



# National Milk Producers Federation

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November 18, 2008

Docket No. APHIS-2006-0188  
Regulatory Analysis and Development, PPD, APHIS  
U.S. Department of Agriculture  
Station 3A-03.8  
4700 River Road, Unit 118  
Riverdale, MD 20737-1238

**RE: Docket No. APHIS-2006-0188 Request for Information: Genetically Engineered Animals**

To Whom It May Concern:

The National Milk Producers Federation (NMPF) is submitting the following comments to the U.S. Department of Agriculture (USDA) Animal Plant Health Inspection Service (APHIS) Request for Information on Genetically Engineered Animals; Docket Number APHIS-2006-0188. 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 31 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 40,000 dairy producers on Capitol Hill and with government agencies.

Dairy producers have routinely been at the fore-front of technological innovation in reproduction to enhance the genetic merit of dairy animals. Artificial insemination was first commercialized in the dairy industry over 60 years ago and is used routinely on dairy farms today. Although not as common as artificial insemination, *In vitro* fertilization and embryo transfer have nearly three decades of proven efficacy allowing dairy producers to select their best cows to serve as the foundation for future generations of dairy cattle. Cloning has been conducted on a limited basis in the dairy industry for twenty years, initially in the form of embryo splitting which results in two or more identical offspring from the same zygote. Genetically engineered animals containing heritable rDNA (GE animals) is a future step in the technological innovation in reproduction for dairy animals.

We understand that GE animals that may be developed can be divided into six broad classes based on the intended purpose of the genetic modification: (1) to enhance food quality or agronomic traits; (2) to improve animal health; (3) to produce products intended for human therapeutic use ("biopharm" animals); (4) to enrich or enhance the animals' interactions with humans; (5) to develop animal models for human diseases; and (6) to produce industrial or consumer products. While the first two uses are of most interest to the dairy industry, our comments to the three questions that APHIS asked in the Request for Information are applicable to the use of dairy animals in all of these circumstances. In reiterating our comments to FDA, **we support a comprehensive mandatory pre-market approval process for GE animals regardless of their intended use.**

***What research on GE animals is currently being conducted or planned for the future?***

While NMPF does not undertake nor plan to undertake research on GE animals, we can envision potential research being conducted on GE dairy animals in the following areas (not all inclusive):

Agri-Mark, Inc.  
Arkansas Dairy Cooperative Association  
Associated Milk Producers, Inc.  
Continental Dairy Products, Inc.  
Cooperative Milk Producers Assn.  
Dairy Farmers of America, Inc.  
Dairymen's Marketing Cooperative, Inc.  
Dairylea Cooperative Inc.  
Ellsworth Cooperative Creamery  
Farmers Cooperative Creamery  
First District Association  
Foremost Farms USA  
Humboldt Creamery  
Just Jersey Cooperative, Inc.  
Land O'Lakes, Inc.  
Lone Star Milk Producers, Inc.  
Manitowoc Milk Producers Coop.  
MD & VA Milk Producers Cooperative Association, Inc.  
Michigan Milk Producers Assn.  
Mid-West Dairymen's Company  
Northwest Dairy Association  
Prairie Farms Dairy, Inc.  
St. Albans Cooperative Creamery, Inc.  
Scioto County Co-op Milk Producers' Assn.  
Select Milk Producers, Inc.  
Southeast Milk, Inc.  
Swiss Valley Farms, Co.  
Tillamook County Creamery Assn.  
United Dairymen of Arizona  
Upstate Niagara Cooperative, Inc.  
Zia Milk Producers

Jerry Kozak, President/Chief Executive Officer

Randy Mooney, Chairman

- Disease resistance for the cows themselves:
  - Cows more resistant to mastitis (USDA has been conducting such research)<sup>1</sup>
  - Cattle resistant to other diseases, including BSE (research conducted in Japan)<sup>2</sup> and brucellosis
- Milk production:
  - Increased yield
  - Less fat content
  - Less/no lactose
  - Hypoallergenic milk (inactivation of the gene for beta-lactoglobulin)
  - Increased proportion of unsaturated fatty acids
  - Increased similarity to human breast milk
  - Faster coagulation for cheese production or increased casein content, for better cheese yields (research conducted in New Zealand)<sup>3</sup>
  - Increased casein components to increase milk's calcium content
- Pharmaceutical production of antibodies that prevent animal and human disease; Human polyclonal antibodies have been produced in the blood of transgenic and cloned cattle.
- Milk containing beneficial nutraceutical proteins

***What, if any, implications would activities such as the importation and interstate movement of such animals have for the health of the U.S. livestock population?***

The importation and interstate movement of GE animals and their products (including embryos and semen) present may present health risks to the larger general domestic livestock population. These risks will vary among GE animals based upon the transgene construct. In the next question, we describe aspects of animal health to be evaluated to examine the herd and population effects of GE animals (including semen and embryos) which should be considered prior to their importation or interstate movement.

***What, if any, activities should APHIS consider with respect to U.S. livestock health under the AHPA that would complement the requirements and recommendations described in FDA's draft guidance?***

There appears to be a gap in the potential herd or population effects that the GE animal may have on the general livestock population. The New Animal Drug Application process proposed by FDA provides a mandatory pre-market approval process for the safety of food products derived from GE animals and the safety of the transgene construct on that GE animal. We believe that APHIS through an appropriate evaluation process should consider the potential herd and population effects of a GE animal on the general livestock population, as part of the Interagency Consultation process prior to an FDA approval of a GE animal through the NADA process. This evaluation on the effects on the herd and population level should include:

- General health and performance indicators, including mortality and morbidity, behavior, growth and development, general anatomy, and reproductive function, if appropriate;
- Physiological measures including clinical and analytical parameters;
- Donor or surrogate animal effects;
- Herd or populations effects;
- Unique impacts on animal care; and
- Other species-specific considerations, where appropriate.

<sup>1</sup> <http://www.ars.usda.gov/IS/pr/2005/050404.htm> accessed November 17, 2008.

<sup>2</sup> <http://www.medicalnewstoday.com/articles/9063.php> accessed November 17, 2008.

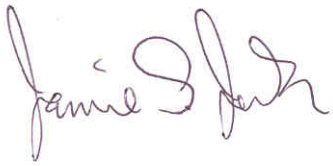
<sup>3</sup> <http://query.nytimes.com/gst/fullpage.html?sec=health&res=9E03EED71539F934A15752C0A9659C8B63> accessed November 17, 2008

**CONCLUSIONS**

We support a comprehensive mandatory pre-market approval process for GE animals regardless of their intended use. The FDA Draft Guidance provides a clear pre-market approval process for GE animals through the New Animal Drug Application provisions of the Federal Food Drug and Cosmetic Act. In addition, APHIS through an appropriate evaluation process should consider the potential herd and population effects of a GE animal on the general livestock population, as part of the Interagency Consultation process prior to an FDA approval of a GE animal.

Thank you for the opportunity to submit these comments. If you have any questions or require any clarification about these comments, please contact me via telephone at 703-243-6111 or email at [jjonker@nmpf.org](mailto:jjonker@nmpf.org).

Sincerely,

A handwritten signature in purple ink that reads "Jamie S. Jonker". The signature is written in a cursive style with a large initial "J".

Jamie S. Jonker  
Director, Regulatory Affairs