COMMENTS ON SUPPLEMENTAL PRODUCE AND PREVENTIVE CONTROLS RULES DOCKETS: FDA-2011-N-0921 AND FDA-2011-N-0920

Introduction

I appreciate this opportunity to comment on the supplemental produce and preventive controls rules. As the GAPs Outreach Coordinator for the University of Vermont Extension’s Center for Sustainable Agriculture since 2010, I have helped over 180 small and mid-scale farms understand and implement basic produce safety practices on their farms, and worked closely with over 20 farms in obtaining GAPs certification. The purpose of these comments is to share my impressions and concerns about how the proposed rules may affect Vermont’s produce sector based on this experience. While my comments are informed by my experience as an Extension produce educator, my views are my own and do not necessarily reflect the views of UVM Extension.

It is obvious from the Supplemental Rules that the FDA heard the concerns of small-scale, diversified and organic farmers in the first round of comments and has taken many of those concerns into consideration. However, there are still ways in which the Supplemental Rules could potentially place excessive burden on small-scale, diversified or organic growers in ways that do not simultaneously improve food safety. In the comments below I have attempted to make recommendations that can protect food safety while complying with Congress’s directions that the rules be science-based and do not unfairly burden small businesses.

General Recommendations

1. There should be consistency between the Produce Rule and the Preventive Controls Rule

Combining the growing of produce with value-added activities is an important strategy for financial viability for Northeast farms and small scale, local agriculture in general. When a small business with limited resources does both growing and processing, staying on top of what regulations apply can be expensive and time consuming. To respond to the congressional directions that FSMA not be burdensome to small businesses, the standards for the Produce Rule and the Preventive Controls Rule should be the same wherever possible.

a. Definitions of “small” and “very small” should be the same for both the Produce Rule and the Preventive Controls Rule.

Being able to have value-added processing on farms has been important for economic viability of small family farms in Vermont and New England. Many family operated farms have on-farm farmstands and small commercial kitchens for making pies, jams, salsas, pickles or other value-added foods. Currently the Produce Rule and Preventive Controls Rule have different scales for exemptions: produce farms that do under $500,000 in annual gross sales to qualified end users have a Qualified Exemption, while the Preventive Control Rules use $1 million in gross sales for all human food (vs. just types of processed foods covered by the PCR) as the cut-off for Modified Requirements. However, Vermont has many farms that both grow RACs and process food and for farms that may be subject to both the Produce Rule and Preventive Controls Rule, it is very hard to determine which rule would apply when/where if the definitions for exemptions and qualified exemptions are different based on gross sales. How will a farm that does $600,000
gros sales in RACs and $400,000 in sales from items processed in their on-farm commercial kitchen know which rules apply to them? The easiest way to address this would be to move the qualified exemption for farms under the Produce Rule to $1 million in annual gross sales. The quantity of RACs produced by farms that fall do under $1 million in annual gross sales is still a small percentage of the RACs consumed in the U.S.. To reassure consumers that farms of all sizes are following produce safety practices, farms that do not fall under the Federal rules should be covered by simpler, scale-appropriate rules developed at the State level (see Rhode Island GAPs for a good example of one such program (http://www.uri.edu/ce/ceec/pdfs/GAP_audit.pdf ). An example of a similar system of state oversight of a Federal law that affects most farms is the Pesticide Safety Education Management Education Program (PSEP) http://pmepp.cce.cornell.edu/

b. Withdrawal of Exemption: 1) The time to respond to withdrawal of qualified exemption should be extended to 60 days for farms; 2) the time to come into compliance should be extended to two years for farms and 3) timelines should be the same for both the Produce Rule and the Preventive Controls Rule

Time to respond: The proposed rules currently give farms only 10 days to respond to a withdrawal of their exemption and 60 days to come into compliance. Given that the FDA has multiple strategies for responding to any urgent concerns about threats to public health, including requiring the producer to recall the food, imposing an administrative detention, seizing the food, or seeking a court injunction, to protect the food supply, these timelines are unrealistic for small businesses to respond to notice to revoke their exemption. A small business should be given at least 60 days to gather all of the information and documentation to respond to a notice of withdrawal of exemption.

