Agritourism Food Safety and Recall Readiness Workshop
Location: Forest Hall Farm, Mechanicsville, Maryland

8:00 a.m. – 8:15 a.m.	Registration/Coffee
8:15 a.m. – 8:30 a.m.	Welcome & Introductions
8:30 a.m. – 9:30 a.m.	GAP Basics for an Agritourism operation (Justine Beaulieu, UMD)
9:30 a.m. – 10:30 a.m.	FSMA 101 for Maryland Produce Growers- (Deanna Baldwin, MDA)
10:30 a.m. – 10:45 a.m.	Morning Break
10:45 a.m. – 11:45 a.m.	Agritourism Food Safety Risks & Recommendations (Sarah Everhart, ALEI)
11:45 a.m. – 12:45 p.m.	Lunch
12:45 p.m. – 1:45 p.m.	Recall Planning (Presenter- Sarah Everhart, ALEI)
1:45 p.m. – 2:45 p.m.	The Role of Regulatory Agencies in Food Safety and Recall- What Happens If Your Farm is the Source? (Presenters Deanna Baldwin, MDA and Kyle Shannon, MDH)
2:45 p.m. – 3:00 p.m.	Questions/Closing Remarks

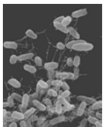
Good Agricultural Practices and Pre-Harvest Contamination

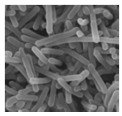
2017 Presentation
Adapted by Dave Martin and Justine Beaulieu
Original by Donna Pahl

psla university of maryland plant science & landscape architecture

UNIVERSITY OF MARYLAND EXTENSION
Solutions in your community

Hazards in Foods





A hazard is something that could cause harm to the consumer.

Hazards commonly associated with fresh produce are:

- **Biological hazards**
- Chemical hazards
- Physical hazards

Escherichia coli (E. coli)

- Lives in the intestines of animals
- Most types are harmless, but some are pathogenic (i.e. they can make you sick)
- Contaminated water, soil, and food
  - Undercooked ground beef
  - Raw milk and juice
  - Soft cheeses made from raw milk
  - Fresh produce (particularly raw sprouts)

Amazon.com

cdc.gov

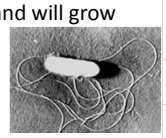
E. coli in the News

- **2016** *E. coli* O157:H7 outbreak on sprouts in Minnesota (8) and Wisconsin (3). Two hospitalizations. No HUS or deaths.
- **2012** *E. coli* O157:H7 outbreak on organic spinach and spring mix blend. 33 persons in five states (NY, MA, CT, PA, VA). Hospitalizations, HUS, no deaths.
- **2012** *E. coli* 0126 outbreak on sprouts reaching 29 persons in 11 states (WA, KS, IA, MO, AR, AL, WI, MI, OH, WV, PA). Hospitalizations, no HUS, no deaths.
- **2006** Fresh spinach: 26 states, 199 people, 3 deaths, 102 hospitalizations, 31 HUS. 22 <5 YO

Listeria monocytogenes

- Causes Listeriosis or Listeria infection
- Found in soil and water and some animals, including poultry and cattle

- Caused by eating contaminated food
- Raw milk, soft cheeses, some processed meats, refrigerated smoked seafood, raw sprouts
- Can grow even in the refrigerator, and will grow faster at temperatures above 40°F



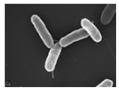
Listeria in the News

- **2016** Packaged salads reaching 19 people in 9 states (MO, MI, IN, OH, PA, NY, NJ, CT, MA). 19 hospitalizations and 1 death.
- **2015** Caramel apples reaching 35 people in 12 states (WA, CAL, NV, UT, AZ, NM, CO, TX, MO, MN, WI, NC). 34 hospitalizations and 7 deaths.
- **2013** Frozen vegetables reaching nine people in four states CT, MD, WA, CA. All hospitalized, three deaths (two were in MD but listeriosis not the direct cause).
- **2011** Whole cantaloupes reaching 147 in 28 states. 143 hospitalizations, 33 deaths

Salmonella


Scientific Institute of Public Health

- Salmonellosis is the most frequently reported case of foodborne illness
- Over 2,300 types
- Annual U.S. estimates:
  - One million foodborne illnesses
  - 19,000 hospitalizations
  - 380 deaths
- Diarrhea, fever, abdominal pain for 4-7 days
- Foods of animal origin


Encyclopedia Britannica


Amazon.com

Salmonella in the News

- **2016** in sprouts reaching 36 people in 9 states. Seven hospitalizations, no deaths
- **2016** sprouts reaching 26 people in 12 states including MD. Eight hospitalizations, no deaths.
- **2015** cucumbers reaching 907 people in 40 states. 204 hospitalizations, six deaths.
- **2014** cucumbers reaching 275 people in 29 states and D.C. 48 hospitalized, one death. *Traced back to Delmarva.*

Fresh Fruit and Vegetable Causes and Concerns

- Grown in an open environment
- Multiple opportunities for contamination
- No absolute kill step without damage
- Likely to be consumed raw
- Yearly consumption of produce increasing

Is Food Safety Just a Problem for Wholesale Growers? … *NO*

- There are five high-risk fruit and vegetable crops….and we grow and direct-market them all locally:
  - **Leafy greens *(Escherichia coli)***
  - **Tomato (*Salmonella enterica and newport*)**
  - **Cantaloupe (*S. enterica* and *Listeria monocytogenes*)**
  - **Berries (*E. coli*)**
  - **Green onions (Hepatitis A)**

The 4 W's

Our focus is on these four topics

- **Workers**
- **Water**
- **Wildlife**
- **Waste**

Worker Health and Hygiene

- Worker hygiene training
  - Washing hands
  - Using restrooms
  - Screening sick workers
  - Injuries and cuts
- **VERY important in food safety!**
- Facilities and Training

Workers Are A Food Safety Concern Because They…

- **Can carry human pathogens**
  - *Shigella*, Hepatitis A, Norovirus, and others
- **Can spread human pathogens**
  - Harvest and pack with their hands
  - Fecal-oral route
- **Require training to reduce risks**
  - Proper handwashing
  - How to handle illnesses and injuries

