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**Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption**
**[Docket No. FDA-2011-N-0921-0199, 78 Fed. Reg. 3504, 3642 (2013)]**
**Comments submitted by**
**Consumers Union**
**Yonkers, NY**
**November 22, 2013**

## Overview

Consumers Union, the advocacy arm of *Consumer Reports*, is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on its proposed rule implementing portions of the landmark FDA Food Safety Modernization Act of 2011 (FSMA) related to growing and harvesting of produce.

One of the key events that led to passage of FSMA was the contamination of bagged spinach in 2006 with deadly *E. coli 0157:H7* that caused hundreds of illnesses and three deaths nationwide. Ultimately, the deadly bacteria were traced back to one small growing area in northern California, focusing attention on the need to set standards for farming practices to prevent human illnesses. This need was painfully reinforced by the 2011 *Listeria* outbreak linked to a Jensen Farms cantaloupe packing facility, which resulted in 33 deaths—one of the most lethal known foodborne illness outbreaks ever.

Consumers Union commends FDA for developing this much-needed proposed rule on growing, harvesting, packing and holding of fresh produce. We agree with much of what FDA is proposing. We have concerns, however, in several of areas and recommend the following:

- FDA should not exempt foods "rarely consumed raw." The profound difficulty of identifying such foods accurately is illustrated by the fact that FDA includes kale and figs on its "rarely consumed raw" list—both of which are frequently consumed raw in the New York City area where Consumers Union is located, as well as elsewhere.

- FDA should require final product testing of high risk produce as a method of ascertaining whether a farm or packing facility's food safety plan is effective. Had such testing been in place at Jensen Farms, the presence of *Listeria* would likely have been identified and many deaths averted.

- FDA should not sanction application of sewage sludge on agricultural land. We support FDA's decision to focus at this time on pathogen control in this regulation, even though FSMA gives them authority to take chemical hazards into account. However, new data on lead and other heavy metals, as well as unregulated synthetic organic chemicals, in sewage sludge is so concerning, especially considering that heavy metals accumulate in the soil with repeated applications, that we recommend that FDA not sanction sewage sludge applications in this rule.

- FDA should alter its proposal for application of untreated manure to agricultural land from requiring nine months between application and harvesting of a new crop, to four months, as is currently required in the National Organic Program. Because the scientific data on survival of pathogens in untreated manure applied to farm land is so limited, and because some studies suggest that FDA's nine-month standard could have negative as well as positive effects on overall pathogen prevalence, we believe that the longer interval should not be required, pending further research.

Consumers Union's more detailed comments on a number of aspects of the proposed rule are presented below.

**Regulatory Approach**

*Covered farms should be required to prepare a written food safety plan*

The Food and Drug Administration (FDA) is not proposing to require each farm to conduct a hazard analysis and develop a written food safety plan for its operation in its proposed produce rule. 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 that 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 which is available at http://onfarmfoodsafety.org.

While 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.

*An integrated approach in developing risked-based requirements for produce*

We support FDA's tentative decision to focus on "risky practices, not risky products." This approach can help put in place regulations aimed at minimizing the potential likelihood of contamination from procedures, processes, and practices employed in the growing, harvesting, packing, and holding of *all* produce commodities, rather than on individual commodities' physical characteristics, known records of contamination, or known outbreak history.

*Limiting initial scope of rule to biological hazards*

We generally support FDA's decision to initially focus on biological hazards in the produce safety rule and not to propose specific standards for chemical, physical or radiological hazards at this time.

At the same time, we agree that measures to minimize risk of serious health consequences for all known or "reasonably foreseeable" hazards should still take into account biological, chemical, physical, and radiological risks, when appropriate. For example, if a covered farm's land was previously used for another activity that may have contaminated the soil with chemical hazards, the covered farm should be required to take appropriate measures (such as collecting and analyzing soil samples for residues) to prevent the introduction of the chemical hazards into or onto the produce.

Consumers Union has a particular concern in this regard with the use of sewage sludge, which can carry a high load of heavy metals and other chemicals. We believe the final rule should address chemical hazards in sewage sludge, as discussed below.

*Foreign Farms*

We agree with FDA that the rule would apply to foreign farms that grow, harvest, pack, or hold produce for import into the United States. It is essential that produce grown in Mexico and other countries be as safe as that grown in the United States, as there have been many disease outbreaks associated with imported produce. FDA actions should also ensure that U.S. farms compete on a level playing field with foreign farms so that all farms must incur the same compliance costs to assure safety.

## Proposed Exemptions for Certain Commodities

*Produce "Rarely Consumed Raw"*

Consumers Union disagrees strongly with the proposed exemption for produce commodities that are "rarely consumed raw." We have a number of concerns with the agency's proposed approach:

- We do not agree with the underlying premise of the exemption. Even if a commodity was "rarely consumed raw" and any contamination could be destroyed by thorough cooking, there are no assurances that they will always be adequately cooked, and the onus should not be on the consumer to kill pathogens in their produce. Further, there would still be ample opportunity for exempt commodities to cross contaminate commodities that are covered by the produce rules -- either by commingling covered commodities with the exempted commodity before it is cooked or even afterwards, if cooking does not actually kill all of the pathogens.