Time to comply: Currently farmers must come into compliance after a notification from the FDA about intent to withdraw a qualified exemption within 60 days, while processors must come into compliance within 120 days of receiving the order. If the FDA is giving large farms two years from the finalization of FSMA to come into compliance, it is unrealistic to expect that a small farm or processor could come into compliance within 60 days, as compliance often means gathering capital to make infrastructure and equipment changes, getting educated on the standards, conduct water tests, develop new protocols and establish an employee training program. Not giving small farms sufficient time to make these changes could essentially drive them out of business. Since the FDA has the above-cited tools to protect the food supply, small farms should be given two years to come into compliance. They could have 120 days to develop a plan of action, but two years to fully implement the plan.

Consistency between Produce Rule and Preventive Controls Rule Timelines: Because many small farms do value-added processing and will fall under both the Produce Rule and the Preventive Controls Rule, the timeframe for response should be same for Produce Rule and Preventive Controls Rule whether it is for RACs or transformed food. If a concern is serious enough for the FDA to notify a business that there is a problem, shouldn’t the business have to respond rapidly regardless of whether the food in question is apples or pudding? If necessary, there could be graduated response times based on the seriousness of the concerns with less time to respond for more serious concerns.
Clarification of FDA responsibilities for due process: In addition, when notifying a farm or processor re: intent to withdraw an exemption, the FDA should include the following standards of due process:

- Include a specific statement of the reasons in the notice of revocation, so the producer can respond to the specific issues of concern.
- Set standards for what FDA must find in order to revoke the exemption and present clear and convincing evidence for revoking the exemption.
- Guarantee a hearing so that producers can present their case in person before having their exemption revoked.
- Provide the standard post-decision procedural protections, such as motion for reconsideration and a motion for stay.

c. It should be made clear that CSAs, on-farm farmstands, farmers markets and other direct marketing venues will be considered retail establishments and not facilities that are required to register with the FDA.

Under pre-existing law, retail food establishments that sell the majority of their food directly to consumers are not considered facilities. In Vermont, retail food establishments are regulated by the Department of Health. Congress mandated that the FSMA should consider CSAs, farmstands and farmers markets as retail food establishments. However, this is still not clear in the current rules. Many farms that sell processed foods through direct markets such as farmstands could believe they fall under the Preventive Controls Rule, creating a great deal of uncertainty for business planning and potential mistakenly missing opportunities for enterprise development. It needs to be made clear that merely having a CSA or roadside farmstand will not trigger a farm to fall under the Preventive Controls Rule.

d. It should be made clear that food hubs, multi-farm CSAs, non-profit distributors and other aggregators that are only holding and packing RACs and not transforming RACs will not be considered “facilities” subject to the Preventive Controls Rule. The FDA needs to be clear under which conditions aggregators of RACs such as food hubs would be considered farms, and under which conditions they would be considered retail establishments.

Food hubs, multi-farm CSAs and other aggregators and distributors have been pivotal in the resurgence of local foods systems and are actively supported by the USDA, and many local and regional food system non-profits and community development organizations. If food hubs, multi-farm CSAs and other aggregators and distributors are merely holding or packing RACs, and not introducing risk by transforming foods, they should not have to follow the Preventive Controls Rule regardless of whether they are on a farm or a different location. The FDA should clarify when a food hub or other aggregator of RACs would be considered a farm, and under which conditions they would be considered a retail food establishment.

e. The FDA needs to ensure that the Produce Rule does not result in decreased donations of RACs to the charitable food system and people in need.

Vermont has a robust program that donates tons of fresh produce to low-income households. Farmers are concerned that participating in these programs could affect their standing with FSMA, discouraging them from donating produce that because of size, shape or cosmetic issues
is not sold. If farms stop donating food to the charitable system this would vastly reduce the amount of produce going to households in need. The Produce Rule should include a clear statement as to how RACS donated to the charitable system should be treated, but in a way that does not increase the cost of handling this produce for the grower.

f. FSMA and USDA GAPs should be harmonized.

