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Food Safety Modernization Act:

Produce Safety Alliance – US Food & Drug Administration

Question & Answer Series

on Proposed Produce Safety Rule

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The **Food Safety Modernization Act** passed by congress in 2010 has five main components which affect fruit and vegetable growers:

1. Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (Produce Safety Rule)
2. Preventive Controls for Human Food
3. Foreign Supplier Verification Program
4. Preventive Controls for Animal Feed
5. Accredited Third Party Certification

The first two are open for public comment until September 16, 2013. Below is the information summarized from various conference calls with the Food and Drug Administration on the Produce Safety Rule.

Standards for Produce Safety Proposed Rule

The Produce Safety Alliance hosted a number of conference calls focusing on individual subparts of the proposed Produce Safety Rule of the Food Safety Modernization Act (FSMA). These calls allowed growers, Extension educators and industry representatives the opportunity to ask questions about the rule. There is much that requires clarification with this rule and there are many areas that need comment from the industry. Information on how to comment is at the end of this document. Subparts of the Proposed Produce Safety Rule that were covered during the Food and Drug Administration (FDA Q&A) conference calls were:

Understanding Exemptions, Subpart A
Agricultural Water, Subpart E
Biological Soil Amendments, Subpart F
Domestic and Wild Animals, Subpart I
Growing, Harvesting, Packing, & Holding, Subpart K
Equipment, Tools, Buildings, & Sanitation, Subpart L
Health, Hygiene and Training for Workers, Subpart D
Recordkeeping, Compliance, & Enforcement, Subpart M

The Q&A sessions with the FDA are highlighted below in a question and answer format. You can access audio recordings of each call at the Produce Safety Alliance webpage.

UNDERSTANDING EXEMPTIONS (Subpart A)

1. How are average annual sales for a farm calculated?
"Food" is defined as any and all food produced for human (including chewing gum) or animal consumption (corn, wheat, soybeans etc.) on a farm. This definition is derived from the FDA Food, Drug and Cosmetic Act part 201F. This definition is important in determining a farms need for compliance with the FSMA produce safety rule. All farms need to know what qualifies as food sold on their farm and the dollar amount of food sold. If your farm sells more than $25,000 of food (as defined above) and the majority of your sales are to wholesale buyers, you will need to comply with this rule. Much discussion took place during this conference call since "food" defined this way includes field crop production. The rule as it currently stands will affect many NJ farms.

For example: A farm produces soybeans and field corn on 90% of its land and uses 5% of that land for vegetable production. The fresh produce grown on the farm is sold at their farm stand. More than 50% of the food produced on the farm is sold into the wholesale grain market and therefore the farm must comply with the FSMA produce rule.

The question was posed about when livestock becomes a food sale. If the animal is sold live it is not a food sale, once the animal is killed and then sold it qualifies as a food sale.

2. Farm Facility (Packinghouse) Registration, are farms exempt?
Farms that grow and harvest their own product are exempt from the facility registration rule. If the farm purchases product from another farm to sell at their own retail operation and/or via wholesale transactions they are then considered a facility and are required to register.

3. At what point does the FDA Preventive Controls rule apply to a farm?
If you don't grow it, but you sell it, the preventive control rule applies to you. If you are growing fruits and vegetables and then doing anything beyond standard practices to prepare that fruit or vegetable for sale as a whole product, the preventive control rule applies to you. Drying, baking, cutting, and mixing products all fall under the preventive control rule.

4. Are there any exemptions to the labeling of product to be sold?
All products that are harvested to be sold will need to comply with the labeling portion of the proposed rule, regardless of a farms exemption from the FDA Proposed Produce Food Safety Rule. Any packaged produce must be labeled with the farm name and business address on the master container. Produce grown for direct market sales does not need to be labeled but the farm name and street address do need to be prominently displayed at the point of sale location. A sign or banner with this information is acceptable.

AGRICULTURAL WATER (Subpart E)

1. What is defined as agricultural water?
Agricultural water is defined as water that is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods-overhead, water used for preparing crop sprays and water used for growing sprouts) and in harvesting, packing and holding activities. Essentially if water used on the farm is going to or has the potential to contact a product that is not exempt from this rule that water is subject to the requirements of this rule.

Water that does not have the potential or intent to come in contact with produce covered by this rule is considered indirect water and is not subject to this rule. Drip irrigation would be considered indirect.

