Summary of FSMA Supplemental Revisions for Produce Rule

The Food and Drug Administration (FDA) released the revised ("Supplemental") language on the Produce Safety and Preventive Controls Rules in September 2014. There will be a public comment period until **December 15, 2014.** The table below summarizes some of the most significant changes, what they mean for Vermont growers, and highlights issues on which the FDA is especially interested in receiving comments.

For more detailed information on the revised language and its potential impact, refer to the FDA Produce Rule website: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm, or the FDA's docket for the complete Proposed Rules http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0973

The National Sustainable Agriculture Coalition will be providing updated analysis from the perspective of sustainable agriculture advocates until the close of the comment period at: http://sustainableagriculture.net/fsma/

The FDA is seeking comments on these rules. **Comments on can be made** at http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0973.

Initial Proposed Rule	Revised Proposed Rule	What This Change Means	FDA requesting comments on
Manure and Biological Soil Amendments: Determines interval between application of raw manure or compost and when crops can be harvested			
Was: • **Manure:** 9 month interval between application of raw manure (or grazing animals) and harvest • **Compost:** 45 days between application of compost and harvest	**Now:** **Manure**: FDA still wants a day length interval, but deferring decision. Will work with USDA and stakeholders to: • complete risk assessment • conduct research • develop infrastructure for farms to transition to compost Will reopen docket for comment when above completed (estimate 5 – 10 yrs) Meanwhile will not take exception to NOP 120/90 day rule **Compost:** Removed time interval between application of compost and harvest if compost appropriately treated	**So What?:** • **Manure:** Farms can continue using raw manure for now. FDA not providing an interval, but recommend using NOP 12/90 or GAPs 120 day interval. • Farms encouraged to use compost in place of raw manure • **Compost:** No time interval required for compost.	**Seeking Comment On:** • What are the barriers to using compost instead of raw manure? • What resources will be needed for farms to switch to using compost instead of raw manure?

Testing of Agricultural Water: Determines frequency of testing untreated surface or ground water directly applied to the edible portion of crops that are eaten raw, the level of E.coli at which action must be taken, and what actions should be taken (does not apply to drip or furrow application of water)

Untreated Surface Water

Was:	**Now:**	**So What?:**	**Seeking Comment On:**

• Testing every 7 days
• Must discontinue use if samples reached either:
  ○ geometric mean of 126 CFU *E.coli*/100 mL
  ○ or a single sample of over 235 CFU
	• Raised *E.coli* levels for corrective action to geometric mean (GM) of not over 126 CFU, and Statistical Threshold Value (STV) of not over 410 CFU E.coli/100mL[1]
	• If STV over 410, increase time between application of water and harvest to get 0.5 log reduction in E.coli.[2]
	"Know Your Water" Tiered Risk Assessment
	1. Take 20 samples over 2 yrs to establish baseline and changes needed
	2. After baseline, 5 samples/yr to determine need to adjust time between irrigation and harvest. FDA will provide tool for determining number of days to wait
	3. Re-do baseline every 10 years, using annual data
		• Revisions recognize differences between watersheds, allow farmers more flexibility to base practices on the risk of their water.
		• Use of STV recognizes that levels of E.coli will vary over time
		• Instead of having to stop using surface water if it surpasses standards, farmers can wait between application of water and harvest based on how quickly E.coli die-off.
			Should FDA establish limit above which water should not be applied until corrective actions are taken?
			If so, what would be appropriate maximum level?
			Is allowing a time interval between application of water and harvest an appropriate solution if *E.coli* levels are above designated limits?
			Are there alternative data sources that should be used as indicators of water quality?
			Is 0.5 log/day die-off rate appropriate?
			Should farms be required to keep records of dates of last irrigation and harvest?
			What records would be reasonable for farms to document water quality?

Untreated Ground Water

Was:	**Now:** Tiered approach	**So What?:**	
• Test at start of growing season and then test every three months during growing season	• First year: At least 4 samples over growing season to determine baseline • Thereafter test 1x/growing season	• Number of times farmers test is based on water quality • Reduces the number of times water must be tested if risk is low	

[1] **Statistical Threshold Value** approximates the 90th percentile of the samples, and is intended to be a value that should not be exceeded by 10% of the samples. For example, if a water source tests at 2,100 CFU *E.coli* in 1 of 10 samples, but the other 9 samples are such that the STV based on all 10 samples is 410 CFU or less, it may still be ok to use the water

