Consumer Federation of America

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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.

Introduction

Every year, about 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases, according to the Centers for Disease Control and Prevention. Based on data from CDC, FDA has found that from 1996 to 2010, approximately 131 produce-related reported outbreaks occurred, resulting in 14,350 outbreak-related illnesses, 1,382 hospitalizations and 34 deaths. These outbreaks were associated with approximately 20 different fresh produce commodities.

Illnesses and deaths from foodborne disease are largely preventable. The Food Safety Modernization Act (FSMA), which was passed with bipartisan support in Congress and signed into law by President Obama in January 2011, shifts FDA's approach to food safety from reaction to prevention, with the goal of reducing foodborne illness among consumers. One of the key provisions of FSMA is the provision on standards for produce safety. Under FSMA, FDA is required to develop, for the first time ever, safety standards for the production of fresh fruits and vegetables. Recent outbreaks such as the 2011 Listeria outbreak linked to contaminated cantaloupe that sickened 147 persons in 28 states and killed 33 people reinforce the importance of establishing basic food safety standards for the growing, harvesting and production of fresh produce.

CFA generally supports FDA's proposed approach to produce safety in the proposed rule. The following five points highlight key issues raised in CFA's comments on the proposed rule. However, CFA provides comments on numerous other areas in the proposal where changes should be made to better protect consumers.

1. CFA supports FDA's approach to regulate risky practices, not risky produce. However, FDA should require all produce to be covered under the final produce safety rule and not exempt produce that is "rarely consumed raw."
2. CFA strongly supports FDA requiring a numerical standard for water against which a farm's measures would be compared and actions taken to bring the operation into conformance with the standard.

3. CFA supports FDA's proposal that untreated soil amendments of animal origin that may contact produce after application should have a minimum application interval of 9 months. These soil amendments carry the highest risk of pathogenic contamination.
4. FDA should require environmental testing in packing sheds and on equipment, particularly for high-risk products. The 2011 *Listeria* outbreak linked to cantaloupes from Jensen Farms is a prime example of the importance of environmental testing.
5. FDA must articulate a clear strategy for enforcement to ensure compliance of the produce safety rule. FDA must request from Congress adequate resources to perform these essential inspections.

Subpart A – General Provisions

CFA partially supports FDA's proposed approach
CFA agrees with FDA's approach to focus on the likelihood of contamination posed by agricultural practices applied to the crop. This approach is consistent with what science indicates are the most common routes of contamination of fresh produce. The approach is also consistent with other approaches used in the produce industry.

CFA strongly agrees with FDA that an approach that relies on outbreak data to make determinations about which produce should be covered is inconsistent with a prevention-based approach as called for under FSMA. As FDA notes, the past history of foodborne illness outbreaks is not predictive of future outbreaks. In addition, outbreak data is only the tip of the iceberg in terms of which foods cause specific illnesses. Much foodborne illness is never linked to an outbreak so relying on outbreak data would be insufficient to protect the public. Moreover, data show that the patterns of outbreaks associated with produce commodities change over time.

CFA further agrees that relying on pathogen surveillance data would not provide sufficient information to make risk determinations. FDA collects little data on produce compared to the amount of fruits and vegetables produced. The data the agency does collect is typically targeted to produce that is already known to be risky, which is not a preventive approach. The largest data set on produce contamination was recently discontinued when USDA stopped funding the Microbiological Data Program in 2012.[1] The MDP conducted 80 percent of all federal produce testing for pathogens, far more testing than FDA conducts.

All fruits and vegetables should be covered by FDA's food safety requirements.
CFA strongly disagrees with FDA's proposal to exempt certain produce that is "rarely consumed raw" from the proposed food safety requirements. FDA's rationale is that these products are typically cooked which would destroy potential pathogens on the product. However, this is in contrast with a basic principle that that all food producers are obligated to produce safe food. No one should be exempt from food safety.

FDA's proposed exemption is also in contrast with consumer preference and use of particular foods. Included on FDA's "exempt" list are foods such as beets and kale which are, in fact, consumed raw by

[1] Bottemiller H, "MDP Shuts Down; USDA Testing of Produce for Pathogens Halted." *Food Safety News*, January 3, 2013, http://www.foodsafetynews.com/2013/01/mdp-officially-shut-down-pathogen-testing-for-produce-halted/#.UhTiqX9p13E

consumers.[2] Consumer trends may result in additional "exempt" foods being commonly consumed raw in the future.[3] In addition, some "exempt" foods such as bok choi or asparagus, while frequently cooked before consuming, may not typically be cooked to the necessary temperature to destroy pathogens. Rather than changing agency policy for an "exempt" food every time consumer eating or cooking habits change, FDA should require all foods to meet basic food safety standards.

Further, by not requiring "exempt" produce to meet food safety standards, those foods may be contaminated when they enter consumers' homes and could cross-contaminate other foods in the kitchen, spreading pathogens and putting consumers at risk.

For these reasons, CFA strongly urges FDA to require all produce to be covered under the final produce safety rule. If FDA decides to maintain minimal exemptions for a more restrictive list of fruits and vegetables, FDA should delineate that list in agency guidance rather than in the final rule. Updates to such a list are inevitable and FDA will need the flexibility to revise any list in a timely manner to protect public health. If FDA codified an exemption list in its regulations, the agency would have to go through rulemaking – a time-consuming and slow process – any time the agency needed to make chances to the list. Such a process will delay necessary changes and limit FDA's effectiveness in reacting to new data or information in order to protect the public.

CFA is not opposed to the other exemptions outlined in the proposed rule, including produce grown for personal consumption; fresh-cut produce which will be covered under the FDA's preventive controls rule; and produce that receives commercial processing that adequately reduces the presence of microorganisms, provided that the process is validated.