This may be outside of the parameters of this docket, but many New England farms that will fall in the Qualified Exemption category are required to be USDA GAPs certified by their buyers. If the FDA has determined that produce which is rarely eaten raw, further processed or otherwise goes through a kill step, is of low enough risk that those crops are not covered by FSMA, then the USDA GAPs Audit format should be modified so that farmers who grow these crops do not have to modify their practices and infrastructure to reduce the risk of microbial contamination for crops where these risks are inherently low (i.e. the risks on a potato farm are lower than the risks on a farm that grows a large percentage of leafy greens).

g. Provide clear, concise, farmer-friendly guidance

Finalizing the rules is just the first step in the process of reducing risk in the produce industry, real change will only come when farmers adopt these practices. Unlike large farms, small scale farms that compose the majority of farms in the U.S. do not have the resources to hire dedicated staff or consultants to focus on food safety - they rely on information from the internet or from Extension educators. Farmers need easy to understand food safety materials created by microbiologists in tandem with horticultural specialists and adult educators using the best pedagogical practices for adult learners.

Subpart A – General Provisions

a. The definition of farms that are covered by FSMA should be limited to only covered or regulated produce.

Basing the definition of covered farms on the average annual gross sales of produce – the commodity being regulated - rather than all foods is a significant improvement, in that it will no longer unduly burden diversified farms that make the vast majority of their sales from non-produce food. However, it does not make sense that the rules should apply to products that are not covered by FSMA. If the FDA has determined that some crops are of sufficiently low risk to be excluded from FSMA, then determination of whether a farm falls under the rules should be based on the sales of crops that are covered. Some farms that make over $25,000 in annual gross sales of produce may only grow sweet corn, pumpkins or winter squash, all crops that are not covered by FSMA. It would be economically burdensome and does not make sense from a scientific or risk perspective that farms that only grow crops that normally go through a kill step should have to comply with rules intended for crops that are eaten raw.

We also have many farms in New England that grow a combination of covered and non-covered produce, for example both cabbage and potatoes. Not clarifying that the rules only apply to covered produce will lead to confusion for farms. Determining what types of crops to grow is an important part of business planning. For some farms, making expensive infrastructure changes related to complying with the Produce Rule standards may vary depending on whether non-covered produce is included in the definition. If the regulations only applied to covered
produce, some Small and Very Small Businesses that only grow a small amount of covered produce may wish to adjust their business plans and the types of crops they grow.

b. The monetary cut-off for produce farms that would be excluded from the rules should be raised from $25,000 to $250,000 for covered produce.

Small produce farms operate on very tight margins. Farmers that are only making $25,000 in annual gross sales will have very few employees or resources to devote to ensuring that they are in-line with FSMA. Very likely they are probably not full-time farmers and setting the cut-off point so low will make it economically challenging for them to make the transition to full-time farmers. Using $25,000 as the cut-off for farms not covered by FSMA means that a farm that makes $30,000 and 65% of their sales are to wholesale market, would have to comply with FSMA. Under this scenario, it is likely that the owner-operator is also the primary worker and chief bottle washer. Having to comply with the record keeping and complexities of understanding the Produce Rules runs contrary to Congressional direction to not burden small businesses with record keeping. The $25,000 limit could mean that many small farms will choose to stay under the 50% wholesale limit, thus limiting the growth of “agriculture in the middle” that the USDA has identified as essential for growing and stabilizing local food systems and rural agricultural economies. It would make more sense to require that all farms, regardless of size, have to adhere to a few basic practices, determined by the state (similar to the Rhode Island GAPs checklist), and that farms that make over $250,000 and can actually afford to comply with the rules, be required to follow them.

c. The phrase “in one general location” should not be included in the definition of farm in the final rule.

