



James Mulhern, *President & Chief Executive Officer* | Randy Mooney, *Chairman*

December 24, 2015

Docket Clerk
Office of Resource Conservation and Recovery
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Management of Standards for Hazardous Waste Pharmaceuticals (Docket No. EPA-HQ-RCRA-2007-0932)

To whom it may concern:

The National Milk Producers Federation is pleased to provide the U.S. Environmental Protection Agency (EPA) comments on Management of Standards for Hazardous Waste Pharmaceuticals (Docket No. EPA-HQ-RCRA-2007-0932)¹. The National Milk Producers Federation (NMPF), 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 more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

EPA regulates disposal of some pharmaceuticals as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. For a variety of reasons **healthcare facilities** (as defined by EPA) which generate hazardous waste pharmaceuticals as well as associated facilities have reported difficulties complying with the Subtitle C hazardous waste regulations. EPA has proposed to revise the regulations to improve the management and disposal of hazardous waste pharmaceuticals and tailor them to address the specific issues that hospitals, pharmacies and other healthcare facilities face. The revisions are also intended to clarify the regulation of the reverse distribution mechanism used by healthcare facilities for the management of unused and/or expired pharmaceuticals.

At this time NMPF is only commenting on the definition of healthcare facilities and not on the broader proposed rule. In the EPA proposed rule, the term healthcare facility is defined as follows:

“Healthcare facility means any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals. This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians’ offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals.”

Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards' Creameries
Cooperative Milk Producers Association
Cortland Bulk Milk Producers Cooperative
Dairy Farmers of America, Inc.
Dairymen's Marketing Cooperative, Inc.
Ellsworth Cooperative Creamery
Farmers 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
Mid-West Dairymen's Company
Mount Joy Farmers Cooperative Association
Northwest Dairy Association
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
Scioto County Cooperative Milk Producers' Association
Select Milk Producers, Inc.
Southeast Milk, Inc.
St. Albans Cooperative Creamery, Inc.
Swiss Valley Farms Company
Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

While dairy farms are not specifically mentioned in the healthcare facility definition or listed in Table 1—NACIS Codes of Entities Potentially Affected by this proposed rule, NMPF is concerned that the definition of healthcare facility is quite expansive and could be misconstrued in the future to include agricultural production operations in which animals are receiving veterinary medical care. In fact EPA states:

*“This table [Table 1] is not intended to be exhaustive, but rather provides a guide for readers regarding entities potentially impacted by this action. This table lists examples of the types of entities of which EPA is aware that could potentially be affected by this action. **Other types of entities not listed could also be affected.** [emphasis added].”*

NMPF believes it is not the intent of EPA for this rule to include dairy farms and agricultural production facilities among the entities affected by the rule. This policy perspective would seem sensible since households/consumers are clearly stated as being exempt from the regulatory requirements in the proposed rule. To that point EPA states:

“The Agency would like to emphasize that the regulatory requirements in this proposed rule do not apply to households or to household pharmaceutical collection and take-back events and programs.”

Additionally, we do not believe that dairy farms routinely maintain on their premises pharmaceuticals that classify as hazardous under the proposed rule. In the rare event of a hazardous veterinary pharmaceutical being present, farms and agricultural production facilities should qualify as conditionally exempt small quantity generators (CESQGs) and not become subject to the regulations in this proposal. **In order to provide clarity for the agricultural community, we would request that in the final rule EPA clearly exempts dairy farms and agricultural production facilities from the healthcare facility definition of entities affected by the proposed rule for management standards for hazardous waste pharmaceuticals.**

NMPF appreciates the opportunity to comment on the proposed rule by EPA to establish management standards for hazardous waste pharmaceuticals. Please contact me if you have any questions about these comments.

Sincerely,

A handwritten signature in purple ink that reads "Jamie Jonker". The signature is written in a cursive, flowing style.

Jamie Jonker
Vice President, Sustainability & Scientific Affairs

ⁱ <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-RCRA-2007-0932-0150>