrients

# Producing a Gallon of Milk is Getting Greener

- 19% less GHG emissions
- 21% less land used
- 30% less water used


Judith L. Capper, Roger A. Cady

The effects of improved performance in the U.S. dairy industry on environmental impacts between 2007 and 2017

Journal of Animal Science, Vol. 98, Issue 1, January 2020

# STRATEGIES TO REACH OUR 2050 GOALS

*FOR PROCESSORS*

## Processor Working Group

Led by the Innovation Center, a working group of more than 60 participants representing over 30 processing organizations convenes regularly and engages in facility-focused workstreams.

GHG

PACKAGING

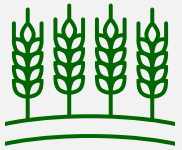
WASTE

WATER

*FOR FIELD AND FARM*

## U.S. Dairy Net Zero Initiative

A collaboration of dairy organizations to advance research, on-farm pilots and new market development to make sustainability practices more accessible and affordable to farms of all sizes – an essential first phase to accelerate progress toward the 2050 goals.



FEED

ENTERIC METHANE

MANURE

ENERGY

# Mitigating U.S. Dairy's Environmental Footprint

**Estimated GHG contribution of each "print" to the total*:**

Feed (26%) | Enteric (35%) | Manure (33%) | Energy (6%)

## FEED 26%

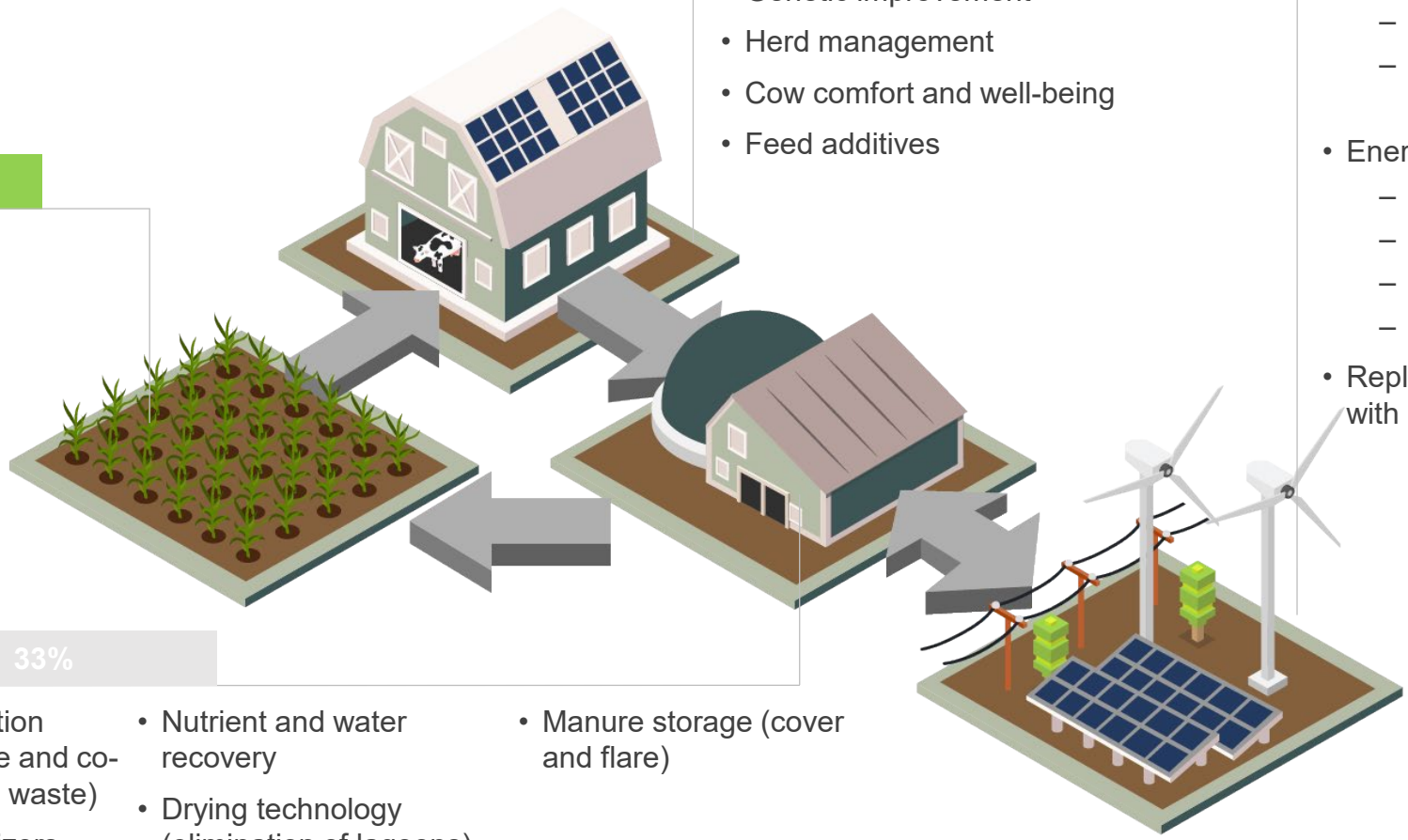
- No/low-till farming
- Cover crops
- Nutrient management
- Precision agriculture
- Water use efficiency