- Products "rarely" consumed raw may still be consumed by many people, including vulnerable populations like small children and the elderly. Many people eat a cranberry relish made of raw cranberries at Thanksgiving, for example. We don't believe that people with atypical eating preferences should simply be written off in terms of safety. Certain ethnic groups may also be more at risk. Figs are widely eaten raw by people of Italian descent (as well as many others). Particular cultural groups should not be penalized in terms of safety for their culinary preferences.

- The proposed list of produce rarely consumed raw is based on old data from the National Health and Nutrition Examination Survey (NHANES). This leaves the regulation blind to current food trends. Kale is a perfect example of changing eating habits – while this green has traditionally been eaten cooked, raw kale is currently very popular. It is included in bagged salad mixes in some supermarkets. A Google search for raw kale recipes offers several million choices.

- FDA should in any case not exempt any produce that is commonly cooked by methods which will not necessarily kill microbial contaminants (such as blanching or stir-frying)—for example, bok choy.

- If FDA does decide to retain this exemption, it should be limited to foods that cannot be eaten raw due to being inedible in that form, such as dried beans.

## Compliance and Enforcement

We applaud FDA for acknowledging the importance of developing an overall compliance and enforcement strategy for the produce safety standards by discussing it in the Preamble, even though the issue is not directly covered by the proposed regulations.

FDA indicates its intention 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." In order to do this, FDA must request in its budget adequate resources to perform these essential inspections either

using its own inspectors or, through contracts, with inspectors from the relevant state agencies.

Achieving compliance on foreign farms will be a particular challenge. FDA will have to make similar efforts with foreign governments as it does with domestic regulatory partners.

There is no question that education and technical assistance are of utmost importance to the success of this new regulatory program. We agree that FDA should target its education efforts to the smaller farms that may not be as familiar with the specific safety requirements as some of the larger operations. FDA also notes that significant incentives and accountability for compliance with a final produce safety rule will come through non-regulatory audits and supply chain management initiated by private entities. In light of this fact, the agency should do what it can to encourage retailers and other customers who require audits to minimize the number of individual audits and bring the standards against which growers are audited as close as possible to FDA's final produce standards. This will minimize the economic and operational burden created by multiple audits, especially on smaller operations.

**Agricultural Water Standard**

The proposed rule accurately acknowledges that agricultural water can be a source of pathogen contamination of produce and therefore must be safe and sanitary. We agree that water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods. And similarly, the microbial quality of source water, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices.

Consumers Union supports the following aspects of the proposed standard:

- the requirement that growers inspect, maintain, and undertake follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce.

- the requirement that agricultural water must be treated if a grower knows or has reason to believe that the water is not safe and of sanitary quality, including the requirement that any treatment be monitored.

- provisions requiring periodic analytical testing of water used in certain circumstances and that public water and treated water are exempted from this requirement.

- requiring that certain actions be taken when water does not meet the quality standards;

- the need to keep records related to water quality, including: documentation of inspection findings, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, water testing results, and scientific data or information relied on to support any permitted alternatives to requirements; and

- a quantitative standard, which a farm's agricultural water must meet.

The appropriate quantitative standard is at the heart of the controversy surrounding agricultural water quality. As a general proposition, we agree with FDA's view that a numerical standard is appropriate where, as here, the effectiveness of individual measures to protect agricultural water sources from contamination is not complete or fully known, and/or because much of what affects the on-farm route of contamination is outside the control of a farm.

Given the costs associated with pathogen testing, the difficulty of detecting pathogens and the sporadic nature of their occurrence, we agree that it is reasonable for FDA to propose requiring that growers test for the presence of an indicator organism. In the absence of a better indicator, we support the use of generic Escherichia coli (E. coli) as best suited for this purpose. As FDA explains in its proposal, generic E. coli can be found in at least 90 percent of all human and animal feces and is most closely associated with incidents of fecal contamination. Again, generic E. coli monitoring serves as a measure to assess the potential for fecal contamination, not to directly predict the presence of pathogens.

The availability of multiple test methods, commercial kits, and formats to test for generic E. coli at relatively low cost, and the accuracy, precision, and sensitivity of these analytical testing options should make it relatively easy for growers to satisfy this testing requirement.

In addition, Consumers Union supports:

- F DA's proposal related to testing frequency.

  That water used for certain purposes should be tested at the beginning of each growing season, and every three months thereafter during the growing season.

  The agency's tentative decision to require that untreated surface waters be tested more frequently than ground water sources, because surface watersheds are subject to a greater number of external forces that shape their overall composition, chemistry, and microbial water quality (e.g. erosion, run-off, dust, suspended sediments).

- The agency's tentative decision to require that equipment used to hold or convey water should be inspected to ensure that it is clean.

The agency's tentative decision to require that equipment used to hold or convey water should be inspected to ensure that it is clean.

Consumers Union is concerned, however, about FDA's statement that if you know or have reason to believe that water is not of sufficient sanitary quality for its intended use

you must treat the water "(such as with an EPA-registered antimicrobial pesticide product)." We urge FDA to delete this phrase since by its own admission there are no such products.

