



## Consumer Federation of America

December 15, 2014

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

**RE: Docket No. FDA-2011-N-0921**

Consumer Federation of America appreciates the opportunity to comment on the Food and Drug Administration's proposed rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption [Docket No. FDA-2011-N-0921]. This rule is fundamental to prevention of human illnesses from fresh produce.

CFA appreciates the efforts FDA has made to draft this rule, seek stakeholder input through public meetings and the public comment process, and remain open to ideas and suggestions to improve the rule. CFA's comments on the supplemental proposal follow.

**Interim Standard for Soil Amendments of Animal Origin**

It is important to address biological soil amendments of animal origin since those products are likely to contain pathogenic bacteria that can cause foodborne illness in humans. Yet in the supplemental proposal, FDA proposes to withdraw its original proposal of a 9-month minimum application interval for the use of raw manure and defer any decision on an appropriate interval until the FDA conducts further study and research on the issue. FDA estimates that such activities will take 5-10 years.

CFA strongly opposes this approach as outlined in the supplemental proposal. The lack of any interval for the application of raw manure in the final produce regulation does not protect public health. In fact, it likely increases the risk to consumers. While CFA recognizes that current science may not be sufficient for the agency to develop a definitive interval today, moving forward with no interval is unacceptable. CFA supports the detailed comments submitted to FDA by the Center for Science in the Public Interest on biological soil amendments, and strongly urges FDA to set an interim interval while the agency conducts additional research to develop a more science-based interval.

CFA is in agreement with members of the sustainable agriculture community and other consumer groups that, as an interim measure, FDA should require farms to adopt the intervals for raw manure application in the National Organic Program (NOP). While not food safety standards per se, the NOP standards do provide some measure of protection for consumers that would not exist if FDA moved forward without any interval whatsoever.

CFA would consider this an interim interval while FDA develops a more appropriate, science-based interval for the application of raw manure. CFA would further support a "sunset clause" to encourage

the agency to complete its risk assessment and research agenda in a timely manner. CFA encourages FDA to engage all stakeholders, including consumer groups, in developing a more appropriate minimum application interval.

**Withdrawal of an Exemption Applicable to a Qualified Farm**

In the supplemental proposal, FDA modified its proposed provisions on withdrawal of exemptions for qualified farms to include a series of steps that provide qualified farms with due process before withdrawal. These steps are reasonable and will provide qualified farms greater clarity on the withdrawal process. Though CFA notes that it may not be necessary to enshrine those steps in regulation; guidance could serve the same purpose while not locking FDA into those steps if the agency needs to act more quickly to protect the public health.

CFA opposes FDA’s decision to provide for reinstatement of an exemption that is withdrawn. Reinstatement was not provided for under FSMA, reflecting Congress’ determination that the exemption was a privilege, not a right, and that if a qualified farm was linked to a foodborne illness outbreak that sickened consumers, that qualified farm should no longer be permitted to be exempt from federal food safety regulations. This was a “one strike, you’re out” approach that was carefully negotiated by stakeholders during the debate on FSMA in Congress. There should be no means for restoring a qualified farm’s exempt status after its withdrawal. No exempted farm, once linked to an outbreak of foodborne illness, should be allowed to continue to operate under an exemption. CFA opposes the inclusion of a reinstatement provision and urges FDA to remove it from the final rule.

CFA appreciates the opportunity to provide comments on this important proposed rule. We urge FDA to finalize the rule as soon as possible.

Sincerely,



Chris Waldrop  
Director, Food Policy Institute  
Consumer Federation of America