National Association of State Departments of Agriculture
4350 North Fairfax Drive
Suite 910
Arlington, VA 22203
Tel: 202-296-9680 | Fax: 703-880-0509
www.nasda.org

April 21, 2017

The Honorable Stephen Ostroff
Acting Commissioner
Food & Drug Administration
10903 New Hampshire Avenue
WO1
Silver Spring, MD 20993

Dear Dr. Ostroff:

RE: PMO and Dairy Policy

Thank you for coming to the NASDA Winter Policy Conference on February 1, 2017. We appreciated your candor and dialogue with us regarding issues important to the NASDA membership. Several priority issues came up during the meeting. One of those is the changes to dairy policy created by the publication of the Preventive Controls for Human Food Rule and the subsequent proposed changes to the PMO.

NASDA is concerned about the intersection of FSMA with proposed changes to the PMO. There now is a growing history between the FDA and the NCIMS regarding these issues, and the NCIMS liaison committee and FDA have recently had discussions regarding these changes. The liaison committee has put together a draft proposal to be discussed at the upcoming NCIMS conference, but we understand the FDA has proceeded with preparing and putting forward its own proposal. The dueling proposals are missing critical implications and have a host of unresolved issues that also need attention. These unresolved issues go beyond the NCIMS community and include NASDA members and other state agency administrators that have cooperated with FDA in the past and will continue to cooperate with FDA in the future.

As you know administration of the PMO has been at the state-level. The program is a rather unique partnership between the federal government, state government and the regulated industry. Two contrasting proposals that will come before the NCIMS next month seek to amend the PMO to include proposals outlined in the preamble of the Preventive Controls: Human Food Rule. Regardless of which changes are made, they will require extensive training of inspectors in new program responsibilities, expand inspection time exponentially, while at the same time provide no funding mechanisms for either federal or state employees to perform these additional responsibilities.

Even though the proposed changes, which FDA anticipates as necessary for the PMO to align with the Preventive Controls: Human Food Rule, were outlined in the preamble to the final rules, the industry and, frankly, even many state dairy regulatory program staff are confused and unaware of some of the changes now being discussed as necessary changes to the PMO.

There is confusion about how the programs will operate – both in the interim as FSMA compliance dates kick in and in the future, as the potential for portions of the inspections may be conducted by state dairy inspectors and other portions by Preventive Controls inspectors. Questions/concerns also remain

regarding the regulatory framework for the Grade A and non-Grade A FMSA inspection programs in the same manufacturing facility. This exacerbates an already complex regulatory arena. This also brings to the forefront the concern that many are not convinced it was necessary to have the extra level of regulatory burden placed on one of the most regulated and safest foods being produced within the US.

Another issue which deserves attention is funding. Cooperative programs have historically been funded by the states. FSMA – and the move to preventive controls – expands the responsibilities for inspection. The funding issues associated with this expansion, as a result of these new requirements, need to be revisited. Following the recession and continuing cuts in state budgets, it is clear that funding for administration of any federal law will require federal funding at the state level. State departments of agriculture cannot accept any more federal unfunded or underfunded mandates. It is straightforward for states that, if an issue results in a federal law to establish goals, then federal funding will be needed. Alternatively, the states will have to, as matters of course, consider passing the program administration back to the federal government.

FSMA is changing institutional relationships between FDA and state programs, including in the dairy policy arena. Determining better processes to discuss the changes that FSMA brings and determining appropriate modifications to programs and institutional relationships is imperative to managing this new food safety environment.

To address the confusion, we would like to propose that FDA upper management initiate discussions such as a 'listening session' to assure the regulators and the regulated community understand the actions being proposed by FDA – perhaps as an effort beyond the NCIMS process. In addition, and separate but concurrent with the discussion suggested above, **we would like to propose a recurring dialogue with NASDA (and other appropriate state agency authorities) specifically on dairy issues.** Such a dialogue could determine the institutional hurdles and options available to assure the public health mandate of FSMA is met and institutional relationships are sound and supported going forward.

We are looking forward to continuing this discussion with NASDA's Steering Committee on Food Safety. For more information, contact Bob Ehart, senior policy & science advisor (bob@nasda.org).

Sincerely,

Barbara P. Glenn

Barbara P. Glenn, Ph.D.
Chief Executive Officer

cc: Erik Mettler
Jeff Farrar
LarryMorris
Nicole Clapp,
Cathy McDermott
NASDA Steering Committee on Food Safety