Produce Safety ALLIANCE

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Routes of Contamination

Feces

Clothing

Hands

Footwear

Tools & Equipment

Illness & Injury

Produce Safety ALLIANCE

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Importance of Training Workers

- Fresh fruits and vegetables often receive no additional processing (such as cooking), so contamination with a pathogen can result in illness when the produce is consumed
- Workers need to use food safety practices every day to reduce produce safety risks
- Food safety practices are learned so training is key to successful implementation

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Resources Provided to Support Food Safety Practices

- Toilets
- Toilet paper
- Soap
- Clean water
- Paper towels
- Container to catch wastewater
- Garbage cans
- First Aid Kit
- Break Areas

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Drinking Water & Break Areas

- Workers should be provided with drinking water to reduce the risks of heat exhaustion
- Break areas do not need to be a separate building but must be in a designated area
- Healthy workers are better able to do their jobs and implement food safety practices!

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Proper Use of Toilets

- All urination and defecation should be done in a toilet, NEVER in the field or nearby production areas
- Toilet paper should be deposited into the toilet, not in a garbage can or on the floor
- Always wash hands after using the toilet

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Worker Clothing

- Clean clothes should be worn each day
- Footwear cleanliness is important
  - Designated footwear helps prevent cross-contamination
- Gloves, if worn, must be changed when they become contaminated or torn
  - If reusable gloves are used, clean often or as needed
- Aprons, gloves, and other food safety equipment should be removed before using the toilet and should be stored in a clean, designated area when not in use

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Worker Illness

- Workers who are sick or show signs of illness can contaminate fresh produce
- Ill workers must not handle fresh produce
- Symptoms of illness can include:
  - Nausea
  - Vomiting
  - Diarrhea
  - Fever
  - Jaundice

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Worker Injury

- **Worker injuries may pose food safety risks**
  - A first aid kit should be available, stocked, and monitored
  - Clean and bandage all wounds
    - If the wound is on the hands, a glove should be worn to create a double barrier
  - Discard any produce that may be contaminated
  - Clean and sanitize any items that came in contact with bodily fluids
  - Report all injuries to supervisor

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How to wash your hands

1. Wet hands with warm water
2. Apply soap to hands
3. Lather hands for 20 sec.
4. Rinse thoroughly
5. Towel dry thoroughly with disposable paper towel

When To Wash Your Hands

- After using toilet
- After cleaning restroom
- After smoking, eating or drinking
- After changing diapers or linens
- After handling dirty equipment, utensils or farm machinery
- After caring for or touching animals
- After handling garbage
- After engaging in other activities that soil hands
- Before you eat
- Before you start to work
- Before handling food
- Between changing tasks or changing gloves

KY Cabinet for Health and Family Services

What is required of a hand-washing station?

- Potable (drinking) water
- Soap
- Paper towels (non reusable towels)
- Catch basin for grey water
- Cannot use just hand sanitizer

Source: www.hallsservall.com, www.doitandhow.com

Water Quality: Uses of water in agriculture

Preharvest

- Irrigation
- Pesticide application
- Frost protection

Postharvest

- Washing and processing
- Refrigeration and cooling

Water Sources

- Water for agricultural use may come from:
  - Surface sources
    - Rivers, streams, irrigation ditches, ponds, and canals
  - Wells
  - Municipal water systems

high
RISK
Low

Water Uses in Irrigation

Choose the **application method** and treatment to reduce risk

- Drip irrigation vs. Overhead irrigation
  - Level of microbial contamination in the water?
  - How risky is the crop?

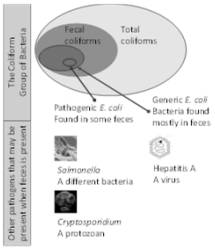
How do you know if your water is suitable for agricultural use?

Test it!

Send it in to a lab for an *E. coli* test.

Why Monitor Generic *E. coli ?*

- Species within the fecal coliform group
- Indigenous member of the intestinal flora in warm-blooded animals
- Used by EPA for drinking and recreational water standards
- Not considered to be an environmental organism
- Considered the most reliable fecal indicator organism



Water tests: How often?

Well: Once at the beginning of the year

Surface water: Three times (planting, peak use, harvest)

City water: Obtain records from municipality

Water Quality Requirements

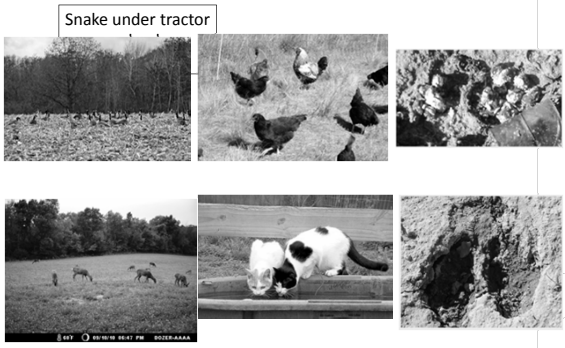
Depends on what you're using the water for:

- Irrigation
  - Contact water (overhead irrigation): Average of 126 colony forming units (CFUs) in a 100 mL generic *E. coli* water sample with no one sample above 235 CFUs.
  - Non-contact water (drip irrigation): Average of 126 colony forming units (CFUs) in a 100 mL generic *E. coli* water sample with no one sample above 575 CFUs.
- Pesticide spray water: "Microbially safe" <1 or 0 CFU generic *E. coli* in a 100 mL water sample.
- Post-harvest water (water coming into contact with produce during/after harvest, handwashing and drinking water): 0 CFU **total coliforms** in a 100 mL water sample.