2. How often should agricultural water be tested?
Municipal water does not need to be tested. A copy of the municipal water analysis is sufficient. Well water should be tested at the beginning of the production season and every three months when in production. For surface water, there are two options. Water that is pumped from a well into a holding pond would need to be tested once a month and water from streams, lakes, rivers, ponds, etc. would need testing at least every seven days.

3. What do you do if your generic E. coli water test results come back higher than they should?
This question was asked in regards to the Food Drug and Cosmetic Act rule which states that if a food product is contaminated with a human pathogen the crop is deemed adulterated. A crop that has been irrigated with water that is later shown to be above the accepted generic E. coli standard is not considered adulterated since generic E. coli is not a true indication of the presence of pathogenic E. coli. In this case the grower would need to stop using that water source, identify the problem and fix it or treat the water before he/she could begin using that water again.

4. When is it OK to use water with generic E. coli levels above the stated thresholds?
Many growers use water that has known levels of generic E. coli, including water from ponds, streams, snow melt, and other types of surface water. Drip irrigation and sub-surface methods of irrigation are acceptable forms of irrigation for surface water. The question was posed regarding root vegetables, was sub-surface irrigation considered as not having contact with the produce? The FDA seeks comments from growers using these types of irrigation methods with root crops so that it can better understand production practices and therefore contamination risks.

Generic E. coli thresholds for agricultural water according to the FDA proposed rule:
Average 5 sample mean of 126 CFU per 100 ml water and no more than 1 sample above 235 CFU per 100 ml water.

5. Is frost protection water included in this rule?
If the frost protection water is coming in contact with a harvestable product than yes, it is covered by this rule

BIOLOGICAL SOIL AMENDMENTS (Subpart F)

1. If raw manure is applied to a field and then plastic is laid prior to seeding or transplanting is this a practice that is accepted to reduce the days to harvest to zero?
The only situation where raw manure can be applied to a production area and a zero days to harvest would be applicable would be if there was no possible way for that raw manure to touch the harvestable product. Growers must consider the ability of the manure to splash onto the crop during rains or watering as well as the ability of dust to travel onto the crop.

2. Was there an attempt to create formulas based on different types of manures (horse, sheep etc.)?
The FDA recognizes that there are different levels of risk associated with varying types of manures and production methods. The FDA decided to use the most restrictive measures. The FDA does encourage growers to utilize the ability to create alternatives to the rule when there is scientific evidence that alternative practice would be an acceptable alternative.

3. Is domestic animal waste considered to be of animal origin as covered in the rule?
Yes, it is considered animal manure.

4. How are composts that are made from vermiculture and/or cured or cold composted for several years affected by the rule?
These types of composts will need validation of die-off of human pathogens in order to prove that they meet the standards of the proposed rule.

5. What is required of purchased composts to verify that they meet the standards of the proposed rule?
A certificate of conformance from the producer is needed.

6. If you are producing your own compost and using it yourself, is testing required?
No, testing is not required when you are producing compost for your own use. USDA NRCS and the EPA-California have documents that outline compost production methods that would meet the standards of the proposed rule. Growers are encouraged to adopt these methods of composting so that there is a multiple hurdle approach to reducing pathogens.

7. If windrows are only turned two times how would that compost be classified?
It would not have completed the needed turning and would be considered raw manure and therefore need to comply with the raw manure standards.

8. Are blood meal, bone meal etc. considered to have already completed a kill step?
These amendments are considered biological and of animal origin. Validated procedure info is needed in order to qualify for the zero days to harvest. A certificate of conformance is needed, but this information may also be found on the product label. (This type of documentation is acceptable.)

9. How does the National Organic Program (NOP) and FSMA differ on composting regulations?
The FDA looked at the NOP regulations when creating FSMA. FDA also reviewed literature that was published after the NOP standards were put into place. The FDA recognizes that composting

reduces a significant, but not complete, amount of pathogens. The FDA decided to add 45 days to the timing. This additional time should not affect a significant number of farms.

10. NOP states that manure should be tilled into the soil 3-4 months prior to harvest, why does FSMA not state this as well?
If the FDA had information on a validated study showing that tillage adequately reduced pathogens in the soil they would consider it. The FDA does seek comments regarding tillage and raw manure use.

11. Why is there such a difference in the NOP standard of 120 days and FSMA standard of 9 months from application to harvest?
The FDA found little scientific basis for the 120 day wait time. The FSMA rule needs to be universally applicable. Again, we expect that some groups will need to rely on the scientifically based alternative methods to the rule.