[2] **Calculating die-off period:** If E.coli levels are higher than the proposed limits, farmers could apply a waiting period between application of water and harvesting crops to allow *E.coli* to die-off to at least GM of 126 CFU and 410 STV CFU. FDA will supply tool for determining days to wait. For example:

If Water Tests at	**Calculated Days to Wait between Application & Harvest**	**Calculated Reduced Level After Wait**
241 GM and 576 STV	1 day	76 GM and 182 STV
241 GM and 4,600 STV	3 days (for a 1.5 log reduction)	8 GM and 145 STV

Definition of Who is Covered: Whether farm size is based on gross sales of *all* food sales vs. *produce* sales
Determines: 1) whether a farm qualifies for a full exemption or 2) is considered a very small business or small businessfor compliance timelines. Definition of Farms falling under Qualified Exemption *cannot* be changed.

Was:	**Now:**	**So What?:**	**Seeking Comment On:**
• Farms covered by FSMA was originally based on sales of *all food* (produce and meat, milk, grain, eggs, animal feed, etc...) • This meant farms that made the bulk of gross sales from non-produce food items would be covered by the regulations, even if they only did a small amount of annual gross sales in produce.	• Definition of farms NOT covered is now based on annual sales of *all produce* averaged over 3 years.[3] • "Very small businesses" = less than $250,000 in annual gross sales for all *produce*. • "Small businesses" = less than $500,000 in annual gross sales for all *produce*. Farms doing 50% or more of sales to qualified end users and under $500,000 in gross sales for *all food* still have qualified exemption[4]	• Farms with less than $25,000 average annual sales in *produce* are NOT covered by FSMA • Very small businesses: 4 yrs from finalization to comply • Small businesses: 3 yrs to comply Because definition of farms under Qualified Exemption cannot be changed, revision will not significantly change number of covered farms, but may shift number of farms in the $250,000 and $500,000 categories, giving more farms a longer time to comply.	• Is proposal to cover farms with annual gross sales of *produce* of more than $25,000 appropriate? If not, what would be better? • Should definition of covered farms be based on averaged annual gross sales of *covered produce only* instead sales of *all produce*? • If the definition should be for covered produce only, how should the monetary threshold be applied?

Definition of Harvesting, Holding and Packing as Covered Activities: Determines whether farms that buy in, hold, label or pack produce from other farms will have to follow the Preventive Controls Rule or Produce Rule

Was:	**Now:**	**So What?:**	**Seeking Comment On:**
• A business could only be defined as a farm if all food grown, raised, packed or held on that farm was from that farm or another farm *under the same ownership*. If a farm packed or held food from a farm not under its ownership it would be considered a "mixed-type facility" and fall under the Preventive Controls Rule.	• Revised definition includes businesses that pack, hold or label raw agricultural commodities (RACs). • Farms that pack or hold RACs from a farm under different ownership are *no longer considered a "mixed-type facility."*	Farms that buy in produce from other farms for CSA shares, to fill gaps in supply, or pack or hold produce for other farms will still be considered farms and fall under Produce Safety rule, and will not have to comply with the Preventive Controls Rule (PCR) solely for those activities. However, off-farm activities, such as an off-farm packinghouse *do* still fall under Preventive Controls Rule – see below)	Should phrase "in one general physical location" be included in definition of farm? Should farms with off-farm packinghouses fall under PCR? Should farms supplying produce to second farm provide name, address & description of produce in individual shipments? Should on-farm packinghouses under cooperative ownership by multiple growers be considered under same ownership as any or all of the growers' farms?

[3] **Only some produce is covered under FSMA.** Produce rarely eaten raw or goes through a kill step is not covered under FSMA. This includes: sweet corn, pumpkins, winter squash and potatoes. For complete list see FDA FSMA Produce Rule website http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

[4] **Qualified Exemption:** Farms that do less than $500,000 in annual gross sales of all food AND at least 50% of sales are to qualified end users will still be under qualified exemption. Qualified end-user is either a) consumer of food or b) restaurant or retail establishment located in the same state or if out of state, not more than 275 miles from the farm.

