



Consumer Federation of America

**Consumers
Union**
POLICY & ACTION FROM
CONSUMER REPORTS



July 19, 2016

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

RE: Docket ID: FDA-2016-N-0321--Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments

Consumer Federation of America, Center for Foodborne Illness Research & Prevention, STOP Foodborne Illness, Consumers Union, and Center for Science in the Public Interest appreciate the opportunity to submit comments in response to this Risk Assessment by the Food and Drug Administration. Manure plays an important role in sustainable agriculture by returning nutrients to the soil and reducing the need for chemical fertilizers. It can also act as a transmission vehicle for deadly pathogens when handled inappropriately. In the interest of public health, we encourage FDA to act expeditiously in developing time intervals and other standards to guide the safe application of manure on farms. As with any scientific inquiry, some uncertainty surrounds the question of how best to minimize the risks associated with manure. However, a robust body of research demonstrates that manure harbors pathogenic bacteria, that pathogens can survive a long time in untreated manure, and that common agricultural practices can transmit pathogens from manure to food crops.

In light of this evidence, we continue to support an interim measure requiring a minimum application interval for the use of raw manure. In previous comments on FDA's supplemental proposed rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, we noted our strong opposition to a "produce rule" without such a minimum application interval.¹ We reiterate that objection now. FDA's "zero-interval" manure standard imposes

¹ See, e.g. Comments of Chris Waldrop, Consumer Federation of America RE: Docket No. FDA-2011-N-0921 (Dec. 15, 2014) available at: <http://consumerfed.org/wp-content/uploads/2010/08/CFA-Produce-Supplementary-Proposal-comments-12-15-14.pdf>; Comments of Patricia Buck, Center for Foodborne Illness Research & Prevention

an unacceptable risk on consumers handling or consuming raw produce, whether domestic or imported. In addition to the comments we filed independently on FDA's produce rule, we joined members of the sustainable agriculture community in recommending that FDA issue an interim measure in its final produce rule that would require farms to adopt the National Organic Program's intervals for raw manure application. We noted that this measure could include a "sunset clause" to encourage the agency to develop a more appropriate, science-based interval for the application of raw manure in a timely manner.² Although the final produce rule omitted this interim measure, we see no reason why FDA could not promulgate a rule implementing it now.

A brief survey of the scientific literature suffices to underscore the public health threat posed by poor manure management practices, and the urgent need for a minimum application interval. For instance, an abundance of research links one of the most deadly pathogens, *E. coli* O157:H7, to raw manure. *E. coli* O157:H7 causes diarrhea, urinary tract infections, respiratory illness and pneumonia, among other ailments. The Centers for Disease Control and Prevention (CDC) estimate that 265,000 Shiga toxin-producing *E. coli* (STEC) infections occur each year in the United States, and STEC O157 causes about 36% of those infections.³ *E. coli* O157:H7 commonly shows up in manure, occurring in 20% of bovine samples taken in one study,⁴ and in 57% of samples in another study.⁵ Likewise, researchers found that 64.2% of cull cow fecal samples taken from dairy farms in Texas contained *Salmonella*, 19.5% of which were resistant to multiple antibiotics.⁶ Another study found the prevalence of *Salmonella* and *Campylobacter* in cattle, chickens, and swine reached levels as high as 31.5% and 94.0%, respectively.⁷

The research also leaves little doubt that treating raw manure and observing minimum intervals between application and harvest can reduce the likelihood of disease transmission. Studies have found that farms that used manure or compost aged for less than 12 months had a prevalence of generic *E.*

RE: Docket No FDA-2011-N-0921 (Dec. 12, 2014) available at: [file:///C:/Users/Buck/Downloads/Comment from Center for Foodborne Illness and Research CFI%20\(1\).pdf](file:///C:/Users/Buck/Downloads/Comment%20from%20Center%20for%20Foodborne%20Illness%20and%20Research%20CFI%20(1).pdf); Comments of Nils Fischer and Caroline Smith DeWaal, Center for Science in the Public Interest, RE: Docket No. FDA-2011-N-0921 (Dec. 15, 2014) available at: <https://www.regulations.gov/document?D=FDA-2011-N-0921-1377>.

² See Joint Statement of Center for Foodborne Illness Research & Prevention, Center for Science in the Public Interest, Consumer Federation of America, Consumers Union, National Consumers League, National Farmers Union, National Good Food Network, Wallace Center National Organic Coalition, National Sustainable Agriculture Coalition, New England Farmers Union, and The Pew Charitable Trusts re Docket No. FDA-2011-N-0921; RIN: 0910-AG35 (Dec. 12, 2014) attached as an addendum to Comments of Nils Fischer and Caroline Smith DeWaal, Center for Science in the Public Interest, RE: Docket No. FDA-2011-N-0921 (Dec. 15, 2014) available at: <https://www.regulations.gov/document?D=FDA-2011-N-0921-1377>

³ The Centers for Disease Control and Prevention, *E. coli* (*Escherichia coli*) General Information <http://www.cdc.gov/ecoli/general/>

⁴ C'ez'ek1, P. Alexa, I. Litera'k, J. Hamr'ik, P. Nova'k and J. Smola. Shiga toxin-producing *Escherichia coli* O157 in feedlot cattle and Norwegian rats from a large-scale farm. *Letters in Applied Microbiology* (1999) available at <http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2672.1999.00549.x/epdf>.

⁵ Rhoades, J.R., G. Duffy, K. Koutsoumanis. Prevalence and concentration of verocytotoxigenic *Escherichia coli*, *Salmonella enterica* and *Listeria monocytogenes* in the beef production chain: A review. *Food Microbiol* (2009). 26:357-376.

