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November 14, 2018

Commissioner Scott Gottlieb
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: Romaine Outbreak – Need for Action to Address CAFO Risk

Dear Commissioner Gottlieb:

Stop Foodborne Illness (“Stop”) is a 25-year old national organization that represents and supports individuals and families who have been directly impacted by serious foodborne illness. Our constituency is committed to the prevention of illness and death caused by foodborne illness. We work to explain the “why” of food safety in compelling personal terms and we believe in the power of collaboration with government and industry to take effective action on food safety.

I am writing to share Stop’s perspective on the importance of collaboration in response to this year’s tragic, multi-state outbreak associated with *E. coli* O157:H7 in romaine lettuce, in which at least 96 people were hospitalized and 5 died. Our perspective is outlined in the enclosed commentary by the co-chairs of our Board of Directors: Lauren Bush, who was seriously injured in the 2006 spinach outbreak, and Michael Taylor, who served until June 2016 as FDA’s Deputy Commissioner for Foods and Veterinary Medicine.

We applaud your strong commitment to the public health mission of FDA and we deeply respect the dedication of FDA’s staff to the protection of consumers. We also know FDA and the leafy green industry are taking the romaine outbreak seriously and we appreciate the efforts FDA, growers, and retailers are making to learn from it and improve practices. We appreciate FDA’s investigation of the outbreak and the agency’s call for “bold action” to prevent future outbreaks, as outlined in FDA’s November 1 letter to the Arizona and California Departments of Agriculture and the leafy green industry groups.

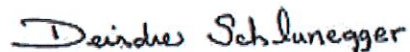
As outlined in the enclosed commentary, we strongly agree that additional bold action is needed, most urgently to address the significant hazard posed by the close proximity to irrigation canals and growing fields of a large concentrated animal feeding operation (CAFO). **In our view, this action should include immediate steps by FDA to provide guidance on risk-reduction measures, such as water treatment, that can reduce the risk of leafy greens being contaminated.**

Given the significance of the CAFO hazard, as reflected in the romaine outbreak, leaving decisions about risk mitigation steps solely to individual growers and retailers, without guidance from FDA, is inadequate to protect food safety and to restore consumer confidence. While we respect the need for flexibility in a variety of growing environments, a piecemeal approach to the CAFO issue without guiding principles is not in the best interest of any stakeholder at the table.

We know there are no simple answers, but we strongly believe all responsible parties – federal and state governments, growers, cattle feeders and retailers – must be at the table working collaboratively to provide clear and transparent guidance on what needs to be done to ensure the safety of leafy greens and advance public health.

Thank you for considering our perspective as conveyed in this letter and the enclosed commentary by Ms. Bush and Mr. Taylor. We welcome dialogue with you and the FDA team.

Sincerely,

A handwritten signature in cursive script that reads "Deirdre Schlunegger".

Deirdre Schlunegger
CEO, Stop Foodborne Illness

cc: Dr. Stephen Ostroff
Dr. Susan Mayne