FDA states in the Preamble: "Any chemicals used in the treatment of water would require EPA registration under the Federal Insecticide, Fungicide and Rodenticide Act before they can be lawfully used. We note, however, that at the present time, no such registration for chemical treatment of irrigation water exists." Thus it seems this is not a particularly helpful illustrative example.

Consumers Union is also concerned that antimicrobials that FDA allows in personal care products, such as triclosan, are overused already, with resistance already emerging in bacteria,[1] and may pose safety risks as well. For example, some studies indicate triclosan is an endocrine disruptor (see discussion in Sewage Sludge, below).

If FDA believes it should provide an example of treatment methods, we urge it to choose water treatment options that currently are available and that minimize potential environmental and public health impacts, such as hydrogen peroxide and UV treatment.

**Produce Testing and Environmental Monitoring**

Consumers Union supports FDA's proposed requirement for significant testing procedures related to the growing, harvesting, packing, and holding of sprouts. We urge the agency to consider establishing similar testing programs for others high-risk produce commodities.

Consumers Union disagrees with FDA's conclusion that finished product testing is impracticable as a component of science-based minimum standards proposed in this rule except for sprouts. FDA itself notes that "At least one company is reported to use product testing to verify the efficacy of good agricultural practices programs and to prevent contaminated product lots from entering commerce." It is true that periodic sampling will not catch contamination that occurs rarely. However, it will catch contamination that has become quite prevalent. FDA should consider, for example, the 2011 outbreak of illnesses linked to Listeria-contaminated cantaloupes at Jensen Farms, which resulted in 33 deaths and one miscarriage. We note that in a follow-up investigation, FDA itself found Listeria on cantaloupes still at the facility. In a batch of 10 melons taken from a cooler, 5 were positive. FDA also tested a batch of melons from a retail store in Denver, and found 9 of 10 were positive. [2] FDA should evaluate whether

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[1] For evidence of triclosan causing cross-resistance to antibiotics, see: Braoudaki, M., and A.C. Hilton. 2004. Low level of cross-resistance between triclosan and antibiotics in Escherichia coli K-12 and E. coli O55 compared to E. coli O157. FEMS Microbiol. Lett. 235:305–309. and Braoudaki, M; Hilton, AC. Mechanisms of resistance in Salmonella enterica adapted to erythromycin, benzalkonium chloride and triclosan. International Journal of Antimicrobial Agents 25 (2005) 31–37.

[2] US Food and Drug Administration, Information on the Recalled Jensen Farms Whole Cantaloupes, Updated January 9, 2012, www.fda.gov/Food/FoodSafety/CORENetwork/ucm272372.htm

the presence of Listeria could have been detected by periodic testing of cantaloupes at that facility, thereby avoiding this tragedy. We urge FDA to consider requiring finished product testing for produce that has repeatedly been associated with disease outbreaks, such as cantaloupes and spinach.

FDA should consider establishing performance standards as well for pathogens in very high-risk produce types. There should be a zero tolerance for Salmonella, Listeria and STECs. We also urge FDA to consider indicator organisms and limits set for high-risk foods by other countries. The United Kingdom, Ireland and Germany have selected generic *E. coli* as an indicator, and set the limit of 100 CFU/gm for ready-to-eat leafy greens. Switzerland set a limit at 10 CFU/gm. France and Brazil selected fecal coliforms and set limits of 1,000 and 100 CFU/gm respectively. Israel set a standard for total coliforms of 100 CFU/gm in salads made of vegetables. A discussion of these standards appears in a Consumers Union Report "Bacteria and Bagged Salads: Better Standards and Enforcement Needed," published February 2, 2010. A copy of that report is appended to and should be considered part of these comments.

The Jensen Farms case also demonstrates the need to ensure that packing houses are designed, operated, and maintained in a way that minimizes contamination. FDA should require environmental monitoring of such packing facilities.

**Biological Soil Amendments**

Biological soil amendments of animal origin can contain pathogenic bacteria that can cause foodborne illness in humans. Therefore, special precautions must be taken in their use. Certain such amendments may also contain serious chemical hazards, which should not be permitted.

*Human waste should be prohibited from use both for domestic and imported produce.*

We strongly agree with 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, including viruses, parasites and bacteria. 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 in 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 review this practice in conducting comparability assessments of foreign countries.

*The proposed application interval of 9 months for untreated soil amendments of animal origin, if the edible portion of the crop comes in contact with the soil, should be reduced to 4 months.*

Proposed § 112.56(a)(1)(i) requires that if you apply a biological soil amendment of animal origin, i.e. manure, that is untreated, then the material must be applied in a manner that does not contact covered produce during application and that minimizes the potential for contact with covered produce after application. It also specifies a minimum application interval of nine (9) months.

The application interval, which governs how long untreated manure must be left on a field – that is, how much time must elapse after the untreated manure is applied – before a crop can be harvested in that field is one of the most controversial provisions of the regulation. Currently, conventional farmers are not required to meet any standard for how long untreated manure must be left before harvesting a crop. Organic farms, however, must leave untreated manure for four months. The proposed rule would raise that time interval to nine months for all farmers.