Mitigation Strategies

- Investigate what is causing the elevated microbial counts
  - Obvious animal contamination or runoff?
  - Is the irrigation intake sucking up sediment?
  - Cracked well casing?
  - Weather?
- Consider an alternative water source
  - Switch to a different water source a few weeks before harvest?
- Use less risky irrigation methods (for example trickle)


Wildlife (Wild and Domestic Animals)



Animals Are A Produce Safety Concern Because They:

- Can carry human pathogens
  - e.g., *E. coli* O157:H7, *Salmonella, Listeria monocytogenes*
- Can spread human pathogens
  - By depositing feces in fields
  - By spreading fecal contamination as they move
- Are very difficult to control
  - Birds and small animals travel unnoticed
  - If fencing is used, even the best fence can be breached
  - Complete exclusion is not possible

Wildlife on the Farm

- Can be a natural and valuable part of the landscape and farm environment
- Depending on species, management options may be limited by county, state, or federal law
- May be resident or transient (e.g., migrating species)
- Wildlife with close association to human activities may pose greater risks
  - e.g., seagulls feeding at dumps, starlings feeding in cattle feedlots

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Assessing Risks: Wildlife

- Do you find wildlife feces in your produce fields?
  - How often? Is it widely distributed? Is it in contact with produce?
- Is your farm in an area that large numbers of animals visit (e.g., flocks of migrating birds, herds of deer)?
- What management practices can limit wildlife contamination of produce fields and water sources?

Produce Safety ALLIANCE §

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Monitoring Wildlife Activity

- **During the growing season:**
  - Monitor for feces and evidence of intrusion
  - Evaluate the risk of fecal contamination on produce (e.g., tree vs. root crop)
  - Consider past observations and wildlife attractants
- **Immediately prior to harvest**
  - Monitor for fecal contamination, signs of animal activity (e.g., trampling, rooting, feeding, tracks)
  - Assess risks and decide if the crop or a portion of the crop can be safely harvested

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Assessing Risks: Domesticated Animals

- Are domesticated animals allowed in the field while the crop is present as part of the production process?
  - Are they working animals?
- Are workers aware of cross-contamination risks from fecal contamination of hands, clothing, shoes, and equipment after handling animals or fecal material?
- Are production fields rotated into grazing land?
  - If manure is present on the ground, one recommendation is to extend the period of time between when animals were grazed and when produce can be planted

Produce Safety ALLIANCE §

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Pets

- Should be excluded from produce fields
- Visitors to the farm should be instructed to leave their pets at home
- Farms with petting zoos should have handwashing sinks available and signage instructing visitors of the food safety policies

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Animal Exclusion and Control

- **Hunting**
  - controlled hunting of hogs, deer and other wild animals may be permitted
- **Control**
  - Traps eg. rodent control
  - Restrictions on poison (away from produce)
- **Buffer zones around fields**
- **Construction of barriers**
  - fences, deer gates, electric fences
- **Deterrent devices**
  - scarecrows, propane cannons

Waste (animal manure)

- Abundant supply
- Great source of nutrients
- Great way to recycle waste
- Great for soil health

BUT …

Can harbor human pathogens

Survival of Pathogens in Manure

E. coli O157:H7			*Salmonella*		
Soil	**Manure**	**Other**	**Soil**	**Manure**	**Other**
50 to 150 days or more	5°C – 70 days 22°C – 56 days 37°C – 49 days Slurry: 21 to > 70 days Feces: > 90 days	Water: 222 to 257 days *E. coli* O157:H7 found to persist for 120 days in water trough sediments Feed: *E. coli* O157:H7 has been shown to proliferate in moist feeds	Surface or incorporated – 300 days or more	Feces of carrier cows – 159 days Slurry 10°C 132 days 20°C 57 days 30°C 13 days	Pasture 91 to 231 days

From: JIFSAN GAPs Train the Trainers Manual

Survival depends on:

- Temperature (5C=41F; 22C=72F; 37C=99F)
- Environmental medium
- Water availability

Current Manure Standards

- National Organic Program

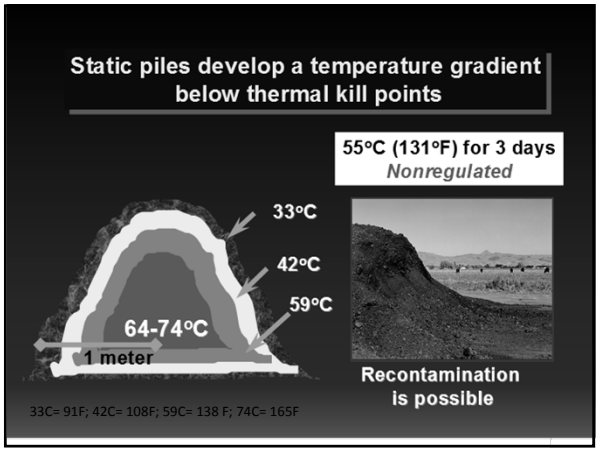
Manure	Contact	Time Interval
Untreated	Contact	120 days
Untreated	Non-contact	90 days

- Must incorporate the manure within two weeks of application (NOP Std. not Nutr. Mgt.)
- Earlier FDA FSMA proposal was modified to NOP

Compost vs. Manure

Unless the compost has been produced under very strictly regulated circumstances then treat it as manure

Maintain a Compost Log …
(if you don't write it down; it didn't happen)



Compost

Active composting "rules":
- Compost must heat up to 131˚F -- 170˚F for 15 days
- Compost must be turned 5 times during the process
- C:N ratio between 25:1 and 40:1

Amendment	Contact	Time Interval
Composted	Contact	0 days
Treated by physical or chemical means	Contact/no contact	0 days

Questions?