The revised definition of farm to include packing, holding and labeling activities is an important improvement on the original definition and more accurately reflects the spectrum of activities that occur on small-scale diversified farms that compose the nation’s local food systems. In Vermont and other hilly or heavily settled Northeast states, agricultural land is at a premium. Farms that still fit the USDA definition of a small-scale farm often lease land for cultivation that is at some distance from the street address of the main farm/packshed and storage facility. Including the term “in one general location” is too general and could force many farms that are effectively only engaged in farming activities, to be considered under the PCR. Having to follow the PCR standards would negatively impact small scale operations when simply having a packing house that is not “in one general location” would not significantly increase the risk associated with these packinghouses.

d. Determination of whether Packinghouses under cooperative ownership by multiple growers fall under the Produce Rule or the Preventive Controls Rule should be based on the activities and handling practices and not on ownership

On-farm or off-farm packinghouses under cooperative ownership by multiple growers, such as a growers’ cooperative, incubator or food hub should only fall under the Produce Rule and not be subject to the Preventive Controls Rule if all they are doing is packing and holding RACs. The infrastructure, practices and risks associated with a packinghouse that is only packing and holding RACs is similar whether the packinghouse is owned by a single entity or by multiple growers. Cooperatives, food hubs or other situations where businesses can share resources such as a packinghouse, provide many benefits, including environmental sustainability. Making the rules different for cooperatively owned facilities would harm the growth of local agriculture and food systems and not increase protection of the food supply.
e. Farms supplying produce to a second farm should not have to label master containers with farm name, address and description of produce in individual shipments.

Farms that sell produce to a second farm should be required to provide a record of farm name, address and description of produce in individual shipments, but this should not have to be a label on each master container. Rather, as long as the sending farm is providing the information in a format that will work for the receiving farms traceability system, this should be acceptable. Many small farms use hard copies of invoices combined with field maps and order sheets for their traceability and recall systems. This system is cost-effective and is working well (it is often tested if they have a quality issue with an order). Investing in new software and hardware for labeling or barcode systems would be cost-prohibitive for many smaller growers.

Subpart E- Agricultural Water

a. The proposed rules are not based on actual risk – the FDA should take a similar approach as they did with the manure rules and conduct more science on the Agriculture Water standards. In the interim, they should adopt standards that are more practical.

While the supplemental proposal of having growers do a baseline assessment to “know their water” source is an improvement over the previous proposed standard, this practice still only makes sense for springs and ponds. Water coming from rivers and streams will still vary too much from day-to-day, and even potentially hour-to-hour for the STV to make much sense.

Under the current supplemental rules, if a farm has six intakes from two different river sources, then over 2 years they would need to take 20 samples from each intake at $20/ sample for testing and shipping, that would come to $2,400. This would be a significant amount for a small farm ($25,000) that has primarily wholesale accounts.

Congress mandated that the FSMA rules be based on science and actual risks. *E.coli* levels based on swimming water standards are not representative of the risks associated with fresh produce. But existing research indicates that:

1. The presence of generic *E.coli* does not necessarily indicate the presence of pathogens.
2. The absence of *E.coli* does not mean that water is free of pathogens – for example, *E.coli* has been show to not be a good predictor for either *Listeria* or *Salmonella*.
3. Watersheds vary considerably from place to place, but even so, much of the surface water of the US would not pass the 126 GM level.

We recognize that the quality of water and risks of chemical or pathogen contamination in different watersheds can vary tremendously both within and between states, and that the FDA must come up with rules that will work for the entire nation. Rather than forcing an entire industry to adopt standards that do not reflect the actual risks associated with the spraying of surface water on crops that are exposed to desiccation and sunlight,
b. the FDA should work with scientists and farmers to conduct research on the actual risks of surface water on produce and to develop inexpensive rapid test kits that can be utilized just prior to applying surface water.

c. In the interim, the standards for agricultural water from surface water should be less burdensome, less expensive and more practical practices that farmers can take to reduce the risk of microbial and chemical contamination. These should include:

- Identifying potential sources of risk of contamination (livestock, wild animals, point sources of pollution), that can be easily determined by visual inspection and/or communicating with municipal water districts
- Documenting steps that have been taken to protect water sources from contamination, such as fencing around ponds.
- A baseline “know your water quality assessment” of: 10 samples for first two years (5 each growing season to establish baseline) followed by 3 samples per year (at beginning of season to identify any potential problems with system, at peak use, and close to or at harvest)
- If E.coli levels from surface water sources are above the geometric mean of 126 CFUs, then growers should wait 2 days between overhead application of agricultural water and harvest.

d. If farms do not apply surface water to the edible part of the crop within 15 days of harvest, they should do an initial water quality assessment at the beginning of every spraying season, to have a baseline understanding of their water quality, but not be required to sample again since risk is greatly reduced when there is such a long interval between application and harvest.