Farms should be required to have a written food safety plan for their farm.
Under the produce safety proposed rule, FDA is not proposing to require each farm to conduct a hazard analysis and develop a written food safety plan for its operation. Conducting an assessment of likely hazards that could occur on the farm (such as unsafe water, poor employee hygiene, or animal excrement in the fields) can help farmers identify potential situations which could lead to contaminated food. Developing a written food safety plan can help farmers think through the potential food safety risks and identify ways to reduce those risks.

Recognized industry guidance for on-farm food safety recommends that farms tailor their food safety practices to the activities and conditions on the individual farm. Many of those guidance documents also recommend that farms identify likely hazards on the farm and develop a plan to control those hazards. Even small farms now have tools to help them develop written food safety plans. USDA, the produce industry and small farmers worked together to develop a free, easy-to-use online tool for small farms to develop a simple food safety plan: http://onfarmfoodsafety.org/.

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[2] Andrea Cespedes, Can You Eat Kale Raw?, **Livestrong.com**, May 12, 2011, http://www.livestrong.com/article/441153-can-you-eat-kale-raw/#ixzz2cGOGn4yX; Shane Gray, Can I Eat Beets Without Cooking Them? **Livestrong.com**, Sept 29, 2011, http://www.huffingtonpost.com/2012/07/16/raw-beet-recipes_n_1676238.html; Raw Beet Recipes, The Huffington Post, July 17, 2012, http://www.huffingtonpost.com/2012/07/16/raw-beet-recipes_n_1676238.html; Mario Batalia, Bresaola with Raw Artichokes, **The Cooking Channel** http://www.cookingchanneltv.com/recipes/mario-batali/bresaola-with-raw-artichokes.html;

[3] David L. Katz, The Raw Food Diet, Overcooking, **The Huffington Post**, Oct. 25, 2012, http://www.huffingtonpost.com/david-katz-md/raw-food-diet_b_2015598.html; Gisela Williams, Resorts Refining the Raw Rood Scene, **N.Y. Times**, Apr. 2 2006, http://www.nytimes.com/2006/04/02/travel/02heads.html.

While the statutory language of FSMA does not explicitly require written food safety plans under the produce safety provision, the language does not rule out such a requirement. At the very least, FDA should require farms to conduct a written hazard analysis. This would ensure that a farm is considering the hazards that are unique to its operation, as well as those general food safety hazards that FDA has identified. The analysis would also provide inspectors—whether state or federal—with a mechanism for understanding the particular hazards the farm believes it is mitigating.

Subpart C – Standards Directed to Personnel Qualifications and Training

Qualifications and Training for Personnel

CFA supports FDA's decision to require that all personnel who handle produce or food-contact surfaces receive adequate training, as appropriate to the person's duties. This should include temporary, part time, seasonal, and contracted personnel, as well as supervisors. CFA also supports FDA's determination that training should be conducted upon hiring, at the beginning of each growing season (if applicable), and periodically thereafter. While initial training is essential, regular refresher courses can reinforce key concepts and can address identified deficiencies. The training, in combination with education or experience, should be sufficient so that the person is able to perform their assigned duties in a manner that ensures compliance with regulations under the Food Safety Modernization Act.

CFA supports FDA's determination that training must be conducted in a manner that is easily understood by the personnel being trained. This could include visual materials as well as conducting training in the appropriate language. FDA should provide, via guidance, specific examples, such as pictograms, that can help facilitate understanding across language barriers. FDA should also recommend that training be conducted in the dominant native language of the workers, but that training must be communicated sufficiently to all workers, even those who may not speak the dominant language. CFA agrees with FDA that training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA. FDA should provide guidance to members of the industry to help them identify when additional training may be necessary and how that training may be conducted.

Training Requirements for Personnel

CFA supports FDA's determination that training for personnel who handle covered produce or supervisors should at minimum include principles of food hygiene and food safety, the importance of health and personal hygiene for all personnel and visitors, and the food safety standards established by FDA as part of FSMA that are applicable to the employee's job responsibilities.

It is especially important that training include instructions on how to recognize symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance. The Centers for Disease Control and Prevention has found that 46% of foodborne outbreak-associated illnesses from 1998 to 2008 were attributed to produce, suggesting that the large number of norovirus illnesses was a major driver.[4]

[4] Painter JA, Hoekstra RM, Ayers T, Tauxe RV, Braden CR, Angulo FJ, et al. "Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008." *Emerging Infectious Disease*, March 2013 http://dx.doi.org/10.3201/eid1903.111866.

Norovirus is a highly contagious virus that can be spread by a sick person, contaminating food and drinks that they touch. Food safety training must help workers recognize when they may be sick and what they should do about it so they do not spread contamination to produce, food contact surfaces or other workers.

Food safety training should be reinforced and strengthened through a clear understanding of how food safety practices on the farm can affect consumers who purchase the farm's products. As such, training should include a review of why food safety practices are necessary and should be followed, focusing on the effects of contamination and foodborne illness on consumers and families. Personnel should be instructed on their role in public health prevention as the first line of defense to prevent contamination.

CFA supports FDA's decision that training should include instructions on how to recognize covered produce that should not be harvested, including covered produce that may be contaminated. We agree that persons who conduct harvest activities should receive training on inspecting, correcting, and reporting harvest containers and equipment to ensure that they are clean, functioning properly, and maintained so as not to become a source of contamination of covered produce. Growers should implement procedures that incentivize reporting of unclean or damaged harvest containers and equipment that could serve as a source of contamination. Growers should also incentivize reporting of potential contamination in the fields from animals or other sources. An incentive system would better assure that workers carry out this responsibility.

A system which provides workers with certification that they have been adequately trained on food safety could be a useful tool in promoting and encouraging food safety training. Workers who work at multiple farms during the year could carry their certification to other farms so that growers would know that they had previously received food safety training. This should not obviate the need for training upon hire, at the beginning of each growing season and periodically thereafter, but could provide growers with a better sense of the food safety capacity of their workforce. As additional training is provided, the certification could be updated to note the training(s) the worker received.