Maryland Department of Agriculture

Agriculture | *Maryland's Leading Industry*
Office of Marketing, Animal Industries and Consumer Services

Larry Hogan, Governor
Boyd Rutherford, Lt. Governor
Joseph Bartenfelder, Secretary
Mary Ellen Setting, Deputy Secretary

The Wayne A. Cawley, Jr. Building
50 Harry S. Truman Parkway
Annapolis, Maryland 21401
Internet: www.mda.maryland.gov

410.841.5700 Baltimore/Washington
301.261.8106 Washington, D.C.
800.492.5590 Toll Free

FOOD QUALITY ASSURANCE PROGRAM

(410) 841-5769 FAX (410) 841-2750

Good Agricultural Practices (GAP) Resources for Fruit and Vegetable Producers

Maryland Department of Agriculture

Deanna Baldwin
Food Quality Assurance, Program Manager
50 Harry S. Truman Parkway
Annapolis, MD 21401
410-841-5769
Deanna.Baldwin@maryland.gov
http://mda.maryland.gov/foodfeedquality/Pages/good_ag_practices.aspx

Agreement with USDA to provide GAP auditors for the USDA GAP and Harmonized Standards Program
Worker Hygiene Training Materials – DVDs and signs – Provided at no charge to Fruit and Vegetable Producers
Cost share for USDA GAP and Harmonized audit costs
Cost share for implementation of GAP practices (Limited funds available)
GAPs Training
MDA GAPs for Direct Marketers

University of Maryland

Justine Beaulieu
2125 Plant Sciences Building
College Park, MD 20742-4452
301-405-7543
jbeauli1@umd.edu

Donna Pahl
2174 Plant Sciences Building
College Park, MD 20742-4452
410-440-2047
dpahl@umd.edu

Christopher S. Walsh
2102 Plant Sciences Building
College Park, MD 20742-4452
301-405-4351
cswalsh@umd.edu

David Martin
University of Maryland Extension
1114 Shawan Road
Cockeysville, MD 21030
410-887-8090
dmarti@umd.edu
GAPs Training and Resources
Assistance to fruit and vegetable producers with writing Food Safety Plans

Larry Hogan, Governor
Boyd Rutherford, Lt. Governor
Joseph Bartenfelder, Secretary
Mary Ellen Setting, Deputy Secretary

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USDA
http://www.ams.usda.gov/AMSv1.0/gapghp

USDA GAP Audit Checklists, Guides to USDA Audits
Lists of Producers USDA GAP Certified
FDA's Guide to Minimize Microbial Food Safety Hazards

National GAPs Program
http://www.gaps.cornell.edu/

GAPs Training
Downloadable record keeping forms
Links to GAPs Information
Educational Materials

UMass GAPs Food Safety Manual
http://www.umassextension.org/nutrition/index.php/programs/food-safety/programs/good-agricultural-practices/gap-manual

Record keeping forms
Guide to developing a food safety plan
Examples of food safety plans for download and use

Washington State GAP/GHP Audit Verification Program
http://agr.wa.gov/inspection/fvinspection/docs/GHP_GAP_Presentation.pdf

Section-by-section briefing of the USDA GAPs audit form
How to prepare for a food safety audit

Maryland
Department of Agriculture

Agriculture: *Maryland's Leading Industry*
Office of Marketing, Animal Industries and Consumer Services

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FOOD QUALITY ASSURANCE PROGRAM

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MDA GAP Program

The Maryland Department of Agriculture has developed a food safety program for direct marketers of fresh fruit and vegetables. The program is designed to minimize the risk of microbial contamination through good production practices and is based on guidance developed by the US Food and Drug Administration.

Program Requirements

1. Attend an approved GAP training program. MDA and the University of Maryland are offering producer training sessions. Other University and/or State Department of Agriculture GAP training programs are acceptable, as are online trainings offered by these institutions. Watch for upcoming trainings at:
http://www.gaps.cornell.edu/eventscalendar.html
www.mda.state.md.us

2. Complete a self assessment using the National GAPS Program Self Assessment or the Direct Marketers Self-Audit. The National GAPs program Self-Assessment can be found at http://www.gaps.cornell.edu/farmassessmentws.html.

3. Develop a written food safety plan that addresses any risks identified in the self assessment. Assistance in developing the plan is available through a joint project of MDA and the University of MD. For assistance, contact Donna Pahl, 2176 Plant Sciences Building, College Park, MD 20742-4452, 301-405-4372, dpahl@umd.edu.

4. Implement the food safety plan.

5. Contact MDA's Food Quality Assurance Program at 410-841-5769 or baldwiDL@mda.state.md.us to schedule an inspection to verify the plan adequately addresses food safety risks and has been implemented. USDA Specialty Crop Grant funds will be used to cover the entire cost of the inspection.

6. MDA will issue a Certificate of Compliance to producers that pass the inspection. A list of producers that have been issued a Certificate of Compliance will be maintained on MDA's website – www.mda.state.md.us.

Maryland
Department of Agriculture

MDA Good Agricultural Practices (GAPs) Inspection Report

Review Date _____

Farm Name
Location Address
City, State, Zip
Person Responsible for Overseeing GAPs

What high-risk crops are grown on your farm?
Leafy greens, tomatoes and melons are thought to be the high-risk crops. Other uncooked crops can also pose a risk.

_____

_____

Does the farm have a written GAP/GHPs plan that addresses the requirements of the program?

☐ Yes ☐ No

Documentation: *Note that audit points 1, 9, 12, 13,15,19, 21(optional), 30, 33, 34, 35, 41, and 42 require documentation. This is shown as "Doc" in bold on the audit. The type of documentation required is explained under each corresponding statement. Example logs can be found on the Cornell National GAPs website (www.gaps.cornell.edu).*

Farm and Field Section

Workers

1. Training on proper sanitation and hygiene practices is given to all staff and family.
   ☐ Yes ☐ No ☐ **Doc**

   Showing the Cornell Health and Hygiene video, and having workers sign a log after seeing it will be adequate.

2. Employees are following good hygiene/sanitation practices, including washing hands after eating and when using the bathroom, and before or when returning to work.
   ☐ Yes ☐ No

3. Signs are posted in bathrooms to remind workers of hand-washing and sanitation practices.
   □ Yes □ No

4. All toilet/restroom facilities are cleaned on a scheduled basis. They are supplied with paper towels, toilet paper, hand soap, and potable water.
   □ Yes □ No

5. Smoking and eating are done in designated areas, separate from where food is grown and handled.
   □ Yes □ No

6. Sick workers (with diarrheal disease or symptoms of other infectious diseases) are kept from handling fresh produce.
   □ Yes □ No

7. There are procedures in place for dealing with produce or food contact surfaces that have come into contact with bodily fluids. All workers follow these procedures.
   □ Yes □ No

8. Workers are required to seek treatment for cuts, abrasions, and other injuries.
   □ Yes □ No

9. Pesticide applicators applying restricted materials must have a pesticide applicator's license or work under the supervision of a licensed applicator.
   □ Yes □ No ☐ **Doc** □ N/A, we do not use restricted materials.