Withdrawal and Reinstatement of Qualified Exemption: Determines criteria for taking farm out of "Exempt" category			
Was:	**Now:**	**So What?:**	**Seeking Comment On:**
• The FDA could withdraw a qualified exemption: 1) in the event of a food borne illness outbreak associated with that farm or 2) if they determine that it is necessary to protect the public health and prevent a food borne illness outbreak	• FDA must provide notification and opportunity for farm to respond before deciding to withdraw exemption. • Before withdrawing an exemption, FDA may take alternative actions such as a warning letter, injunction, or a recall and consider steps taken by farmer to correct problem. • FDA must provide farm with a process for reinstatement of exemption that has been withdrawn.	• The original language did not provide alternatives to withdrawal of exemption. Although there is no requirement that the FDA utilize those options, there are alternative options now, and the FDA must provide notice to the farm of intent to withdraw the exemption, time to respond to the notice, and provide instruction on what is needed to reinstate exemption. • Farmers must respond to a notice to withdraw an exemption on the date the notice is recieved, while the Preventive Controls Rule provides processors 10 days to respond. • Farmers have 60 days to come into compliance, while processors have 120 days from receipt of order to come into compliance.	• Should farms be given 120 days from date of receipt to comply with an order to withdraw an exemption so that the guidelines are consistent between the Produce Rule and the Preventive Controls Rule? • General feedback on this approach and suggestions for refinements or alternatives
Wildlife Management and Conservation Practices: Wildlife, hedgerows and other soil and water conservation issues			
Was:	**Now:**	**So What?:**	**Seeking Comment On:**
• Farms should evaluate whether produce can be safely harvested if there is evidence of animals in production areas. • Take all measures reasonably necessary to identify and not harvest contaminated produce	• A new provision has been added that states that FSMA *does not require measures to destroy animal habitat or exclude animals* from outdoor growing areas, or authorize the "taking" of threatened or endangered animals.	• This provision is intended to clarify that the FDA encourages co-management of land for wildlife and conservation, and is not encouraging farmers to remove riparian buffers, filter strips, hedgerows or other conservation practices.	• General feedback on this approach and the new provision and suggestions for alternatives

Selected Points from Revised Preventive Controls Rule That Could Apply to Produce Growers

Below are revisions in the Supplement of the Preventive Controls Rules (PCR) that might apply to produce growers. If you process food or produce a value-added product, you should refer to the PCR page on the FDA website for more detailed information about the Preventive Controls Rule and whether it will apply to your operation http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

- **On-Farm vs. Off-Farm Packing Houses:** Under the current proposed rules, off-farm packinghouses are not considered a farm and are subject to the Preventive Controls Rule. The FDA is seeking comment on this.
- **Definition of a very small business:** businesses with less than $1 million in total annual sales of human food will be considered "qualified facilities" subject to modified preventive controls requirements and have three years after publication of final version of FSMA to comply.
- **Definition of a Facility:** On-farm or off-farm activities that are transforming food will be considered a "facility" or "mixed-type facility" and subject to registration with the FDA. Table 1 of the Appendix to the Preventive Controls Rule (PCR) for human food categorizes activities for farms and farm mixed-type facilties.
- **Requirements for mixed RACs (such as bagged greens):** Table 1 in the PCR Appendix lists mixing Raw Agricultural Commodities (RACs) as a packing activity *and* as a manufacturing/processing activity (e.g., it could be considered manipulating or modifying the food). The FDA is seeking comments on how to handle different scenarios where raw agricultural commodities are mixed and suggestions for how to address the issue in the final rule. So for example, if the activities leading to a mixture of RACs only consist of harvesting and packing, (e.g. harvesting and bagging mesclun or mixed baby greens) and no additional cutting it might stay under the Produce Rule, but if there is an added step of cutting (chopped lettuce and grated carrots mixed together) it could potentially come under Preventive Controls.
- **Supplier Controls and Verification:** The FDA is seeking comments on whether if a receiving manufacturing or processing facility identifies a significant hazard for a raw material or ingredient, the facility should be required to conduct an annual on-site audit of the supplier (unless the facility can show that other verification activities and/or less frequent on-site auditing of the supplier provide adequate assurance that the hazards are controlled). The concern is that this could require some farms to go through duplicative requirements.
- **Drying/Dehydrating Raw Agricultural Commodities**. The revised rule recognizes that drying is a part of harvesting activities for many raw agricultural commodities. The revised definition of farm includes drying and dehydrating of RACs as long as no additional processing is conducted and the drying/dehydrating is not creating a distinct commodity, keeping these activities under the Produce Rule (e.g. cured onions are not distinct from recently harvested onions, but raisins are distinct from grapes)
- **The definition of "holding"** was modified to include activities performed incidental to storage (such as blending the same RAC, or breaking down pallets), but do not include any activities that would transform a RAC into a processed food.
- **Retail Establishments:** It is still unclear whether CSAs, on-farm farmstands, farmers markets and other direct marketing venues will be considered facilities and required to register with the FDA. The FDA is seeking comment on this.

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Created October 2014, by Ginger Nickerson. Center for Sustainable Agriculture, University of Vermont Extension.
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