In the preamble, the FDA writes that the proposed required time interval (9 months) between application of untreated manure and harvest may be "more than what is necessary for minimizing the likelihood" that it will pose a risk to public health, and requests comments on this proposal.[3]

Consumers Union is concerned about the limitations on the data supporting both the National Organic Program's 4-month interval and the FDA's proposed 9-month interval. A review of the scientific literature on this topic indeed reveals a wide range of time intervals between application of contaminated manure and pathogen die-off. Published results show a range from 7 days to 231 days between introduction of the pathogens and reduction to nondetectable levels in the soil or on the plants.

| Authors/Year | pathogen tested | survival time | Max. Days |
|---|---|---|---|
| Fenlon, D. R., I. D. Ogden, A. Vinten, and I. Svoboda. 2000 | E. coli O157:H7 | detected only during first 7 days after land application | 7 |
| Nicholson, F. A., S. J. Groves, and B. J. Chambers. 2005 | E. coli O157, Salmonella, Listeria and Campylobacter | manure: 30 days for e. coli., campylobacter and salmonella<br>manure: "more than" 30 days for Listeria | > 30 |
| Himathongkham, S., S. Bahari, H. Riemann, and D. Cliver, D. 1999 | E. coli O157:H7 and Salmonella typhimurium | cattle manure: 6 days to 21 days<br>manure slurry: 2 days to 35 days<br>(decimal reduction time; depending on temperature) | 35 |
| Maule, A. 2000 | E. coli O157 | cattle feces: 50 days<br>cattle slurry: 10 days<br>river water: 27 days<br>(to undetectable levels) | 50 |

[3] FR Page 186.

| Authors/Year | pathogen tested | survival time | Max. Days |
|---|---|---|---|
| Oliveira M, Viñas I, Usall J, Anguera M, Abadias M 2012 *and* Oliveira M, Usall J, Viñas I, Solsona C, Abadias M. 2011 | E. coli O157:H7 and L. innocua | up to 63 days (possible longer) | 63 |
| Wang, G., T. Zhao, and M. Doyle. 1996 | E. coli O157:H7 | cattle feces: 42 to 70 days (depending on temperature - fewer days for higher temperatures) | 70 |
| Islam, M., M. P. Doyle, S. C. Phatak, P. Millner, and X. Jiang. 2004 | E. coli O157:H7 contaminated composts | 77 to 177 days on lettuce<br>154 to 217 days in soil | 217 |
| Islam, M., J. Morgan, M. P. Doyle, S. C. Phatak, P. Millner, and X. Jiang. 2004 | Various types of composts inoculated with avirulent strain of Salmonella | 63 to 231 days on lettuce and parsley<br>161 to 231 days in soil | 231 |

We appreciate FDA's taking a precautionary approach in this situation where data is insufficient but points to a risk. However, it is also possible that the proposed interval requirement may lead to unintended negative consequences for food safety, under certain circumstances.

Our literature review revealed a wide range of factors that influence pathogen die-off in the soil and on crops. Studies show that introduced pathogens are much more likely to thrive under certain conditions. To improve food safety, we would want farmers to create the conditions in the soil and on their farms that have been shown to interfere with pathogen survival.

Some of these conditions are largely beyond a farmer's control; for example, several studies have shown that both E. coli O157:H7 and Salmonella are less likely to survive in sandy soil than in clay soil.[4] Other conditions that interfere with pathogen survival can be created through the adoption of certain farming practices. Specifically, numerous

[4] Gagliardi JV, Karns JS. (2002) Persistence of Escherichia coli O157:H7 in soil and on plant roots. Environ Microbiol. 2002 Feb;4(2):89-96.
See also: England LS, Lee H, Trevors JT. 1993. Bacterial survival in soil: effect of clays and protozoa. Soil Biol. Biochem. 25: 525-531.
See also: Franz E, van Diepeningen AD, de Vos OJ, van Bruggen AH. (2005) Effects of cattle feeding regimen and soil management type on the fate of Escherichia coli O157:H7 and salmonella enterica serovar typhimurium in manure, manure-amended soil, and lettuce. Appl Environ Microbiol. 2005 Oct;71(10):6165-74

studies have shown that pathogens introduced into sterile soil survive longer than when introduced into biologically active soil.[5]

One study, from the University of Groningen in The Netherlands, measured the survival of introduced *E. coli O157:H7* in soils that had undergone varying levels of fumigation and therefore had various degrees of microbial life. The results show a correlation between fumigation depth and enhanced survival of the introduced pathogen. The authors wrote that their results support the hypothesis that "soil systems with reduced biological complexity offer enhanced opportunities for invading microbial species to establish and persist."[6]

A study from the University of Georgia compared survival of *E. coli O157:H7* in manure-amended autoclaved soil versus manure-amended unautoclaved soil. Under the same conditions, the researchers found pathogen populations declined more rapidly in the unautoclaved soil. Autoclaving soil kills active microbial biomass, whereas unautoclaved soil contains naturally occurring microorganisms. The authors wrote that the more rapid decline in *E. coli* in the unautoclaved soil is "likely due to antagonistic interactions with indigenous soil microorganisms."[7]

