January 13, 2012

The Honorable Tom Vilsack
Secretary
U.S. Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250

RE: Vaccine Approval for E. coli O157:H7

Dear Secretary Vilsack:

Foodborne illness from E. coli O157:H7 has been a public health crisis facing consumers and the meat industry for many years. Since USDA declared that pathogen an adulterant in 1994, progress has been made in reducing the frequency and severity of outbreaks—but it is clear that more needs to be done. Promising vaccines are in development that could reduce the presence of E. coli O157:H7 in cattle, which could in turn lessen its presence in meat. On behalf of CSPI's 900,000 members, I wanted to bring to your attention the troubling lack of transparency and progress in approving these vaccines. I am concerned that public health may be suffering as a result.

Licensing of vaccines for food animals falls under the control of the Center for Veterinary Biologics (CVB), part of the Animal and Plant Health Inspection Service (APHIS). The agency derives its authority from the Virus-Serum-Toxin Act of 1913 (VST) and performs a stated mission to assure that pure, safe, potent and effective veterinary biologics are available for the diagnosis, prevention, and treatment of animal diseases. That mission requires CVB to consider relevant scientific data to ensure the safety and efficacy of biologics presented for approval. In the past, CVB’s focus was limited primarily to vaccines with only animal health implications.

While these new vaccines target a pathogen that does not routinely sicken animals, the pathogens have a severe public health impact. Thus, in reviewing these vaccines, CVB also has a commensurate obligation to consider public health. CVB has no stated or implied authority to assess or establish the marketability or practicality of the biologics it licenses.

Unfortunately, I now believe that CVB is in fact considering marketability and practicality as part of its vaccine licensing process. In doing so it has unnecessarily delayed development of at least two important vaccines. In a recent meeting with CSPI and several other consumer groups to discuss delays in licensing, a CVB official stated that there is "no scientific downside" to the E. coli O157:H7 vaccines currently under consideration, but that there are concerns about cost to the industry and the logistical challenges of administering the vaccines. In that same conversation, when asked to clarify CVB’s definition of efficacy required for vaccine licensing, that official noted that the “industry would like to see efficacy that would bring [E. coli O157:H7] shedding rates down from summer to winter levels” (an efficacy of 55 to 65 percent). When asked whether the Food Safety and Inspection Service (FSIS) had an opinion of what efficacy might represent a significant public
health outcome, the official did not indicate knowledge of FSIS’ position or any inter-agency collaboration on that issue.

If this official’s account is accurate, it is deeply troubling. CVB appears to be considering tangential and unauthorized elements well beyond the scope of its authority in its licensing determinations, and simultaneously appears to be ignoring the public health impact of its actions. Failing to work directly with FSIS on establishing an expectation of efficacy for vaccines that could impact public health is a serious problem, as is the seeming focus on industry desires and outcomes rather than public health.

Under the Obama administration and your leadership, USDA—and in particular FSIS—has made significant strides toward becoming a more proactive public health agency. In an effort to ensure that CVB is similarly focused, I urge you to direct CVB to outline a strategy for approving vaccines and other technologies that have an impact on public health. That strategy should include a formal collaborative process with FSIS and—as necessary—with FDA’s Center for Veterinary Medicine, and should be as transparent as possible.

Sincerely,

Michael F. Jacobson, PhD
Executive Director

CC:
Mr. Edward Avalos, Under Secretary for Marketing and Regulatory Programs
Dr. Elisabeth Hagen, Under Secretary for Food Safety
Dr. Gregory Parham, Administrator of APHIS
Dr. John Clifford, Deputy Administrator of APHIS