Training Requirements for Supervisors

CFA supports FDA's proposed requirement that at least one supervisor or responsible party from a farm must successfully complete food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA.

CFA supports FDA's decision to require an identified person to supervise and be responsible for the farm's operations to ensure compliance with FDA's produce safety regulations. Assigning responsibility for compliance will better assure that a specific individual is responsible for carrying out the requirements of the law and will provide FDA with a point person with whom to communicate during an inspection or investigation.

Recording Keeping

CFA supports FDA's proposed requirements for record keeping and documentation. Training records should document the training of personnel, including the date of training, topics covered, and the persons(s) trained. In addition, FDA should require supervisors to attest that workers participated in the training and have an adequate understanding of the material. FDA should review these records during an inspection of the farm.

Subpart D—Standards Directed to Health and Hygiene

Preventing Contamination from Ill or Infected Persons

CFA supports FDA's determination that persons with a health condition, such as a communicable disease, should be excluded from working in operations in which they could contaminate produce or food contact surfaces. Growers should designate the worker to another part of the operation until the health condition no longer presents a risk to the public. For cuts or open wounds, growers should be required to issue bandages, wound covers, and gloves before allowing workers with open wounds to handle produce. FDA should recommend via guidance that bandages, wound covers or gloves be brightly colored so as to be easily identified if they come off in the fields, harvest bins, or during post-harvest activities. This is common practice in the produce industry today.

Additionally, CFA agrees that preventive measures must include instructing personnel to notify their supervisor if they have, or if there is a reasonable possibility that they have a health condition. Workers must be explicitly empowered to provide this information without fear of reprisal or lost wages.

Hygienic Practices

CFA supports FDA's decision to require personnel to use hygienic practices when working in an operation in which produce or food-contact surfaces are at risk of contamination. CFA agrees that hygienic practices must include maintaining adequate personal cleanliness, avoiding contact with animals other than working animals, minimizing the likelihood of contamination of covered produce when in direct contact with working animals, and hand washing. In addition, FDA should require the prohibition of jewelry, gum, spitting, chewing, eating, and drinking (excluding water) in growing areas. Jewelry can be a personal safety risk for workers who are on or near moving equipment. Jewelry or pieces of jewelry can also fall into the product creating a risk for consumers. Spitting, chewing and eating can result in human saliva unknowingly contaminating produce. Food in growing areas can attract pests such as rodents, birds or deer which can spread pathogens to produce.

Additionally, FDA should require that hand washing and toilet facilities are available at all times and should be accessible to growing areas during harvest. A 2013 study by Park et al found that produce contamination was significantly reduced when workers used hand-washing stations or when farms provided portable toilets for workers and trained workers on how to use them.[5] Considering that, hand washing and toilet facilities should even be available for work that extends for less than three hours. The Occupational Safety and Health Administration (OSHA) defines "readily accessible" toilets as one toilet for twenty employees and within a ¼ mile walk to growing areas during harvest. FDA cites the OSHA standards in the proposed rule but should be more specific in its final regulation about what the agency means when it uses the term "readily accessible" with regards to hand washing facilities and toilets.

Doors should be required for toilet facilities to provide workers with adequate privacy. CFA supports FDA's determination that hands should be washed before starting work, before putting on gloves, after using the toilet, upon return to the work station after any break or other absence from the work station, as soon as practical after touching animals (including livestock and working animals), or any waste of animal origin, and at any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of produce. CFA also supports FDA's determination that the

[5] Park S, Navratil S, Gregory A, Bauer A, Srinath I, Jun M, Szonyi B, Nightingale K, Anciso J, Ivanek R, "Generic Escherichia coli Contamination of Spinach at the Preharvest Stage: Effects of Farm Management and Environmental Factors." *Appl. Environ. Microbiol.* 79(14): 4337, 2013.

water used for hand washing must meet the standards under proposed regulation 112.44(a) and should be tested to ensure there is no detectable generic *E. coli*.

Growers should be required to provide and maintain outer garments relevant for their work, including gloves, for workers. Outer garments and gloves should be maintained in an intact and sanitary condition and replaced when no longer capable of being intact and sanitary. Proper glove use should be included as part of the food safety and hygiene training. FDA should specify examples of when gloves should be changed, including but not limited to before starting work, after using the toilet, upon return to the work station after any break or other absence from the work station, as soon as practical after touching animals (including livestock and working animals), or any waste of animal origin, and at any other time when the gloves may have become contaminated in a manner that is reasonably likely to lead to contamination of produce.

Visitors

CFA supports FDA's decision that visitors must be made aware of policies and procedures to protect produce and food-contact surfaces from contamination by people, and that the farm must take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. Toilet and hand washing facilities must be accessible to visitors.

Subpart E—Standards Directed to Agricultural Water

Measures Regarding Water Sources and Distribution Systems

CFA supports FDA's determination that all agricultural water must be safe and of adequate sanitary quality for its intended use. Agricultural water should include water that is used both in growing activities as well as harvesting, packing and holding activities. Water used in growing activities is especially important because irrigation water is recognized as a likely source of produce contamination and serves as a source of pathogenic microorganisms of human health concern.[6] [7] While water is most frequently used for irrigation, it has multiple other uses on the farm that must be considered as well. FDA should consider how those other uses might impact the safety of fresh produce on the farm. For example, a recent study suggests that contaminated water used in agricultural pesticides may be one vector for norovirus to enter the food supply.[8]

CFA agrees that water which directly contacts the harvestable portion of the plant is more likely to contaminate produce than water applied via indirect methods that does not contact the produce. CFA also agrees that the risk of water depends on the source of the water and that surface water poses the highest risk of contamination and the greatest variability in quality of agricultural water sources.