Studies suggest that indigenous microorganisms have an effect on the survival of introduced bacteria through several mechanisms. These mechanisms include predation (certain species of soil protozoans ingest bacteria, including pathogens) and competition for nutrients/starvation.[8] Scientists at the Produce Safety and Microbiology Unit of the USDA have written that "good agricultural practices that encourage the growth of competing bacteria, like E. asburia, may reduce the incidence of produce contamination."[9]

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[5] Farhangi MB, Safari Sinegani AA, Mosaddeghi MR, Unc A, Khodakaramian G (2013) Impact of calcium carbonate and temperature on survival of Escherichia coli in soil. J Environ Manage 119:13-9.
See also: Franz E, van Diepeningen AD, de Vos OJ, van Bruggen AH. (2005) Effects of cattle feeding regimen and soil management type on the fate of Escherichia coli O157:H7 and salmonella enterica serovar typhimurium in manure, manure-amended soil, and lettuce. Appl Environ Microbiol. 2005 Oct;71(10):6165-74.
See also: Jiang, X., J. Morgan, and M. P. Doyle. 2002. Fate of Escherichia coli O157:H7 in manure-amended soil. Appl. Environ. Microbiol. 68:2605–2609.

[6] van Elsas JD, Hill P, Chronáková A, Grekova M, Topalova Y, Elhottová D, Kristůfek V. 2007 Survival of genetically marked Escherichia coli O157:H7 in soil as affected by soil microbial community shifts.ISME J. Jul;1(3):204-14.

[7] Jiang, X., J. Morgan, and M. P. Doyle. 2002. Fate of Escherichia coli O157:H7 in manure-amended soil. Appl. Environ. Microbiol. 68:2605–2609.

[8] Sinisa Vidovic,a Hushton C. Block,b Darren R. Korbera (2007) Effect of soil composition, temperature, indigenous microflora, and environmental conditions on the survival of Escherichia coli O157:H7Canadian Journal of Microbiology 53(7): 822-829.

[9] Cooley, MB, Chao, D and Mandell, RE (2006) Escherichia coli O157:H7 survival and growth on lettuce is altered by the presence of epiphytic bacteria. Journal of Food Protection. 69(10): 2329-35.

Amending soils with organic matter, such as manure and compost, leads to increased levels of biological activity in the soil, which has food safety benefits by promoting "good" bacteria that outcompete pathogenic bacteria.[10].

FDA should therefore consider whether its proposed nine-month waiting period between application of untreated manure and harvest may have detrimental effects on food safety by interfering with farming practices that promote biological activity in the soil
We urge the FDA to investigate the impact of a nine-month waiting period on crop rotations and on farmers' ability to use manure rather than synthetic fertilizers.

The science strongly suggests that high levels of indigenous microorganisms in the soil are an important variable to monitor, and one that we believe the FDA should study. This may play an even larger role in pathogen mitigation than an overall waiting period between manure application and harvest.

Therefore, overall, we believe that the scientific data does not offer a clear conclusion that imposition of a nine-month waiting period for untreated manure between application to the soil and harvest will benefit food safety, or that it is the best method of controlling pathogens. Data are scanty and incomplete, and some point toward a possible negative effect on food safety if long waiting periods interfere with farming practices that promote high levels of indigenous soil microorganisms. We therefore urge FDA to take a more conservative approach, and, on an interim basis, require that all farms at least observe the waiting periods for untreated manure currently required of organic production, namely a 120-day waiting period for crops whose edible parts come in contact with the soil and a 90-day waiting period for crops whose edible parts do not come in contact with the soil. We urge that FDA apply these limits while further studying, in cooperation with USDA, what soil attributes are important in determining safety. FDA may want to consult its Scientific Advisory Committee or its Food Advisory Committee on these questions.

*Sewage Sludge Should Not Be Permitted as a Soil Amendment*

FDA proposes that sewage sludge (also called "biosolids") can be applied if done in accordance with requirements of 40 CFR Part 503 Subpart D. We urge FDA to make an exception to its general policy not to consider chemical hazards in this rulemaking, and, because of the unusual degree of chemical hazards involved, and the resulting risks to food safety, to consider chemical hazards with regard to sewage sludge.

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[10] Nishio M., Kusano S. Fluctuation patterns of microbial numbers in soil applied with compost. Soil Sci. Plant Nutr. 1980;26:581–593.
See also: Lundquist E.J., Jackson L.E., Scow K.M., Hsu C. Changes in microbial biomass and community composition and soil carbon and nitrogen pools after incorporation of rye into three California agricultural soils. Soil Biol. Biochem. 1999;31:221–236.
See also: Mohammadi K, Heidari G, Karimi Nezhad MT, Ghamari S, Sohrabi Y. 2012 Contrasting soil microbial responses to fertilization and tillage systems in canola rhizosphere. 19(3): 377-83.