12. If there is enough science and comment to validate the 120 days from raw manure application to harvest time frame will the FDA be willing to change the rule as it stands now?
Yes, provided there is enough scientific information to validate the 120 day wait time.

13. What exactly qualifies as an alternative method?
An alternative method is expected to be used by a community/group of growers whose production practices are similar. The foundation of this alternative method is scientifically validated research data on specific production practices.

14. There does not seem to be a lot of funding out there to research alternative methods and to document practices. Will funding become available?
The FDA encourages researchers and groups to utilize USDA NIFA and Block Grant funds. Large groups should pool their resources to fund production practice research.

15. The 9 month waiting period is a hardship, did the FDA take into consideration the short growing season experienced in some regions?
Yes, this is a good reason to put regional alternative methods into place. Growers are encouraged to use compost rather than raw manure.

16. Extension labs are experiencing a high number of requests for microbiological testing resources, but there is little funding to support equipment and supplies. Will there be funding for labs?
There is funding for FSMA technical assistance in NIFA alternatives grants. The contact for food safety at NIFA is Jodi Williams.

17. The animal feeds rule is expected to impact raw manure use on farms. When can we expect to see that rule released?
We do not know, but is should be soon. There will be interplay between the two rules and this is in part why the comment period has been extended 120 days.

18. Is FSMA set up to incorporate new research as it becomes available?
Yes, the alternative methods provision allows for this.

DOMESTIC AND WILD ANIMALS (Subpart I)

1. The phrase "growers will act appropriately" is used regarding potential contamination from animals on the farm. This phrase is very vague; will there be guidance from the FDA detailing what is "appropriate" action?
We did not want to give concrete metrics because we wanted there to be flexibility within the rule for growers. Currently we have a company contracted to prepare technical data which the FDA will then use to prepare guidance documents.

2. If a grower does not "act appropriately" what will the penalties be? Growers are expected to take all measures reasonably necessary to prevent cross-contamination.
Unsanitary conditions are a violation of the act. Section 401-A1 contains pathogen compliance information and section 402-A4 contains information on the course of action should unsanitary conditions be found. Inspectors will not be looking for deer or birds but will be looking for fecal material that is left by them. The question is will this fecal material come in contact with or be likely to come in contact with the product? Growers should avoid this situation.

3. Will there be an opportunity for input into the governing guidance document?
Yes, we are tracking questions now and this will help inform the rule making and inform the guidance documents. The guidance documents are non-binding and can be easily changed. Comments will always be accepted on the guidance documents.

4. When will these guidance documents become available?
Soon after the final rule is published.

5. Deer droppings are not always evident, how do you monitor large areas of land?
We want to leave it up to your judgment; you should deem what is appropriate.

6. Will thresholds be developed, such as number of pellets per acre acceptable?
No. We do not want to do this; we are looking at the potential for commodity contamination. We suggest that you review commodity specific guidance documents (leafy greens, green onions, fresh culinary herbs, etc.) that are already in existence and apply them to your situation . Obviously if fecal material is observed in direct contact with the produce it should not be harvested.

7. Is product testing required?
No product testing is required.

8. When the guidance document is released will it first come as a draft?
Yes, it will be released as a draft through the federal register.

GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE (Subpart K)

1. Will growers be expected to use food grade containers?
Containers do not have to be food grade. Wooden containers and canvas bags are acceptable but they must be sanitary.

2. Wood is difficult to sanitize.
Wood does not have to be sanitized but it does need to be sanitary.

3. How do you define sanitary in regards to wood?
Sanitary wood would be wood that is likely to not contribute to contamination.

4. Can galvanized metal buckets be used for harvest?
Yes, they need to be clean and sanitary.

5. What regulations do the sanitizers fall under?
Sanitizers used on surfaces and in water need to contain an EPA pesticide label, and they must be used according to that labels directions. If the sanitizer is going to be used to kill microbes (on fruit, on surfaces etc.) then it must have a label that specifies that use.

6. Would trimming lettuce cause a farm to fall under the definition of a facility? What does this mean for this farm/facility?
Typical trimming of produce (removing outer leaves) does not cause a farm to fall under the category of a facility. When the actual raw agricultural commodity is cut (trimming ends of green onions to be uniform in length etc.) that activity would cause a farm to fall under "facility" and therefore the preventative control rules. More information on the preventative control rules can be found at the FDA FSMA website. FDA would like comments related to trimming as a general practice at or after harvest for specific commodities.