CFA agrees with the basic approach underlying FDA's proposed requirements on agricultural water. CFA supports FDA requirements that, in order to assure that water is safe and of sanitary quality, farms must

[6] Suslow TV, "Produce Safety Project Issue Brief: Standards for Irrigation and Foliar Contact Water." The Produce Safety Project, The Pew Charitable Trusts, 2011.

[7] Park S, Szonyi B, Gautam R, Nightingale K, Anciso J, Ivanek R, "Risk factors for microbial contamination in fruits and vegetables at the preharvest level: a systematic review." *J. Food Prot.* 75:2055–2081, 2012.

[8] Verhaelen K, Bouwknegt M, Rutjes SA, de Roda Husman AM, "Persistence of human norovirus in reconstituted pesticides — Pesticide application as a possible source of viruses in fresh produce chains." *International Journal of Food Microbiology*, Volume 160, Issue 3, 1; Pages 323-328, January 2013.

inspect their water system, identify conditions that are likely to introduce hazards, and take steps to reduce the risk those conditions create. This should include maintenance of all water sources by regularly inspecting the water source as well as appropriate storage of all equipment used in the system. Even if the farm is relying on a public water source which has been found to be safe, the farm must still inspect its water distribution system to ensure that the farm's system does not inadvertently contaminate the water. If problems are identified, the farm must immediately discontinue the use of the water source, take steps to address the cause of the contamination and/or treat the water in accordance with the regulations and verify that those actions were successful in addressing the problem.

Testing Water Sources

CFA strongly supports FDA requiring a numerical standard for water against which a farm's measures would be compared and actions taken to bring the operation into conformance with the standard. A numerical standard is appropriate where the effectiveness of individual measures, such as the protection of agricultural water sources from contamination, is not complete or fully known. It is also appropriate because the quality of a particular water source (such as surface water) may be outside the control of the farm. A numerical standard is also necessary to provide some objective evidence that the water system is functioning adequately and corrective actions employed by the farmer are working as intended. In addition, a numerical standard specified in the regulation will provide FDA with a clear and enforceable way to hold farmers accountable for checking and maintaining their water systems.

As FDA notes in the preamble to the proposed rule, generic *E. coli* has a long history of use as an indicator of fecal contamination. However its use in setting a water standard is complicated by the fact that the presence of an indicator organism may or may not indicate the presence of microbial pathogens and the record of generic *E. coli* as a predictor of pathogens is mixed.[9] CFA recognizes the problems with using generic *E. coli* as the indicator in the water standard. However, the use of generic *E. coli* does have a scientific basis, is relatively inexpensive to test for, has a variety of testing formats and is a relatively familiar standard. Since CFA believes that a numerical standard is necessary, in the absence of a better option, the generic *E. coli* standard proposed by FDA is reasonable.

Specifically, CFA supports FDA's determination that water used in growing activities should have a limit of 235 CFU generic *E. coli*/100 mL. CFA also supports FDA's proposed requirement that if water samples exceed that level, the farm must discontinue the use of that water source, re-inspect the water system, identify conditions likely to introduce a hazard, make necessary changes and/or treat the water and retest the water before using it again to make sure it meets the requirements in the regulation. FDA should provide guidance on sampling procedures including frequency and location of testing to assist farmers in ensuring they are adequately sampling the water source.

CFA also supports FDA's determination that water should have a no detectable generic *E. coli* limit/100 mL for water used as sprout irrigation water, water which directly contacts produce during or after harvest, water used to make treated agricultural tea, water used to contact food contact surfaces, water used to make ice, and water used for hand-washing. CFA also supports FDA's proposed requirement that if there is any detectable generic *E. coli*/100 mL of water, the farm must discontinue the use of that water source, re-inspect the water system, identify conditions likely to introduce a hazard, make necessary changes and/or treat the water and retest the water before using it again to make sure it

[9] Suslow TV, "Produce Safety Project Issue Brief: Standards for Irrigation and Foliar Contact Water." The Produce Safety Project, The Pew Charitable Trusts, 2011.

meets the requirements in the regulation. Again, FDA should provide guidance on sampling procedures including frequency and location of testing to assist farmers in ensuring they are adequately sampling the water source.

CFA agrees that water should be tested at the beginning of each growing season and periodically thereafter. We support FDA's decision that untreated surface water should be tested more frequently than ground water sources as surface water is subject to a greater number of external forces (run off, animal intrusion, erosion, dust) that can impact the quality of the water. It is unclear from the proposed rule how frequently water used in harvest and post-harvest activities should be tested. Considering that this water comes in contact with the edible portion of the crop and can be applied closer to the point of sale, FDA should require greater testing frequencies to ensure that this water meets the standard of no detectable limit.

FDA maintains that violations of the microbial water quality standards do not automatically establish evidence of adulteration of covered produce. CFA disagrees with this position. If the edible portion of produce is exposed to water that is likely contaminated, particularly post-harvest, then that produce may be contaminated as well. FDA has identified instances in outbreak investigations in which water was the likely source of contamination for produce that made consumers sick. If the edible portion of the produce has been in contact with water that does not meet the standards established in the regulation, than the produce should be disposed of or otherwise made safe through cooking. FDA should affirm this in the final rule and delineate the steps that farms must take when produce is contacted by contaminated water.

Water Used in Harvesting, Packing and Holding Activities

CFA supports FDA's determination that water used during harvest, packing and holding activities should be managed appropriately including through the use of water-change schedules, sanitation, visible monitoring for organic material, and monitoring water temperature. As noted above, CFA supports the FDA's determination that water used for these activities should have no detectable generic *E. coli* limit/100 mL of water.

FDA does not specify whether water used during harvest, packing and holding activities should be tested. Since water contacting produce during these activities is closer to the time when the produce will be sold to consumers, CFA believes this water should be tested more frequently than FDA proposes for water used during growing. FDA should require farms to test this water and should provide guidance on sampling procedures including frequency and location of testing to assist farmers in ensuring they are adequately sampling water used in these activities.