⁶ Rodriguez-Rivera Lorraine D., et al. *Salmonella* Prevalence and Antimicrobial Susceptibility Among Dairy Farm Environmental Samples Collected in Texas. *Foodborne Pathogens and Disease* (2016) available at: <http://online.liebertpub.com/doi/abs/10.1089/fpd.2015.2037>

⁷ Erickson, Marilyn C. Horticulture Production, Food Safety, and Organic Amendments: Effects on Public Health. Center for Food Safety, Department of Food Science and Technology, University of Georgia.

coli 19 times greater than conventional samples,⁸ and that the odds of *E. coli* contamination on spinach were almost 13 times lower when the time from the last manure spreading was greater than 200 days.⁹ More recently, a longitudinal study of spinach crops from Spain confirmed that guidelines in that country to apply manure at least 90 days prior to harvesting can reduce pre-harvest contamination with generic *E. coli*.¹⁰ In addition, drying manure to very low moisture levels, as well as using chemical treatments such as alkaline, have been shown to result in extensive inactivation of pathogens.¹¹

To be sure, the understanding of many factors that contribute to the survival and transmission of pathogens in manure continues to evolve. As researchers have pointed out, despite hundreds of years of practice, our understanding of composting continues to evolve, and particularly the conditions that lead to heat-shocked pathogens that resist inactivation by heat and the necessary remediation to address those contingencies.¹² Similarly, the impact of rain water on pathogen growth in manure and subsequent transmission remains poorly understood.¹³ Nevertheless, as FDA noted in the preamble to its initial proposed produce rule in 2013, the agency's understanding of the risks associated with manure already support immediate adoption of an interim measure that would require farms to adopt the National Organic Program's intervals for raw manure application.

At the same time, the agency should proceed without delay to develop comprehensive, science-based rules governing manure treatment and application, which may take into account geographic, climatic and other site specific characteristics. In order to develop these rules, FDA should conduct a risk assessment that 1) evaluates risks associated with manure from farm to fork; 2) includes a fully quantitative, probabilistic microbial risk assessment, and 3) adequately quantifies uncertainty as well as variability. The assessment should employ different scenarios to assess risks associated with different types of soils, humidity and temperature levels, and other geographic and climatic factors. The risk assessment should take account of risks specific to certain popular produce items, such as leafy greens, tomatoes, and cucumbers, and it should consider all major foodborne pathogens including *Salmonella*, STEC *E. coli*, *Listeria*, and *Campylobacter*. It should also consider the risks posed by residues of animal drugs, which can occur in significant concentrations in animal manure from large scale confined animal feeding operations.¹⁴

In general, the risk assessment should provide for a robust accounting of the costs associated with foodborne illness. It should consider foodborne illness risks that may relate only to certain population

⁸ A. Mukherjee, D. Speh, E. Dyck, F. Diez-González. Preharvest evaluation of coliforms, *Escherichia coli*, *Salmonella* and *Escherichia coli* O157:H7 in organic and conventional produce grown by Minnesota farmers. *J. Food Prot.*, 67 (2004), pp. 894–900.

⁹ S. Park, S. Navratil, A. Gregory, A. Bauer, I. Srinath, M. Jun, B. Szonyi, K. Nightingale, J. Anciso, R. Ivanek. Generic *Escherichia coli* contamination of spinach at the preharvest stage: effects of farm management and environmental factors. *Appl. Environ. Microbiol.*, 79 (2013), pp. 4347–4358.

¹⁰ Castro-Ibáñez, et al. Assessment of microbial risk factors and impact of meteorological conditions during production of baby spinach in the Southeast of Spain. *Food Microbiology* (2015) available at: <http://www.sciencedirect.com/science/article/pii/S0740002015000283>

¹¹ M.D. Sobsey, L.A. Khatib, V.R. Hill, E. Alocilja, and S. Pillai. "Pathogens in Animal Wastes and the Impacts of Waste Management Practices on Their Survival, Transport and Fate." in *Animal Agriculture and the Environment: National Center for Manure and Animal Waste Management White Papers*, J. M. Rice, D. F. Caldwell, F. J. Humenik, eds. 2006, pp.609-666.

¹² <http://www.pewtrusts.org/~media/assets/2009/psp20issue20brief20seriespdf.pdf?la=en>

¹³ *Id.*; see also M. D. Stocker, et al., Depth-Dependent Survival of *Escherichia coli* and *Enterococci* in Soil after Manure Application and Simulated Rainfall Applied and Environmental Microbiology (2015) available at: <http://aem.asm.org/content/81/14/4801.short>

¹⁴ See, e.g. J.C. Chee-Sanford, et al. (2009). "Fate and Transport of Antibiotic Residues and Antibiotic Resistance Genes following Land Application of Manure Waste," *J. Environ. Qual.*, 38: 1086-1108.

sub-groups, such as listeriosis among pregnant women, as well as risks that affect the general population. It should also consider metrics such as Quality Adjusted Life Years, Disability Adjusted Life Years, and cost of both acute and chronic illnesses, and where appropriate, it should estimate the overall number of illnesses and deaths that could be avoided. Finally, the risk assessment should, at a minimum, compare the impacts associated with any proposed soil amendment standards to those associated with the current NOP standards, and with no standard at all.

The undersigned organizations appreciate the opportunity to provide comments on this important agency action. We urge FDA to both issue an interim rule and develop a comprehensive final rule as soon as possible.

Sincerely,

Consumer Federation of America

Center for Foodborne Illness Research & Prevention

STOP Foodborne Illness

Consumers Union

Center for Science in the Public Interest