Some farms, such as tree fruit orchards, may only apply agricultural water far in advance of harvest, at intervals equal to or great than 15 days prior to harvest, such as when applying pesticides or fungicides early in the growing season. In such cases because pathogens will have died off before harvest, it does not make scientific sense to require growers to conduct water testing to get a GM or STV.

e. Language should be clarified so that farms are not required to take samples from every intake source.

Rather, farmers should be required to test every body of water used for agricultural water, and if any one body of water has more than one intake source, a minimum distance should be given, for example, test any intakes that are equal to or greater than one mile away from each other. Therefore, a farm that has two intake sources 100 feet apart from each other, would not have to take a sample from each intake, but a farm with two intakes a mile apart, would have to sample from each intake.

f. Farms should not be required to keep records of last irrigation and harvest.

This would constitute burdensome recordkeeping for smaller farms. Rather, farms should be required to keep documentation of their water tests, other efforts to assess and protect water quality.
g. Clear guidance should be given on how farmers can share data for establishing water quality baselines for the GM’s and STV’s. Along with acceptable sources for that information (ex: citizen watershed groups, state health department water tests).

h. The FDA should not require farms to have to calculate the GM and STV until the beginning of the 3rd growing season after the date they need to be in compliance, and after the tools the FDA has promised to provide to calculate those numbers are available.

i. The Supplemental Rules state that farmers can include a log die-off rate for washing produce if they can supply the science. This puts smaller farms at a disadvantage. If the FDA is providing this option, they should provide the log-die off rate they consider reasonable for washing produce.

Subpart F- Biological Soil Amendments

a. The FDA should adopt the NOP standards for Raw Manure until research and stakeholder input on raw manure is completed.

Given what we know about pathogens in manure, it is surprising that the FDA eliminated the interval for raw manure rather than using NOP 120/90 standard during the period for research and stakeholder input. Farmers understand how to use the NOP standards they are well accepted, and there are existing educational materials. To not adopt these standards while the FDA is conducting research and gathering stakeholder input on raw manure standards will confuse farmers and consumers and does not make sense.

b. Raw manure should not be entirely removed as a potential soil amendment.

While we support the FDA’s encouragement of the use of compost, raw manure remains an important soil amendment for produce growers, especially for organic farmers and farms that integrate livestock in diversified systems. Disallowing the application of raw manure on produce areas would also have a negative impact on dairy farms.

c. Research on systems that combine the application of raw manure to cover crops should be included in the research agenda.

Many small and diversified farms, especially organic farms will apply raw manure to a production area, plant a cover crop, then incorporate the cover crop before planting a vegetable crop. We suspect that this practice probably significantly reduces the levels of pathogens in the soil and reduces the risks of applying raw manure to fields for vegetable production. Research on this practice should be included so that appropriate guidance can be given to farmers who wish to continue this practice and it is not unnecessarily prohibited under final rules.
d. Research on grazing or pasturing livestock, especially chickens, should be included in the research agenda for raw manure.

Many small scale and organic farms in Vermont and nationally strive to have a closed loop system and produce their own soil amendments by integrating livestock enterprises with raising fruits and vegetables. This includes silvopastural systems promoted by the USDA Natural Resource Conservation Service. By eating drops, weeds and pests, livestock can reduce the need for chemical pest controls and enrich soil quality with their manure. While such systems can include pigs under apple trees (to control Plum curculio); grazing sheep among blueberries; geese or ducks under fruit trees, or cattle under pecan trees, the most common system in small farms in New England appears to be chickens or turkey following vegetables. The FDA should consider including research on this practice so that appropriate guidance can be given to farmers who wish to continue this practice and the practice is not prohibited under final rules.

e. In the interim, the withdrawal period for grazing animals and growing produce should be the same as applying raw manure to produce areas – preferably 90/120 days.