   Make a copy of your pesticide applicator's license to include in the plan.

10. If field sanitation units (ex: porta-potties) are used, they are placed in a location accessible to workers, and are not placed in crop production areas, and measures are taken to reduce the possibility of contamination.
    □ Yes □ No □ N/A, we do not use portable toilets.

    An example distance would be having porta-potties placed at least 30 feet from fields.

11. Procedures are in place in the event of a spill or leak of field sanitation units or toilet facilities.
    □ Yes □ No

Maryland
Department of Agriculture

Water

12. Water tests for *E. coli* have been completed for each water source. If test results are undesirable, sufficient mitigation tests have been taken.
    □ Yes □ No ☐ **Doc**

    Water test results should be attached. Mitigation steps include treating pond with potassium permanganate, using sand filters, allowing time barrier between the application of water and harvesting crop, shocking the well, using chlorine injectors or using a different irrigation method.

    List the water sources and type of irrigation you use on your crops, and what crops they are used on:

    _____

    _____

    _____

    Water testing guidelines
    Water testing frequency:
    Surface water source test: 3 times a season (at first use, peak use, harvest).
    Well water tests: once a season (at first use).
    Municipal: at least once a season, records obtained from county.

    Water test results:
    Contact water: Average should be less than 126 cfu/100ml water.
    One sample is allowed to be 235 cfu/100ml water.
    Contact water includes irrigation methods where water will touch the crop, such as sprinkler/overhead irrigation, frost protection, etc.

    Noncontact water: Average should be less than 126 cfu/100 ml water.
    One sample is allowed to be 576 cfu/100ml water.
    Noncontact water includes irrigation methods where water does not touch the crop, such as drip/furrow irrigation.

13. Potable (drinkable) water is available to all workers.
    □ Yes □ No ☐ **Doc**

    Include a copy of any water tests for potable water sources. There should be one test done at the beginning of each year.

14. A water quality assessment has been performed to determine the quality of water used for irrigation purposes and frost/heat protection on the crops being applied.
    □ Yes □ No

The water quality assessment should address type of irrigation used, water source, and risks associated with each practice.

15. Potable water is used for the application of pesticides and other chemical materials on crops.
    □ Yes □ No ☒ **Doc** □ N/A, pesticides and chemicals are not applied

16. Steps are taken to prevent the contamination of irrigation water (from direct or indirect sources).
    □ Yes □ No

    These steps may include preventing runoff with fecal matter to water sources in low-lying areas, having the septic system and wells located a reasonable distance from each other, and ensuring that the well casing and cap are secure, among others.

17. If land has been flooded with potential fecal contamination, the field is considered adulterated and is not harvested.
    □ Yes □ No □ N/A, land has not been contaminated or flooded.

    According to the FDA, produce flooded with fecal contamination is "adulterated", and must be thrown out. Any later plantings are fine (for example, if a field is flooded in July, a fall crop can still be planted and is considered fine).

Animals

18. Crop production areas are not located near manure lagoons, manure storage or animal production areas. If so, barriers exist to prevent contamination from those areas.
    □ Yes □ No □ N/A, we have no manure lagoons, manure storage, or animal areas.

    Barriers may include a grasser buffer strip, keeping crop fields/packinghouses uphill from animals, keeping animal production areas a distance from crop fields, and not planting high-risk crops near these areas.

19. Crop production areas and agricultural water sources are monitored for signs and presence of wild and domestic animals. Reasonable measures are taken to prevent animals from entering the fields and water sources.
    □ Yes □ No ☒ **Doc**

    Keep a log of animal (both domestic and wild) activity seen in fields. Reasonable measures of animal prevention include traps, kill permits, propane canons, etc.

20. If animal feces are found in fields, steps are taken to reduce contamination.
    □ Yes □ No

    This may include walking the fields before harvest and flagging fecal contamination. During harvest, crops are not picked within a specified radius of fecal matter.

21. **Fertilizer Type (check the option that applies, then answer questions under that option)**

□ *Option A: No Manure/Compost is Used*

a. No manure or compost is used.
   □ Yes □ No

b. Only synthetic fertilizers are used.
   □ Yes □ No

□ *Option B: Raw manure*

a. If raw manure is used, it is incorporated into the soil at least 2 weeks before planting and is applied 120 days before harvest (90 days for crops that do not touch the ground).
   □ Yes □ No □ **Doc**

b. Manure is stored properly prior to use, with efforts made to reduce contamination into crop production areas.
   □ Yes □ No

□ *Option C: Composted Manure*

a. Only composted manure is used as a soil amendment.
   □ Yes □ No

b. Composted manure is properly treated and composted.
   □ Yes □ No □ **Doc**

   A log needs to be kept of date, temperature, and how often compost is turned.
   Proper composting includes: Carbon to Nitrogen ratio of 25:1 – 40:1.
   Compost reaching temperatures between 131°F -- 170°F for at least 15 days.
   Turned 5 times during the process.

c. Composted manure is properly stored, so that contamination to fields is minimized.
   □ Yes □ No

d. If compost or treated manure was bought, a certificate of competence is included from the manufacturer.
□ Yes □ No ☒ **Doc** □ N/A, compost was not bought.

Field Harvesting and Transportation

22. If the farm history has been something other than agricultural for the past 3 years, it is explained in the plan. Previous potential land-use risks have been assessed and mitigated.
□ Yes □ No □ N/A, the farm has been agricultural for over 3 years.

23. All harvesting containers and bulk hauling vehicles that have direct contact with crops are cleaned and/or sanitized on a scheduled basis. Measures are taken to remove excess dirt and mud from produce and containers during harvest. Damaged containers are properly repaired or disposed of.
□ Yes □ No

24. All hand harvesting equipment and implements (such as knives, pruners, etc) are kept as clean as practical and are disinfected on a scheduled basis.
□ Yes □ No □ N/A, no hand harvesting equipment is used.