Recordkeeping and Documentation

CFA supports requirements that farms keep records on the findings of the inspection of their agricultural water systems, documentation of test results, documentation of water treatment and monitoring, annual documentation of the results of certificates of compliance from a public water system (if applicable), and training of personnel relating to water systems. FDA should also require documentation of any corrective actions that farms employ to address problems identified with their water system and their verification that those corrective actions were effective.

Further Considerations on Water Standard

Considering the controversy that FDA's proposed water standard has generated among stakeholders, the agency may be considering revisiting its proposal to achieve a more workable solution. CFA would

support such an action provided it does not result in an undue delay in finalizing the rule or meeting the implementation dates set by the U.S. district court. If FDA does decide to revisit the water standard, the agency should do so in a transparent way through public meetings and seeking board stakeholder input. During HACCP implementation under USDA, the Food Safety and Inspection Service hosted multiple public meetings to gather stakeholder comments and work towards possible solutions to difficult problems. FDA should follow a similar process here.

Subpart F--Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

Definition of Soil Amendments

CFA supports FDA's decision to focus on biological soil amendments of animal origin as those products are likely to contain pathogenic bacteria that can cause foodborne illness in humans. CFA agrees that a biological soil amendment of animal origin should be considered untreated if it has not been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements under this rule; has become contaminated after treatment; has been combined with an untreated soil amendment of animal origin; contains a component of untreated waste, or is contaminated with a hazard; has been associated with foodborne illness; or is an agricultural tea that contains an agricultural tea additive.

Handling, Conveyance and Storage of Soil Amendments

CFA supports FDA's determination that soil amendments should be handled, conveyed and stored in such a way as to not become a potential source of contamination, and to minimize the risk of being contaminated by untreated soil amendments. Any soil amendments that have become contaminated must be handled, conveyed and stored as if it was untreated. For further clarity, FDA should provide examples, via guidance, of the best ways to handle, convey and store soil amendments as well as examples of how soil amendments can become contaminated.

Prohibition on Human Waste

CFA strongly supports FDA's determination that human waste should be prohibited from use in growing covered produce. Human waste is a high risk product and can present a significant likelihood of harboring human pathogens, viruses, parasites and bacteria. If sewage sludge biosolids are used, they must be used in accordance with the requirements of 40 CFR part 503, subpart D. FDA should assure that these requirements are followed through its oversight and enforcement activities. It is important to note that some foreign countries have historically used human waste in growing produce. FDA must communicate to the governments and growers of those countries the importance of not using human waste in growing any produce that is to be imported into the U.S. FDA must also specifically review this practice in conducting comparability assessments of foreign countries.

Microbial Standards for Treatment Process

CFA supports the microbial standards for *Listeria monocytogenes*, *Salmonella* species and *E. coli* O157:H7 for validating the treatment process in the proposed rule. These standards are already in use in the industry as a way to measure whether the composting procedures have been effective. CFA supports FDA's determination that all three standards should be applicable as each provides different assurances necessary to protect public health. CFA notes that while FDA is not requiring farms to test soil amendments prior to application, the agency should incorporate testing of soil amendments as part of its compliance measures during inspections or investigations.

Minimum Application Intervals
FDA proposes different minimum application intervals for soil amendments depending on whether the soil amendment is untreated, treated, or composted, and whether the soil amendment contacts product during or after application. For untreated soil amendments that do not contact covered produce or treated soil amendments that minimize contact, FDA proposes a minimum application interval of zero days.

CFA supports FDA's proposal that untreated soil amendments that may contact produce after application should have a minimum application interval of 9 months. These soil amendments are of animal origin and are untreated so they carry the highest risk of pathogenic contamination. Therefore, an extended application interval is appropriate. Most scientific research shows that the majority of pathogens do not survive in the soil past one year and organisms of particular concern such as *E. coli*, *Salmonella*, and *Listeria* are unlikely to survive at detectable levels past 9 months. Consequently, CFA supports FDA's proposal of a minimum application interval of 9 months.

CFA also supports FDA's proposal that soil amendments treated via composting should have a minimum application interval of 45 days. Composting requires a series of steps including stacking, aeration, turning, assuring the proper temperature and curing to achieve adequate reduction of contaminants. If these steps are not appropriately followed, the risk of pathogens remaining in the soil amendments can increase. Therefore a longer minimum application interval is appropriate.

CFA notes that while these proposed intervals are different than the requirements under the National Organic Program, the NOP standards on manure are focused on soil fertility and are not food safety standards. Under FSMA, FDA is obligated to set standards that assure food safety and we support the agency's determinations.

Recordkeeping and Documentation
CFA supports the requirement that farms must keep records of the application of untreated biological soil amendments and composted soil amendments and the date of harvest of covered produce. However, CFA questions why FDA would not just require record-keeping for all applications of soil amendments, treated or untreated. CFA similarly questions FDA's exception for covered produce which does not contact the soil after application of the soil amendment. It would be simpler, and easier to enforce, if FDA required recordkeeping for any application of soil amendments and the date of harvest of covered produce.

CFA supports FDA's proposed requirements for documentation from a third party who supplies soil amendments of animal origin. A description of the treatment process, verification of that process through testing, and how the soil amendment has been handled, conveyed and stored are all necessary pieces of information and consistent with the requirements for farms that produce their own soil amendments. For soil amendments produced on the farm, documentation that process controls were achieved and scientific data on which the farm relied to support alternative composting processes and minimum application intervals should be required. FDA should also require farms to document the particular fields on which third party soil amendments are applied. This could help facilitate traceback investigations if problems are identified in the future, and may help limit the scope of any recall or product withdraw.