7. Would a seasonal open air packing facility, with a wood floor, canopy overhead and a dunk tank and cooler below be acceptable?
Yes, as long as the facility is not a source of contamination.

8. Does the requirement to keep produce contact containers/surfaces clean during the season apply to the off-season?
No. The containers should be clean when taken out of storage and if they are not, appropriate measures should be taken to clean them or discard them. Measures should be taken to exclude pests from storage areas during the entire year.

9. Food Hubs often have store fronts which sell fresh produce as well as trim and package items for sale. Does this fall under the preventative controls rule?
No, the food hub would be considered a retail establishment and would need to comply with the state's food code.

10. Can boxes be reused?
Yes, as long as they are not a source of contamination.

11. How does the rule apply to ladders used in orchard harvests?
Ladders should be clean and sanitary. Could they become a source of contamination in the way that they are used? Workers should be trained on how to avoid cross-contamination.

12. Page 3568 includes the statement that hands that contact produce must be free of microbial contaminants. This statement is impossible.
Yes, this is a word choice error and should read that hands must be free of pathogens.

EQUIPMENT, TOOLS, BUILDINGS AND SANITATION (Subpart L)

1. Are cats permitted in packing houses? They serve as effective rodent control.
There is no rule that cats cannot be used for rodent control but you must consider the potential for contamination of product or product contact surfaces by the cat.

2. Where does OSHA come into play with the Food Safety Modernization Act?
The FDA used 29CFR (OSHA standards) as guidance for toilets and handwashing stations. However, the rule is not exactly the same as OSHA.

3. Is a household toilet facility OK if it is in compliance with OSHA regulations?
Yes, that is OK, but it should be supplied with soap, single use paper towels, toilet paper and a trash can. Cloth towels should not be used.

4. Are cement floors required in a packing house?
No

5. Should hand washing stations be located inside of a portable toilet?
Yes they should but it is not mandated. FDA would like comments on whether the handwashing station should be located outside the portable toilet.

6. What guidance is given regarding rodents?
The FDA wanted to take a holistic approach with rodent control, so that growers can take care of problems as they occur. No specifics are given as to the methods of rodent control so that it can work with existing systems already in place.

7. Are there specifics on how to clean equipment in a packing shed?
The goal is to prevent contamination of product and product contact surfaces. Guidance will be coming on this topic after the final rule is written.

8. Are instruments required for testing to determine how clean equipment is maintained?
No testing is required.

9. Do wooden tables need to be sanitized?
Wooden bins, tables etc. need to be sanitary not sanitized.

10. How about wood surfaces where produce is cut or packed?
Product contact surfaces must be sanitized – how an operation gets to that point is up to them.

11.When picking buckets are emptied, cleaned and returned to the field how should they be transported (upside down on the wagon, right side up, stacked)?
The grower must consider the likelihood of contamination and reduce that likelihood.

12. What is recommended for the disposal of grey water from a hand washing station?
The rule states that it should be disposed of in a way that prevents it from becoming a potential contaminant.

13. What pest control methods are required for packing sheds that are not fully enclosed or enclosed at all.
Measures should be taken to prevent pests from becoming established. These areas should be monitored and if pests are noticed they should be removed and prevented from posing additional problems.

14. Can harvest bins be stored in the field overnight?
Yes, measures should be taken to prevent contamination such as covering the bins. Bins should be inspected before their use and not used if contamination is evident.

15. How stringent is the rule regarding seams of equipment or tools?
Seams should be smoothly bonded or maintained so that they do not pose a contamination risk. In older equipment retrofits may be required.

16. Alternative methods are discussed repeatedly in the rule, and during the last Q&A it was suggested that alternative methods would be applied to groups. Can alternative methods be applied to individual growers?
Alternative methods are appropriate for groups as well as individuals provided they are science based.

17. Vegetable washers often have brushes or sponges that are tough to take apart and clean, what should be considered in this situation?
The FDA would like comments on specific washing practices and equipment. Close attention should be paid to the equipment used for washing produce to determine the potential for it to contaminate produce.