25. Harvesting equipment and/or machinery that comes into contact with the product is in good repair.
□ Yes □ No □ N/A, no machinery comes into contact with the product.

26. Light bulbs and glass on harvesting equipment are protected, so that produce is not contaminated if one breaks. If anything breaks, a procedure is set for cleanup and disposal.
□ Yes □ No □ N/A, no light bulbs or glass are over the produce.

27. If crop contamination by chemicals, petroleum, or pesticides occurs, there is a cleanup procedure.
□ Yes □ No

28. If crops are mechanically harvested, the crop is inspected at harvest for glass, metal, rocks, and other foreign items.
□ Yes □ No □ N/A, crops are not mechanically harvested.

29. Harvesting containers and baskets are not used for carrying/storing non-produce items.

□ Yes □ No

30. Water applied to the harvested product is potable.
□ Yes □ No ☐ **Doc** □, N/A, no water is applied to the harvested product.

Records for this water source may already be included, if source is used for drinking water or irrigation.

31. Transportation equipment for moving crops is clean and in good repair.
□ Yes □ No

32. Containers used in field pack operations are stored under cover and are protected from contamination.
□ Yes □ No

Packing House and/or Storage Area

33. Any water and ice used in the packinghouse or for storage is potable.
□ Yes □ No ☐ **Doc** □ N/A, no water or ice are used in the packinghouse or for storage.

Records may already be included. If the ice was purchased, include a receipt.

34. If dump tanks are used, or water is reused, the water needs to be treated to reduce microbial contamination. If not, alternative mitigation steps are in place.
□ Yes □ No ☐ **Doc** □ N/A, dump tanks are not used.

This may include treating with bleach at a rate of 50-200ppm (or up to 4ppm for organic production). If a sanitizer is used, the ppm, water temperature, and water pH (between 6 -7.5) must be monitored and recorded. This allows for maximum effectiveness of the sanitizer in reducing microbes.

35. Any surfaces that contact water or the crop during packing, storage, and transport (packing lines, dump tanks, flumes, coolers, trucks, etc.), are cleaned and sanitized on a scheduled basis.
□ Yes □ No ☐ **Doc**

Include a log of when cleanings occur.

36. Product flow zones are protected from contamination. Any glass materials over product are contained, and pipes, fans, and the ceiling above product are clean.
    □ Yes □ No

37. Only food-grade materials and chemicals are used on the packing equipment. Chemicals not approved are stored away from the packing area.
    □ Yes □ No □ N/A, no chemicals are used on the packing equipment.

38. The packing house and storage area is reasonably clean, free of litter and standing water.
    □ Yes □ No

39. Worker's break facilities are located away from the product and packing area. No eating, smoking, etc. are done at the packing line.
    □ Yes □ No

40. Pallets and containers are cleaned on a scheduled basis.
    □ Yes □ No

41. Measures are taken to exclude animals and pests (such as flies, pets, rodents, and birds) from storage and packing facilities. The pest control program is explained in the food safety plan, and a log is kept for pest sightings and kills.
    □ Yes □ No ☐ **Doc**

    Various measures can be taken to control pests: mouse traps (sticky, snap traps, and reusable claw traps), live traps, sticky fly traps, and bird deterrents. Poison traps may only be used on the outside of the packinghouse, where contamination to produce cannot occur.

42. The temperature of any climate-controlled rooms and areas (such as coolers) are monitored and recorded on a scheduled basis.
    □ Yes □ No ☐ **Doc** □ N/A, we have no climate-controlled rooms.

    A log should be kept with the date and cooler temperature.

43. Produce is not loaded or stored with potentially contaminating products. Trucks and any means of transportation are thoroughly cleaned before hauling produce.
    □ Yes □ No

Maryland
Department of Agriculture

Audit Summary

Immediate Action Required

The following conditions will result in an **automatic failure**. In order to pass, the grower will correct the unsatisfactory points and have the auditor come out at a later date.

- Having no documented and written food safety program that incorporates Good Agricultural Practices.
- The presence of rodents, an excessive amount of insects and other pests during packing, processing, or storage, and/or other gross unsanitary practices.
- Having a "No" answer for any of the following audit points:
    - 1. Training on proper sanitation and hygiene practices is given to all staff and family.
    - 12. Water tests for *E. coli* have been completed…
    - 17. If land has been flooded with potential fecal contamination…
    - 21, option A, a.: If raw manure is used, it is incorporated into the soil….
    - 21, option B, b.: Composted manure is properly treated and composted.

Corrective Action Necessary

This section refers to any of the audit points not listed in the above "Immediate Actions Required" section. By themselves, a "No" answer to these audit points **does not result in an audit failure**, but may require some attention. The auditor will fill out the suggestions for compliance below.

Suggestions:

Auditor Signature: _____ Date: _____

Grower Signature: _____ Date: _____

_____ Food Safety Plan

(*Farm name)*

DRAFT

This is a food safety and security plan which incorporates Good Agricultural Practices and has been accepted and adopted by this farming operation.

Farm name: _____

Farm address: _____

_____

Date: _____

This food safety program is for the following produce (*list all high-risk crops)*:

_____

_____

_____

There is a designated coordinator for implementation and oversight of this farm's food safety program.

Coordinator name: _____

This food safety program is supplied to all staff and is available to all visitors.

**Include a map of your farm (printed from Google Maps or obtained from your county extension office. The purpose of this map is to lay out the farm and facilities in a visual way for the auditor. On the map, label all:*

Bathrooms and hand washing facilities

Water sources: Wells, surface water sources (used or not)
Packing house
Anything else of importance (house, septic field, etc.)

Food safety is very important to this farming operation. This food safety policy is part of the effort of this farming operation to produce a healthy and safe product.