40 CFR Part 503 Subpart D divides sewage sludge into two classes: Class A and Class B. Class A contains undetectable levels of pathogens. It can be applied to agricultural land without restrictions. In order to get to nondetectable levels of pathogens, it can be treated in many ways, including being "drenched in ammonia."

Class B can contain some pathogens. Specifically, seven samples must be taken, and the mean fecal coliform density must be less than 2 million CFU per gram of biosolids. Then, there are restrictions for applying Class B sewage sludge biosolids to agricultural land:

- 30 days between application and harvest if harvested parts do not touch the soil
- 14 months between application and harvest if harvested parts touch the soil
- 20 months between application and harvest if harvested parts are under the soil and if **more** than 4 months between application to soil and incorporations into the soil
- 38 months between application and harvest if harvested parts under the soil and if **less** than 4 months between application to soil and incorporations into the soil

However, in the 20 years since the final sludge rule (i.e. 40 CFR Part 503) was finalized, numerous scientific findings regarding the environmental and health implications of applying sewage sludge to agricultural soils have appeared. Indeed, many of these studies have found increased risks as well as risks that were not assessed as part of the risk assessment used by EPA. Many of these risks have been summarized in the document posted on the Cornell Waste Management Institute site and written by the present Director (Dr. Murray McBride) and retired Director (Dr. Ellen Harrison)[11]

One area of concern is the heavy metal content of sewage sludge, such as lead, arsenic and cadmium, which are highly toxic substances. While the EPA's rules for sewage sludge establish concentration limits for nine metal contaminants, those limits were set in 1992. Newer studies have found these metals to be more toxic than previously thought. For example, in the last year the Center for Disease Control reduced its "blood lead level of concern" for young children from 10 to 5 mg per deciliter.[12] The EPA 1992 proposed limits for arsenic were 41 ppm for "exceptional quality" sludges (which can be applied without restriction on agricultural lands if pathogens have been controlled, e.g. in Class A sewage sludges) or 75 ppm for sludges being applied to land. In 2001, however, the EPA lowered the drinking water standard for arsenic to 10 ppb, meaning that sewage sludges can have from four thousand times to over seven thousand times the level of arsenic as drinking water.

In addition, a study in Iran involving use of treated wastewater or use of sewage sludge via land application found significant uptake of lead and cadmium in three species of leafy greens

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[11] Harrison EZ and M McBride. 2009. Case for Caution Revisited: Health and Environmental Impacts of Application of Sewage Sludges to Agricultural Land. At: http://cwmi.css.cornell.edu/case.pdf .

[12] http://www.cdc.gov/nceh/lead/acclpp/lead_levels_in_children_fact_sheet.pdf

associated with sewage sludge application.[13] Work with forage crops and animals in the U.S. has found that sheep[14] or cattle[15] that graze on sewage sludge-treated pastures suffer adverse health effects, with the levels of cadmium and lead in the liver and kidney increasing in sheep eating soil amended with sewage sludge.[16] Research has also shown that fetuses of pregnant sheep reared on sewage sludge-treated pastures had reduced body weight, while the male fetuses have small testis.[17] Similar research has not been done on the effects of eating produce from sewage sludge-treated land.

The National Research Council (NRC), in a 2002 report, "Biosolids Applied to Land: Advancing Standards and Practices,"[18] also noted that the EPA's rules for using sewage sludge as fertilizer was based on outdated science. While the original EPA rule established concentration limits for both metals and pathogens, the NRC report stated that EPA should consider "newly recognized chemicals of potential concern," including polybrominated diphenyl ether (PBDE) flame retardants, pharmaceuticals and personal care products (PPCPs) such as shampoos and soaps. In 2009, EPA released their newest sludge survey report,[19] which found elevated levels of some persistent organic pollutants, including PBDE flame retardants and the antimicrobials triclosan and triclocarban, which are frequently found in personal care products such as shampoos and soaps. Triclocarban (found in all 84 sewage sludge samples) and triclosan (found in 79 samples) had peak concentrations of 441,000 µg/kg and 133,000 µg/kg, respectively, in separate sludges. This is concerning as both triclosan and triclocarban are considered to be endocrine disrupting compounds. Laboratory studies have shown triclosan lower levels of thyroid hormone in mammals and fish,[20] lower testosterone[21] and decreased sperm production.[22] Triclocarban has been shown to amplify the effects of sex hormones such as testosterone.[23]

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[13] Behbahaninia A and SA Mirbagheri. 2009. Investigation of heavy metals uptake by vegetable crops from metal-contaminated soil. *World Academy of Science, Engineering and Technology*, 19: 56-58.

[14] Lind PM, Gustafsson M, Hermsen SAB, Larsson S, Kyle CE, Orberg J and SM Rhind. 2009. Exposure to pastures fertilized with sewage sludge disrupts bone tissue homeostasis in sheep. *Sci. Total Env.*, 407: 2200-2208.

[15] Tiffany ME, McDowell LR, O'Connor GA, Martin FG, Wilkinson NS, Percival SS and PA Rabiansky. 2002. Effects of residual and reapplied biosolids on performance and mineral status of grazing beef steers. 2002. *J. Animal Sci.*, 80: 260-269.