## ENTERIC METHANE 35%

- Diet management
- Genetic improvement
- Herd management
- Cow comfort and well-being
- Feed additives

## ENERGY 6%

- Renewable energy:
  - Renewable electricity
  - Renewable natural gas
  - Renewable energy from wind and solar sources
- Energy efficiency:
  - LED lighting
  - Variable speed pumps
  - Milk pre-cooling technology
  - Soft start motors
- Replacement of fossil-fueled engines with electric motors



## MANURE 33%

- Anaerobic digestion (includes manure and co-digestion of food waste)
- Renewable fertilizers
- Nutrient and water recovery
- Drying technology (elimination of lagoons)
- Manure storage (cover and flare)

Visuals do not represent all possible practices, technologies or benefits. Each farm can voluntarily contribute to net zero efforts based on their individual operation.

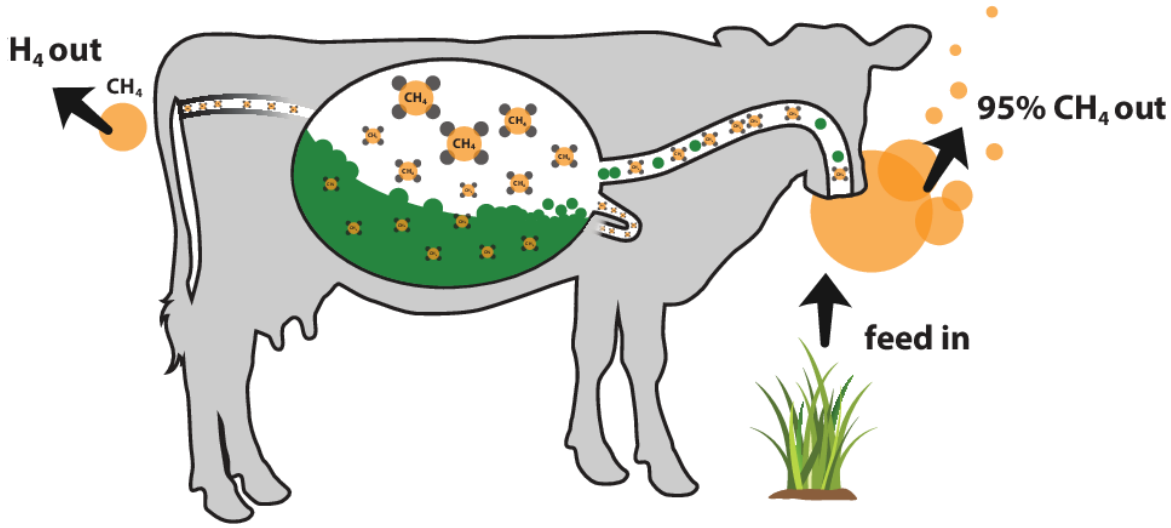
* Adapted from Thoma 2013, Regional Analysis of greenhouse gas emissions from USA dairy farms. A cradle to farm-gate assessment of the American dairy industry, circa 2008



NMPF

# Feed Additives Can Reduce Enteric Methane

- Research has demonstrated several feed additives can reduce enteric methane in dairy cows by 30 percent or more.
- Feed additives already approved in the European Union (EU), Brazil, Australia, Chile
  - The EU regulates the use of zootechnical feed additives in animal diets and allows environmental, animal welfare, and production claims.



# *Current* FDA CVM Program Policy and Procedures Manual Guide 1240.3605

- Last updated 9/18/1998
- "Animal feeds/foods" refers to feed for livestock, poultry, or other animals, and pet food. These articles may ordinarily be thought of as foods as defined in Section 201(f) of the (Food, Drug and Cosmetic) Act, and also, in some cases, as food additives under Section 201(s)."
- ***However***, Guide 1240.3605 then chose to regulate animal feeds/foods and feed additives which may have environmental benefit claims, production claims, and claims about effects on the animal well-being and pre-harvest food safety ***as animal drugs***.

# *Modernized* FDA CVM Program Policy and Procedures Manual Guide 1240.3605

- ***NMPF supports using existing statutory authority***, where FDA can regulate products with data-backed claims of acting on/in the digestive tract that have environmental benefit claims, production claims, and claims about effects on the animal well-being and pre-harvest food safety ***as animal feeds/foods and feed additives***.

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