Tools and Equipment Used in Handling Soil Amendments

As noted by FDA, soil amendments of animal origin are likely to contain pathogenic bacteria that can cause foodborne illness in humans and should be handled in such a way to not become a potential source of contamination. Tools and equipment used in handling or conveying soil amendments can also become contaminated by the soil amendment and then cross-contaminate produce or food contact surfaces if not segregated or adequately sanitized. Subpart L, Section 112.213 of the proposed rule addresses sanitation and storage of tools and equipment but is not specific about tools and equipment used in relation to soil amendments. FDA should be explicit and require tools and equipment used in handling or conveying soil amendments to be either segregated solely for that use or adequately sanitized to protect against contamination of produce, food contact surfaces, and other tools and equipment.

Subpart I – Standards Directed to Domesticated and Wild Animals

CFA agrees that if farms allow animals to graze in fields there should be a waiting period between the grazing activity and the harvesting of crops from that field. FDA should specify the waiting period that would be suitable. Farms should also make efforts to minimize contamination from working animals in fields where crops are being grown.

CFA supports FDA's determination that farms should regularly monitor growing areas in which animal intrusion is likely. Monitoring should be conducted prior to harvest, but also throughout the growing season. However, farms should do more than just monitor for animals; farms should also act to prevent animal intrusion from occurring where practicable. FDA should include a new requirement for farms to take reasonable measures to keep animals out of growing areas, based on the monitoring conducted by the farm. FDA should also require farms to take reasonable measures to keep animals out of water sources.

Finally, CFA agrees that if there is evidence of animal intrusion, and in particular animal feces, the farm must evaluate whether the produce is at risk of contamination and should make a determination as to whether that produce can be harvested in accordance the requirements of § 112.112. Farms should include in their training materials procedures for workers to identify animal intrusion and animal feces and alert management about the potential risk of contamination. The farm should have a policy for cordoning off part of the field in which potential contamination may have occurred as a result of animal intrusion and should not harvest from that part of the field. Workers should be explicitly empowered to identify these contamination events without fear of reprisal or lost wages.

Subpart K – Standards Directed to Growing, Harvesting, Packing and Holding Activities

CFA supports FDA's determination that covered produce must be kept separate from excluded produce and farms must adequately clean and sanitize any food contact surfaces which have contacted excluded produce. This is important to prevent cross-contamination from excluded crops which do not have to meet the produce safety requirements in the regulation. As noted previously, CFA does not believe that produce should be exempted from food safety requirements except in very limited cases (personal consumption, produce covered under preventive controls rule, and produce that receives commercial processing).

CFA supports FDA's requirement that farmers should take all measures necessary to identify and not harvest produce which is likely to be contaminated. As noted in the proposed rule, this should include produce that is visibly contaminated with animal excreta. But it should also include produce that has been contacted by water that has is likely contaminated (as noted above in the discussion on water) as well as produce in fields that have been flooded. CFA also supports the requirement that produce should be handled in a manner that protects against contamination. CFA further supports the requirement to not distribute covered produce that drops to the ground. This is particularly important because produce on the ground could be contaminated with filth or pathogens. In addition, produce on the ground could be bruised or damaged and could become easily contaminated.

CFA supports FDA's requirement that packing produce should be done in such a way as to prevent the formation of *Clostridium botulinum* toxin if that toxin is a known or foreseeable hazard. This is essential because of the seriousness of botulism which can result in paralysis and even death. CFA further agrees that food packing material must be appropriate for its intended use. If food packing material is reused, food contact surfaces must be clean and sanitized.

Subpart L – Standards Directed to Equipment, Tools, Buildings and Sanitation

Tools and Equipment

CFA agrees that equipment, tools, storage containers, transportation and buildings should be held to high sanitation standards. This will reduce the risk of cross-contamination and improve the safety of fresh produce. The requirements proposed by FDA are reasonable and not onerous. CFA supports FDA's determination that the farm must use equipment and tools that are of adequate design and construction to enable them to be adequately cleaned and maintained. Equipment and tools must be installed in such a way as to facilitate cleaning and stored in such a way as to prevent contamination and pests. Additionally, all instruments or controls used to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of pathogens or other contamination, must be accurate and precise as necessary and appropriate in keeping with their purpose and adequately maintained.

CFA supports FDA's determination that all food-contact surfaces of equipment and tools should be inspected, maintained, cleaned and sanitized as frequently as necessary to protect against contamination, and that all non-food contact surfaces should be cleaned as frequently as necessary during harvesting, packing and holding. FDA should develop guidance to farms about the recommended frequency of sanitation. CFA further agrees that equipment used to transport produce should be adequately cleaned prior to use and adequate for its intended use. Equipment that contacts produce such as pallets, forklifts, tractors and other vehicles should be used in a manner that minimizes contamination of produce.

Buildings

CFA supports FDA's determination that buildings must be suitable in size, construction and design to facilitation maintenance and sanitary operations to reduce the potential for contamination. Buildings should be constructed and maintained in a manner such that floors, walls, ceilings, fixtures, ducts, and pipes can be adequately cleaned and kept in good repair, and that drip or condensate does not contaminate produce, food-contact surfaces, or packing materials. Buildings where covered activities occur must be suitably constructed to allow adequate cleaning and sanitizing in order to minimize the presence or persistence of hazards and the potential for damage or contamination of covered produce.

CFA agrees that growers should take reasonable precautions to prevent domesticated animals in and around a fully-enclosed building from contaminating produce, food-contact surfaces, and food packing materials with hazards. CFA further agrees that growers must take reasonably necessary measures to protect produce, food contact surfaces and food packing material from pest contamination, including routine monitoring for pests.

CFA supports the requirements on toilets and hand-washing facilities. As detailed in CFA's comments on the Hygiene section, CFA believes that hand washing and toilet facilities should also be available for work that extends for less than three hours. CFA further supports the requirements for controlling and disposal of sewage. The failure to properly dispose of sewage and waste water has contributed to a number of confirmed multistate outbreaks, including the deadly outbreak of Listeria infections linked to Jensen Farms in 2011. FDA should apply the requirements for sewage disposal to mobile toilets as well.