Farm and Field Section

Workers: Hygiene, Safety, and Illness

Staff receive training on proper sanitation and hygiene practices through watching the Cornell "Health and Hygiene on the Farm" video. All workers are trained on proper hand washing. Workers are instructed (and expected) to wash hands before starting work, after each absence work (such as after the bathroom), and when hands become soiled or contaminated. **After watching the video, all staff members sign a sheet confirming that they have been trained. The log is attached**. All staff are instructed and expected to remove unsecured jewelry before work. *Optional:* [All employees and all visitors to the farm/packinghouses are required to follow this unsecured jewelry policy].

_____ (*What kind of water? It should be potable)* is available to all workers and is verified by testing, according to USDA GAP requirements. The water available to workers is from _____ (*Water source)* and is tested _____ (*How often per year is it tested?),*_____ (*What time of the year?)*. **Results are included in this binder**. *At minimum, wells should be tested 1x per year at the beginning of the season. Ponds/springs/surface water should be tested 3x per year, at spring, summer, and fall.*

This farm provides at least _____ (*Number)* toilet and _____ *(Number)* hand washing facility for employees (*There should be 1 per 20 employees)*. It is located _____ (*Where is your bathroom located?).* **The location can be found on the farm map.** Lavatories have hot and cold running potable water, hand soap, and single use towels. These facilities are clean, well-maintained, and have proper signage instructing employees to wash their hands before beginning or returning to work. These facilities are serviced and cleaned on weekly or more often as needed, on a regular basis. All septic systems are in good working order. All employees and visitors to the farm are required to follow proper sanitation and hygiene practices.

Optional: [If field sanitation units are required (*does your farm have more than 10 workers on a given day?),* the number and placement of units will comply with applicable state and federal regulations. Field sanitation units will have the same supplies as permanent toilet facilities.

These field sanitation units will be cleaned and serviced on a _____ *(How often? Weekly?)* basis (or more frequently if needed), and will be in a location that minimizes the potential risk for produce contamination. Field sanitation units are located _____ (*Where? On the periphery of the field? Shouldn't be in the production field).* **Units are accessible for servicing, and service records are in this binder.**]

Should a toilet or field sanitation unit leak or spill, workers will cease operation immediately. Any affected produce will be disposed of by _____

(*How will leaks be handled? How will produce be disposed of?)*. All effort will be made to insure the contaminated produce does not enter the food chain. Workers are instructed and expected to report such leaks and spills to their supervisors.

There is no eating or chewing food, no chewing gum, no using tobacco, and no drinking beverages in the areas while produce is being handled. Any drinking water near production areas is kept in spray rows or outside the field.

Workers are excluded from working if they have diarrhea, an illness or open lesion (such as a boil, sore, or infected wound), or if _____

_____ (*other examples)*. Workers are instructed and expected to report such health conditions to their supervisors.

Should workers become injured on the job, they must seek first aid help. Injuries include cuts, abrasions, or other injuries. A first aid box is present and available for staff use, _____

_____ (*Where?)*. Workers are instructed (and expected) to report injuries to their supervisor. Should produce or food handling contact surfaces touch blood or bodily fluids, workers will cease operation immediately. The contaminated food contact surfaces must be thoroughly cleaned a disinfected with

_____

_____ (*What do you use? Bleach?).* Any affected produce will be disposed of by _____

_____(*How?).* All effort will be made to insure the contaminated produce does not enter the food chain.

Water

Irrigation on this farm is done with _____

_____ (*What type of water is used for irrigation? You may list several sources).* Irrigation methods include _____

_____ (*Sprinklers, drip, etc). Explain the type of irrigation that you do for each crop (example: tomatoes are drip irrigated with pond water. Sweet corn is irrigated by sprinklers with well water). Think about the risks involved with each type of irrigation. If your water tests high for E. coli, is there any mitigation step or alternative water you can (or do) use?* _____

_____

Our farm is located about _____ *(*number) miles from any sewage treatment facilities, waste material landfills, and fowl, feedlot, or livestock production facilities. All reasonable effort is made to keep livestock (mine and others) and wild animals farther than 200 feet from water sources used for irrigation, to minimize potential contamination to the water source. _____ *(How is that that done? If you don't keep them 200 feet away, change the number – 50? 100?) Are there any ways that you prevent the contamination of irrigation water?*

_____

_____.

The land used by this farming operation has not been flooded with potential fecal contamination. *If it is, are there any steps you have taken (or can take) to minimize contamination?* _____

_____ *(let lay fallow a few months, etc).*

On this farming operation, pesticides, growth regulators, and fertilizers are applied by licensed operators and are compliant under WPS. **The pesticide application license can be found in this binder.** Potable water is used for applying pesticides and a pesticide logbook is properly maintained. On the farm, chemicals are stored _____

(*Where are the chemicals stored? Draw it in on your map).*

Animals

The farming operation is such that wild or domestic animal entry into crop production area is infrequent. **Crop production area is monitored for signs of the presence of wild or domestic animals, and the logs are attached in this binder.** Should it become necessary, active measures to deter entry include

_____
_____ (*How do you deter animals in the field?).* Any repellants would not be placed in the production field. If we see fecal matter in fields, we take steps to reduce contamination. These steps include:

_____

_____ (*flagging and not picking within 2 ft or another certain radius?).*

Animal production areas on the farm are located _____ (*above? Adjacent to? Below? How are away?)* from produce production areas. Produce areas are protected from contamination.

Manure lagoons are well maintained to prevent leaking or overflowing. Should lagoons be located near or adjacent to crop production areas, adequate measures are in place to insure that runoff will not contaminate crop production areas. These measures include _____.