HEALTH, HYGIENE AND TRAINING FOR WORKERS (Subpart D)

1. In the case of farms who sell entire fields of produce, pre-harvest, who is responsible for food safety?
If the ownership of the product in the field changes hands then the responsibility from that point forward belongs to the new owner. Just because the ownership of the crop transferred does not absolve the previous owners responsibility for the field production when it was under their ownership.

2. What constitutes a visitor? Would a sales rep be considered a visitor?
Any person other than personnel is considered a visitor. There is no set time limitation to designate who is a visitor. Growers should consider the potential for contamination from any visitors to the farm.

3. Will testing workers, now or in the future, for asymptomatic diseases be a part of this ruling?
No

4. Is there a recommendation as to the type of soap used in hand washing?
No, soap is the minimum requirement.

5. Is warm water required for hand washing?
No, there is no temperature requirement.

6. When work crews are hired to work on a farm, who is responsible for their food safety training?
The company that manages the work crew is responsible for worker food safety training, not the farm. The farm should obtain documentation from the work crew company to verify worker food safety training.

7. What is the requirement for holding onto worker health and hygiene documentation and records?
A minimum of two years past the date of creation.

8. How strict is the rule regarding eating in the field?
The rule does not cover this specifically, but is covered by hygienic practices and will be a focus of guidance documents.

9. Does eating constitute a break?
Yes. Farm workers must wash their hands after any type of break.

10. Is alcohol based sanitizer acceptable?
No, soiled hands prevent the effectiveness of alcohol based sanitizers. Hand washing has been proven to be much more effective.

11. Can break areas be a separate area, but not necessarily walled off?
Yes

RECORDS, COMPLIANCE AND ENFORCEMENT (Subpart M)

1. Do lot numbers need to stay the same from supplier to supplier? Currently each supplier assigns its own lot number to a box, can this still occur?
Yes, changing the lot number is OK. Each supplier will need to keep records of what they received and the information that they assigned to each box. There needs to be a way to trace product back and forth one step.

2. Small growers do not want their name and address publicized. How will the traceability rule impact small growers and displaying the farms physical location?
The traceability rule is not yet written, growers are encouraged to comment on how advertising the farms physical location (as a part of the labeling rule affecting both FSMA qualified and non-qualified farms).

3. If the FDA removes the exemption status of a farm how does that farm obtain that exemption status once again?
The FDA will treat this situation on a case by case basis. FSMA includes an appeals process (section 112.204b, 05, 06, and 07). Growers who are exempt are not required to keep the records that farms who are not exempt must keep. Should an exempt farm become non-exempt they will be expected to start keeping the required records at that point.

4. What will be expected of farms going through an appeals process?
Growers will want to show any records that they have kept and would want to show the FDA how they have been complying with Good Agricultural Practices and FSMA. Visually showing the FDA investigator your practices is acceptable. Offering the timeframe that records could be produced is also advised.

5. How can variances be used appropriately?
Variances are appropriate for specific regions that have an economic hindrance for compliance. This can apply to individual regions, foreign governments, and states. Alternative methods are very different than variances. Page 3642 section 112.171 details who may request a variance.

6. What are the penalties for growers who should comply but do not?
There are many steps between the FDA coming onto a farm and the act of shutting that farm down. The FDA has the authority of shutting a farm down if they are found to be producing adulterated product. When an FDA inspection takes place there will be the opportunity for a farm to put corrective actions into place. Growers will need to show the investigator what will be done in that corrective action and will have 15 days to reply to the FDA in writing as to the actions put into place.

7. During a National Organic Program inspection the inspector is not permitted to have dialog with the grower about non-compliance. Is this true also for FSMA?
No, the investigator can share information that is available in guidance documents with the grower.

COMMENT ON THE PROPOSED RULE

The Q&A conference calls highlighted many areas that are in need of comments from growers. The comment period has been extended until September 16, 2013, there is still time to offer your suggestions on the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Safety proposed rule). Commenting on this proposed rule is incredibly important. The FDA recognizes that there are many situations and practices that they may be unaware of and may affect how the regulation should be revised. Comments that are thoughtful and substantive, containing real examples and data that support your position are encouraged and will have the most impact.

How to submit your comment:

When submitting a comment include the title "Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption, Docket No. FDA-2011-N-0921 and Regulatory Information Number RIN 0910-AG35.
Comment electronically at the FDA FSMA webpage.

Written comments may be faxed to the FDA at 301-827-6870 or you may mail them to:
Division of Dockets Management (HFA-305)
Food and Drug Administration
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