[16] Hill, Stark JB, Wilkinson J, Curran M, Lean I, Hall J and C Livesey. 1998. *Animal Science*, 67: 73-86.
[17] Paul C, Rhind SM, Kykle CE, Scott H, McKinnell C and RM Sharpe.

[18] At: http://water.epa.gov/scitech/wastetech/biosolids/upload/2009_04_23_biosolids_nas_complete.pdf.

[19] EPA. 2009. Biosolids: Targeted National Sewage Sludge Survey Report. At: http://water.epa.gov/scitech/wastetech/biosolids/tnsss-overview.cfm

[20] Paul KB, Hedge JM, DeVito MJ and KM Crofton. 2010. Short-term exposure to triclosan decreases thyroxine *In vivo* via upregulation of hepatic catabolism in young Long-Evans rats. *Tox. Sci.*, 113(2): 367-379. At: http://toxsci.oxfordjournals.org/content/113/2/367.full.pdf ; Zorrilla LM, Gibson EK, Jeffay SC, Crofton KM, Setzer WR, Cooper RL and TE Stoker. 2009. The effects of triclosan on puberty and thryroid hormones in male Wistar rats. *Tox. Sci.*, 107(1): 56-64. At: http://toxsci.oxfordjournals.org/content/107/1/56.full.pdf; Raut SA and RA Angus. 2010. Triclosan has

Several studies have shown that plants can take up PPCPs from soils amended with sewage sludge or irrigated with reclaimed wastewater. A greenhouse study, involving soybeans treated with sewage sludge or wastewater irrigation, looked at uptake of three pharmaceuticals (carbamazepine, diphenhydramine, and fluoxetine) and two personal care products (triclosan and triclocarban), and found that both triclosan and triclocarban could be found in the root tissue and throughout the plant including in the harvested soybeans, with uptake being higher for wastewater treatment compared to sewage sludge application.[24] The authors conclude, "Accumulation of PPCPs through the food chain could also pose potential risks to species consuming plant parts, including humans."[25]

Another greenhouse study, involving Chinese cabbage grown in sewage sludge-amended soils, looked at uptake of five PPCPs, and found that triclosan, carbamazepine and salbutamol could be found in both the root and leaf tissue of cabbage. As the authors noted, "In comparison to many previous studies that have utilized PPCP concentration that exceed environmentally relevant concentrations, plants in this study were exposed to environmentally relevant concentrations of the PPCPs, yet resulted in uptake concentrations similar to or greater than those reported in comparable studies."[26]

Finally, a study involving growing soybeans to maturity in soils treated with two manufactured nanomaterials (MNM)—nano-ZnO and nano-$CeO_2$—found that soybean plants bioaccumulated MNM metals from the soil and, in the case of nano-ZnO, translocated significant amounts of metal into leaves and beans,"[27] while nano-$CeO_2$ impaired soybean growth and yield as well as eliminated nitrogen fixation at high nano-$CeO_2$ levels. The authors concluded that "Juxtaposed

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endocrine-disrupting effects in male western mosquitofish, *Gambusia affinis*. *Env. Tox. And Chem.*, 29(6): 1287-1291.

[21] Zorrilla et al. 2009. Op cit.

[22] Raut SA and RA Angus. 2010. Op cit.

[23] Chen J, Ahn KC, Gee NA, Ahmed MI, Duleba AJ, Zhao L, Gee SJ, Hammock BS and BL Lasley. 2008. Triclocarban enhances testosterone action: A new type of endocrine disruptor? *Endocrinology*, 149(3): 1173-1179.

[24] Wu C, Spongberg AL, Witter JD, Fang M and KP Czajkowski. 2010. Uptake of pharmaceutical and personal care products by soybean plants from soils applied with biosolids and irrigated with contaminated water. Enviorn. Sci. Technol., 44(16): 6157-6161.

[25] Pg. 6160 in Ibid.

[26] Pg. 3029 in Holling CS, Bailey JL, Vanden Heuvel B and CA Kinney. 2012. Uptake of human pharmaceuticals and personal care products by cabbage (Brassica campestris) from fortified and biosolids-amended soils. J. Environ. Monit., 14(11): 3029-3036.

[27] Pg. E2451 in Priester JH, Ge Y, Mielke RE, Horst AM, Moritz SC, Espinosa K, Gelb J, Walker SL, Nisbet RM, An Y-J, Schimel JP, Palmer RG, Hernandes-Viezcas JA, Zhao L, Gardea-Torresdey JL and PA Holden. 2012. Proc. Nat. Acad. Sci. USA, 109(37): E2451-E2456.

against widespread land application of wastewater treatment biosolids to food crops, these findings forewarn of agriculturally associated human and environmental risks from the accelerating use of MNMs."[28] These results are troubling, given that MNMs have a high affinity for activated sludge bacteria and concentrate in sewage sludges that are land-applied.[29]

Neither PPCPs nor MNMs are regulated in sewage sludges. In addition, a review article on "emerging" organic contaminants (OC) in sewage sludge found that "a number of 'emerging' OCs (PFOS, PFOA and PCAs [polycholinated alkanes]) were identified for priority attention that are environmentally persistant and potentially toxic with unique chemical priorities, or are present in large concentrations in sludge, that make it theoretically possible for them to enter human and ecological food-chains from biosolids-amended soil."[30] Experiments involving uptake of these emerging OCs by plants have not been conducted.