CFA supports the requirements for plumbing. CFA agrees that equipment used to hold or convey water should be maintained in a manner necessary to protect against contamination. Similarly, there must be adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building. Finally, CFA supports the requirements for controlling and disposing of trash, litter and waste in areas used for covered activities, which should include fields.

Testing

FDA should require environmental testing in packing sheds and on equipment, particularly for high-risk products. The 2011 *Listeria* outbreak linked to cantaloupes from Jensen Farms is a prime example of the importance of environmental testing. FDA's investigation at Jensen Farms found multiple environmental samples positive for *Listeria monocytogenes*. Positive samples were found along the processing line, on conveyor belts, in the cooler and on cantaloupes. Had Jensen Farms been conducting sufficient environmental testing in their packing shed, the company may have been alerted to the problem and taken steps to address it before contaminated cantaloupe was distributed to consumers.

In order to provide clarity around a testing requirement, FDA should specify the parameters under which testing would be required in different types of environments and the necessary components of a testing program. The testing plan should describe the target organisms, test methods and frequency, points of sampling and corrective actions when positives are found.

FDA should establish the circumstances under which environmental sampling would be required. Such conditions should include, but not be limited, to:

- Handling or processing products with a history of contamination;
- Handling or processing steps that could introduce contamination;
- Producing Ready to Eat (RTE) products; and
- Whether there is potential for colonizing and/or promoting growth of a pathogen once it enters the packing shed, or in the product.

FDA should specify that environmental testing should, when possible, target specific pathogens over indicator microbes. Indicator organisms can serve an important function, but should only be used if specific surrogates have been identified and substantiated for specific pathogens. Generally, indicator organisms identify conditions that can lead to the potential presence of pathogens more than the confirmed presence of a specific pathogen.

Environmental testing should be used as a signal; that is, a positive test result should trigger additional action and provide incentive for improvement. For example, a positive sample from a drain would trigger additional testing of product contact surfaces; a positive on product contact surfaces would trigger product testing; and an established history of negative results could signal it is appropriate to back off intensified testing. Dividing processing into distinct zones should be used, with increased testing within zones in response to positives. Finally, FDA should provide via guidance a decision tree for facilities to determine if and when environmental monitoring is needed.

Subpart M – Standards Directed to Sprouts

General Requirements

CFA strongly supports FDA's determination to address sprouts separately in the Produce Rule and apply more robust safety requirements. Sprouts have been linked to at least 37 foodborne illness outbreaks since 1990.[10] Sprouts are typically grown in a warm, moist, nutrient-rich environment which is also the ideal environment for pathogen growth. The FDA and CDC recommend that children, older adults, pregnant women, and persons with weakened immune systems avoid eating raw sprouts of any kind. FDA should consider whether other produce products which are considered high-risk should be addressed in a similar manner as FDA has done with sprouts in order to assure the products are produced safely.

CFA supports FDA's determination that its regulation should apply to seeds and beans in addition to the edible portion of the produce. We agree that bean sprouts should be subject to the same requirements as green sprouts even though bean sprouts have different outbreak patterns and cooking methods. As discussed previously, consumer cooking and eating patterns change frequently. In the interest of prevention, FDA should not rely on historical consumption patterns and should assure that bean sprouts are covered under these requirements.

CFA supports FDA's requirement that sprout producers take measures reasonably necessary to prevent the introduction of hazards into or onto seeds or beans that will be used for sprouting. This instruction makes clear that sprout producers bear responsibility for safe production regardless of the final dispensation of the product. We agree that growers should not use sprouts if they have reason to believe that a lot of seeds or beans has been associated with foodborne illness. However, FDA should further clarify that if a grower also has reason to believe that a lot has been contaminated with a hazard likely to cause foodborne illness, the grower should not use that lot to produce sprouts. That way if a grower is not sure that a lot has been specifically associated with foodborne illness, but has a suspicion that the lot may be contaminated, the grower should not use the lot.

FDA has determined not to specify the hazards that are reasonably foreseeable. We urge the agency to specify certain known hazards (such as *Salmonella*, *E. coli*, and *Listeria*) that have been most associated with foodborne illness outbreaks linked to sprouts so that growers can be informed of likely hazards to consider.

CFA supports FDA's proposed requirement that growers must treat seeds or beans that will be used to grow sprouts with a scientifically valid method for reducing microorganisms of public health significance

[10] http://bites.ksu.edu/sprouts-associated-outbreaks

immediately before sprouting. We agree with the agency that a prior treatment, such as by a grower, handler, or distributor of seeds or beans does not eliminate the responsibility for treatment immediately before sprouting at a covered farm. This requirement ensures that food safety measures be taken at each step of production instead of relying on a single step to assure the safety of subsequent steps. This requirement is also consistent with the recommendations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

Testing for *Listeria*, *E. coli* O157:H7 and *Salmonella*

CFA supports FDA's decision to require substantial testing procedures for growing, harvesting, packing, and holding of sprouts. Considering the environment in which sprouts are grown and the preponderance of outbreaks linked to sprouts which have occurred, this is a prudent approach. CFA supports FDA's proposal to require testing for *Listeria* species or *L. monocytogenes* in the environment along with the requirement to test spent water for *E. coli* O157:H7 and *Salmonella*. Contamination from *Listeria* in the environment is common and CFA agrees with the agency that environmental monitoring and testing is necessary for sprouting operations, even with the careful application of appropriate sanitation measures. CFA also supports FDA's proposal to require testing spent irrigation water specifically for *E. coli* O157:H7 and *Salmonella.* These pathogens are most commonly associated with sprout-related outbreaks and present the greatest risk to public health. In addition, testing methodology for these pathogens is available and affordable.