Since the FDA does not currently give a waiting period for grazing other than “adequate waiting period.”

f. The FDA should work with the Natural Resource Conservation Service to create grant programs to incentivize composting infrastructure

Subpart I – Domesticated and Wild Animals

Language should be added that explicitly promotes buffer strips, hedgerows and other conservation practices.

By merely stating 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, the FDA is missing an opportunity to improve the quality of agricultural soils and surface waters and pollinator communities. Mycorrhizae and beneficial insects such as pollinators and insectivorous birds are critical players in agricultural production. Populations of all of these organisms have been greatly diminished through the use of agricultural chemicals and other environmental stressors. In order to maintain these organisms and the role they play in producing our food, we need to take active steps to promote habitat for them. Hedgerows, windbreaks, riparian buffers, no-till, soil conservation and filter strips, and planting of pollinator species, are well documented means of reducing soil erosion and run-off, and promoting beneficial soil microbes, insects and birds on agricultural lands. To fully align FSMA with USDA and EPA conservation policies, the FDA should work with the Natural Resource Conservation Service to craft language in this section that actively encourages the use of these practices.

Subpart R – Withdrawal of Qualified Exemption

See comment under “There should be consistency between Produce Rule and Preventive Controls Rule” under General Comments
PREVENTIVE CONTROLS RULE

1. It should be clarified in the PCR that calculations to determine which food hubs or aggregators might fall under the $1 million qualified exemption would be based on the annual gross sales of the individual leases that might use the food hub, rather than the cumulative gross sales of all of the food that is handled through the food hub.

2. “Mixing” should be considered under the Produce Rule if it refers to the mixing of whole RACs that have not been further processed or transformed. Mixing of RACs that have not been transformed (such as bagging mixed baby greens or different types of whole potatoes or beets or carrots) should not put a farm in the category of a mixed-type facility.

3. Language should be added for farms that are also retail food establishments to clarify that a retail food establishment only becomes a facility if it does not sell at least 51% of the manufactured/processed food directly to consumers.

   In New England many farms both grow and sell RACs, and sell value-added or prepared foods at on-farm farmstands. These are important anchors in our rural economies, but it is unclear how they will be treated by FSMA. We agree with our colleague on the New Hampshire Food Safety Task Force who stated in their comments:

   A retail food establishment is defined in this draft as “...an establishment that sells food directly to consumers as its primary function....including food it manufactures/processes...if the annual monetary value of sales of food products directly to consumers exceeds the monetary value of sales of food products to all other buyers”. Where does that leave a farm with a farm stand that sells bags of lettuce as described above or jams and salsa direct to the consumer presumably making it a retail food establishment in addition to a farm, but also sells more than half of their annual sales in the form of direct to consumer RACs and wholesale RACs? Does this farm and retail food establishment become a facility even if more than 50% of the manufactured/processed food they sell is sold direct to consumer? We support adding language to clarify that a retail food establishment only becomes a facility if it does not sell at least 51% of the manufactured/processed food directly to consumers.

4. The language around supplier controls and verification needs to be made more clear and exclude exempt farms.

   The Supplier Verification provision is ambiguous and appears to require many businesses to go through expensive duplicative processes, and cover farms that are supposed to be exempt from FSMA. Ideally the Supplier Verification provision would be deleted. Facilities can already request that farms go through a GAPs audit or choose to not buy from them. For FSMA to require additional verification is unnecessary and burdensome.

   If the supplier verification must remain, at a minimum, in addition to stating: “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,” wording should make clear that receiving
manufacturing or processing facilities should not require supplying produce farms to conduct annual on-site audits if the farm:

a. is not covered by FSMA (e.g. the produce is not eaten raw or the farm is not covered because gross annual sales exclude it) as these farms are so small as to pose minimal risk to the food supply and audits would be cost-prohibitive for them

b. is covered by FSMA by virtue of being above the limits in the Tester-Hagen amendment—as these farms are already regulated

c. has been GAP certified—as this would mean they were going through duplicative requirements

If the supplier is exempt (either completely or under a qualified exemption), then the receiving facility should not need to conduct any supplier verification activities on the items from the exempt farm, so long as the receiving facility (b) obtains written assurance that the farm supplying the ingredient or item is exempt.

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