Given the new data on the safety risks of heavy metals, as well as the many unanswered safety questions and the potential for both PPCPs and MNMs to accumulate in the edible parts of plants grown on sewage-sludge amended soils, we urge FDA not to permit the application of sewage sludge on agricultural land used to grow produce.

**Equipment, Tools, Buildings, and Sanitation**

Provisions on minimizing contamination in buildings, and on equipment, tools, and measuring instruments, underscore the need to address all possible routes through which foodborne pathogens may enter the food supply. Tools and equipment, including that used for storage and transportation, are likely to contact covered produce and therefore must be held to high sanitation standards. Codifying the proposed language calling for structures to be designed to prevent contamination of this kind is the correct approach. The failure to properly dispose 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. The requirements proposed by FDA are reasonable and not onerous.

Consumers Union 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.

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[28] Ibid.

[29] Ibid.

[30] Clarke BO and SR Smith. 2011. Review of 'emerging' organic contaminants in biosolids and assessment of international research priorities for the agricultural use of biosolids. Environ. Int., 37(1): 226-247.

- growers should take reasonable precautions to prevent domesticated animals in and around a fully-enclosed building from contaminating covered produce, food-contact surfaces, and food packing materials with known or reasonably foreseeable hazards.

- equipment must be stored and maintained in a way that minimizes contamination.

- growers should inspect, maintain, and clean and sanitize (when appropriate) all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

- if a grower uses equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or are likely to, contact covered produce, the grower must do so in a manner that minimizes the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards.

- 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.

- 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 such that drip or condensate does not contaminate covered 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.

The spread of contamination, however, is not limited to that which makes direct contact with food. Non-food-contact surfaces, such as tool handles, may easily lead to the spread of pathogens. We therefore recommend that FDA add language that would address this contamination risk.

**Worker Health and Hygiene**

Robust and enforceable health and hygiene standards give workers the opportunity to be a critical line of defense against foodborne illness. FDA appropriately notes that bacteria, viruses, and parasites are frequently transmitted from person to person and from person to food. Therefore, poor worker health and hygiene is a very likely source of contamination.

Consumers Union supports:

- including in training for workers principles of food hygiene and food safety, health and personal hygiene, and other topics as applicable.

- preventive action to ensure that workers with communicable illness do not handle produce (this may include giving workers paid sick leave).

- requiring that personnel who work in operations in which covered produce or food-contact surfaces are at risk of contamination with known or reasonably foreseeable hazards use prescribed hygienic practices.

**Domesticated and Wild Animals**

Consumers Union agrees with FDA that the agency should address within the scope of its regulations related to animal intrusion both the inadvertent introduction of wild animals to the production areas, as well as the intentional use of domesticated animals in farm operations. Grazing animals are an integral component of many farm operations, and they are not only a practical necessity but also provide environmental benefits. At the same time, animal feces can be a source of produce contamination – both from domestic and wild animals. For this reason, it is critically important to observe appropriate waiting periods between grazing, working, and harvest, for any produce that may have been contaminated by animal feces of any kind, and FDA's proposed regulations include this requirement.

We recommend that FDA develop guidance documents for growers relating to animal intrusion issues. Such documents should address the appropriateness of different types of natural and man-made barriers to intrusion, the management of intrusive wildlife, and the balancing of environmental and habitat impact with the need for preventing contamination.

**Standards Directed to Growing, Harvesting, Packing, and Holding Activities**

We support the proposals in this section, which establish basic science-based minimum standards directed to growing, harvesting, packing, and holding activities. These include the following requirements:

- if food-packing material is reused, measures must be taken to ensure that food-contact surfaces are clean.

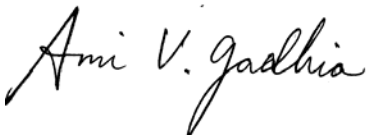
- if a farm grows, harvests, packs or holds produce that is not covered in this part and also conducts such activities on covered produce, measures must be taken during these covered activities, as applicable, to: (a) keep covered produce separate from excluded produce; and (b) adequately clean and sanitize, as necessary, any food-contact surfaces that contact excluded produce before using such food-contact surfaces for covered activities on covered produce.

- farms should take all measures reasonably necessary to identify and not harvest covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. Similarly, if the presence of animal excreta in a field of covered produce precludes the ability to safely harvest the covered produce, the relevant portions of that field should not be harvested.

We agree with FDA's decision not to require washing of produce to reduce the likelihood of contamination. A number of studies have concluded that wash water, with or without an active antimicrobial agent, does not completely disinfect produce that may contain microorganisms of public health, so more scientific support is necessary before establishing a washing requirement.

As noted above, packing facilities handling high-risk produce such as cantaloupes should be required to test final product at periodic intervals for pathogens.

Respectfully submitted,



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