CFA is concerned that additional pathogen strains may be associated with sprouts in the future, similar to the outbreak of *E. coli* O104 linked to sprouts that occurred in Europe in 2012. CFA would prefer FDA take a preventive approach and require testing for additional strains of *E. coli* but recognizes that there may currently be limitations in testing technology and availability. Therefore, CFA urges FDA to develop an efficient mechanism to require sprout growers to test for additional pathogen strains if they are linked to an outbreak or if science identifies additional strains of concern.

Disposal of Potentially Contaminated Sprouts

As discussed in the water section of these comments, CFA believes that if the edible portion of produce (including sprouts) is exposed to water that may be contaminated then that produce may become contaminated. Sprouts in particular are grown in such a way that contaminated water is likely to contaminate the product. If water used for growing sprouts does not meet the standards for *E. coli* O157:H7 or *Salmonella*, then that batch or lot of sprouts should be discarded. CFA does not believe that sprouts can be made safe through cooking as could potentially be done with other produce. FDA should affirm this in the final rule and delineate the steps that farms be required to take when sprout water is found to be contaminated. Similarly, FDA must delineate what actions should be required for sprouts that may be contaminated with *Listeria* when the finished product is tested, including disposal of contaminated lots or batches.

Written Monitoring and Sampling Plan

CFA supports FDA's requirement that growers must establish and implement a written environmental monitoring plan for *Listeria* and a written sampling plan for testing spent irrigation water or sprouts. FDA inspectors should review these plans to be sure they are adequately designed, scientifically valid and effective in monitoring and controlling for pathogens. FDA should expand its regulation to require documentation of any corrective actions that growers employ to address problems identified and verification that those corrective actions were effective. Maintaining robust records of testing results—in addition to plans for testing design and implementation—will allow both growers and FDA to monitor for trends, correct problems, and make adjustments to the system to best protect public health.

Subpart O – Requirements Applying to Records

Recordkeeping is an important component of a food safety program. Records allow farms to keep track of activities and whether they are meeting specific standards required under the law. Records also allow FDA to see whether farms have been complying with the law over time and identify potential problems that may need to be addressed.

CFA agrees that records must include identifying information about the farm, the actual values and observations obtained during monitoring, a description of the commodity, including lot number or identifier if available, location of the growing area, including the specific field, and the date and time of the activity documented. Records should be created at the time the activity is performed or observed, be legible and accurate and be dated and signed by the person who performed the activity. CFA has suggested additional recordkeeping components throughout the various sections of the proposed rule.

CFA agrees that records can be stored offsite provided they can be retrieved within 24 hours and that electronic records are acceptable. CFA further agrees that records should be kept for 2 years.

Subpart R – Withdrawal of Qualified Exemption

Under the Tester amendment, qualified farms are exempt from produce safety requirements if they sell the majority of their produce to qualified end-users and if the annual monetary value of the food sold is less than $500,000. In order to protect the public health, FDA was provided the authority to withdraw the exception for these farms if they are directly linked to an active investigation of a foodborne illness outbreak or "if the Secretary determines it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food produced or harvested at such farm."

FDA's proposed rule correctly interprets the exemption in FSMA and the process for withdrawing the exemption. CFA supports the provision which offers an appropriate level of due process and correctly interprets FSMA to provide no means for restoring a farm's exempt status after its withdrawal. FDA should use this authority early and preemptively to protect public health. The provision provides for adequate due process, but once a farm loses its exemption, its exempt status cannot be restored. This is appropriate and consistent with FSMA.

CFA agrees with FDA's proposal to require that the complete business address (the street address or post office box, city, state, and zip code) be included on the label or other required notifications for products produced by a farm that qualifies for this exemption. Since commodities sold by a farm that receives a qualified exemption will not be subject to the produce safety standards, it is essential that consumers have the information they need to report any problems to the farm or government officials. This information will also be important for traceback activities.

Farms should be required to provide adequate documentation to demonstrate the basis for their qualified exemption. This documentation should meet the requirements for other records, as proposed in subpart O. FDA should also have access to such records upon request. Otherwise, there would be no way to determine whether a farm claiming the qualified exemption actually met the criteria for that exemption.

Subpart Q – Compliance and Enforcement

CFA appreciates FDA's discussion of compliance in the Preamble of the rule and its recognition of the need to assure that the produce industry is meeting the new food safety standards. As the agency notes, education and technical assistance will play crucial roles as FDA implements the rule, particularly for small farms that may not be as familiar with the requirements as larger farms.

However, inspection should be at the center of the agency's compliance and enforcement strategy. Adequate oversight of the produce safety standards is going to be important to assure industry compliance, deter farms from ignoring the rules, and to promote consumer confidence. Unfortunately, FDA's initial public comments regarding inspection have been less than reassuring to consumers concerned about the safety of fresh produce.

CFA acknowledges that FDA does not currently have the inspection resources to inspect all of the farms that fall under the agency's jurisdiction. FDA has indicated that the agency intends to work collaboratively with federal and State regulatory partners to "use available inspection resources to conduct risk-based inspections of farms for compliance with a final produce safety regulation." CFA notes that in recent discussions with State inspection officials, they expressed concern that over-reliance on State agencies to conduct inspection of farms could lead to State agencies conducting fewer retail and restaurant inspections in their States. No other entity maintains oversight of retail and restaurant operations in each State, so this is an issue that needs particular consideration.

In order to provide confidence that the produce safety rule will be adequately implemented, FDA must articulate a clear strategy for enforcement to ensure compliance with the rule. At the same time, it is critically important that FDA request in its budgets going forward adequate resources to perform these essential inspections either using its own inspectors or through contracts with the relevant state agencies that provide additional funding to conduct inspections on behalf of the agency.

Finally, while we do not object to FDA's tentative decision to base compliance dates for the produce standards on the size of a farm, we are concerned that some of the dates are excessive and do not adequately protect public health. For example, for agricultural water, FDA sets compliance dates as much as four or even six years from the effective date. Rather that extending compliance dates to unreasonable lengths, FDA should ramp up its technical assistance to small and very small operations that need help meeting the regulations' requirements.

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