


# ACTION ITEM FORM

Subject of Action Item: \_\_\_ Food Regulation and Safety / FDA's ORA Transformation Process \_\_\_



Submitted By \_\_\_ Bill Northey (IA) & AG Kawamura (CA) \_\_\_  
(Name) (State)

To be discussed by: Animal & Plant Industries and Food Safety & Nutrition Committees

Text:

FDA began an Office of Regulatory Affairs (ORA) Transformation (reorganization) project approximately 2 years ago. Several of FDA's draft / proposed actions would affect not only the FDA infrastructure, but also its relationships with stakeholders, including its state agency collaborators. FDA temporarily suspended this process recently for 2 primary reasons: 1) President Bush independently established a Cabinet-level panel to recommend how to guarantee the safety of imported food and other products brought into the country and how to better police them – this high-level assessment will likely focus on some similar issues that were being addressed in the draft reorganization plans, and 2) some members of Congress raised additional concerns about the potential impact of the draft reorganization plans.

NASDA member agencies have long been partners with the FDA on food and feed safety issues. Several high profile cases, e. g., most recently, the recall of products potentially contaminated with botulism toxin, the incident of pet food and animal feed potentially contaminated with melamine and the E. coli detection in spinach, have only accentuated the significance these issues have on the public and other stakeholders that we jointly serve. State / FDA interaction is an important aspect of dealing with these issues.

Since some of the proposed draft plans could have had a detrimental effect on the States / FDA interactions NASDA seeks to inform FDA Commissioner, Andrew C. von Eschenbach, M.D., and Assistant Commissioner for Regulatory Affairs, Margaret O'K. Glavin:

- 1) Of the need for assessments of the effects of proposed changes on other stakeholders as FDA proceeds to consider reorganization and of the continued value of transparent processes and increased communications and
- 2) Of NASDA's willingness to be involved in any future plans for reorganizing those parts of the agency that directly affect states' relations with FDA.