The land used by this farming operation has not been used to dump livestock bodies or other waste. *If it has, how do you prevent contamination?*

_____

_____*(Length of time, barrier, have land tested for microbes).*

Fertilizers

Pick one of the following:

Option A – Synthetic Fertilizer Use

Raw manure or compost is not used as a soil amendment on this farm. Instead, synthetic fertilizers are used. *If you use some other form of fertilizer, what do you use?*

_____

_____ . When not in use, fertilizer is stored
_____.

Option B – Manure Use

Manure is used on this farm *(where -- produce crops? Field crops?)*. Before use, manure is properly treated, composted, or exposed to environmental conditions that lower the expected level of pathogens and proper documentation is kept. Manure is incorporated at least 2 weeks prior to planting, and a minimum of 120 days prior to harvest for high risk crops (sweet corn – 90 days). **All rates, dates, and locations of raw manure applications are documented, and included in this binder.** No side-dressing of manure is allowed. (*Piled manure or plant material that is not done by a regulated composting process is considered manure!)*

Manure (or biosolids) are stored on this farm before use. Manure is stored
_____
(*where do you store manure?). Manure should be stored with a barrier or some sort of containment system, so that contamination to crop production areas does not occur.* If manure is stored near crop production areas, contamination is prevented by
_____

_____(*How is contamination of crops and equipment prevented, as well as rodent contamination avoided?).*

Option C – Compost Use

Compost is used on this farm. In order to be considered compost, the product needs to be composted/treated with recommended practices. These practices are
_____

_____. **Documentation of these practices are attached in this binder.** Until the composting treatment is finished, the product is stored _____. Measures are taken to prevent contamination of production areas with unfinished compost. These measures include _____.

Field Harvesting and Transportation

Produce Handling

All tables, baskets, totes, hand harvesting implements (clippers) _____ (*What else do you use for picking?)* are cleaned and/or sanitized prior to use. Sanitation and cleaning is done by

_____

_____(*How do you sanitize your supplies? Chlorine water rinse, air spray, etc? How often?) Example: Sanitation and cleaning is done on a scheduled basis or when noticeable dirt/debris is observed.* Workers are instructed (and expected) that harvesting containers, totes, etc are not used for carrying or storing non-produce items. Damaged or soiled containers will be properly repaired or disposed of. No hazardous material containers will come into contact with produce. Heavily soiled containers will be cleaned _____

Produce containers are stored _____

_____ (*where do you store your containers?)*, under cover so that they are protected from contamination.

_____ (*When, How?)*. Harvesting equipment and/or machinery that comes into contact with produce will be kept as clean as is practical and will be in good repair. *The harvested product will be covered when moved from field to storage areas and/or processing plants.*

If glass breaks on harvesting equipment, workers will stop immediately. Affected produce will be disposed of _____ (*How?).* Effort will be made to insure that contaminated produce does not enter the food chain. Workers are instructed to report breakage to their supervisors.

Contamination by chemical, petroleum, pesticide, or other contaminants is a serious matter. If contamination occurs, workers should stop immediately. Any affected produce will be disposed of _____ (*How do you clean up the produce and the area?).* Workers are instructed and expected to report such contamination to their supervisors.

The crew will regularly inspect the harvested produce. Any foreign object (glass, metal, rock or other matter) will be removed. Workers are told to report contamination to their supervisors. *If crops are mechanically harvested, the crop is inspected at least once for foreign items.*

As much dirt and mud (as is practical) are removed from the produce outside the packing facility. _____ (*How is this done?)*.

Trucks and any other equipment hauling produce are to be washed prior to being used (and loaded with produce) and are kept clean while in use.
_____ (*How do you keep trucks clean? Washing them out? Sweeping?).*

House packing facility

All non-food grade chemicals and lubricants will be stored away from the packing area. The packing area should be neat, clean, and enclosed as much as possible. The packing facility grounds should be free of litter, debris, and standing water. All glass over the product flow zone should be non-breakable or covered.

Product will be covered when moving from storage or field to packing area. All product is properly handled to prevent contamination prior to packing. All processing water to manufacture ice, and in wash lines, dump tanks, flumes, and product contact surfaces is potable, as determined by water tests from the _____ (*Water source?*). **Test results are included in this binder.** To prevent contamination between produce, reused water in dump tanks and flumes are sanitized and monitored for temperature, sanitizer strength, and pH. *What type of sanitizer, if any, do you use in dump tanks, wheelbarrows, etc?*
_____

_____**Water monitoring logs are included in this binder.** Any produce that comes in contact with the floor will be disposed of. Manufacturing equipment and containers and all processing lines are cleaned and sanitized on a _____ (*daily, weekly, never)* basis and documented. _____

_____ (*How do you sanitize the equipment? Powerwashing and chlorine solution?)* **Documentation is included in this binder.**

The packing and storage facilities are maintained so that loose insulation and other materials are not protruding from the walls, and cracks are filled in as possible. The facility is well maintained and kept free of debris and soil, when possible. Mechanical equipment used in storage is cleaned and maintained. The storage area is inspected _____ (*How often*), and any foreign materials are removed before loading with produce. Non-food grade substances are not to be stored in close proximity to the produce.

Any product flow zones, or areas where produce is handled or stored, are protected from contamination. Glass materials are contained or made of shatterproof glass. *This includes lights, etc.*

Employees on break use designated lunch/break areas. _____

_____ (*Where do your employees eat/smoke/drink during breaks?)* No consuming of beverages or food and no tobacco use occurs in production areas. All employees shall follow written guidelines regarding wearing jewelry and hair/beard nets. _____ (*What is your jewelry policy? Do you require hair/beard nets? Probably not, unless you are producing ready-to-eat foods).*

Only food-grade lubricants are used on all food contact equipment during the processing line.

No domestic or wild animals are allowed in the packing area. Proactive measures are taken to exclude pests or animals from packing and storage facilities. Pest exclusion methods include

_____

(*How do you exclude pests? Measures may include bird tape, screens, traps, etc).* The storage facilities are sufficiently sealed or isolated so they are protected from external contamination, such as wandering animals. Dogs, cats, or other domestic animals are not permitted inside the packing and storage facilities. A pest control log is maintained that indicates pest sitings, trap inspection dates and catches. *How often do you check the pest traps?* _____ **The pest control log is available in this binder.** Only traps or nonpoisonous baits are allowed inside the facilities, if they are needed. Any area where bait or traps are set out or areas routinely affected will be frequently monitored.

Containers, pallets, storage, and transport

Pallets, pallet boxes, totes, bags, bins, storage rooms, packing containers, and _____ are kept clean, stored properly and protected from contamination by birds, rodents, pests, soil, water, and other contaminants (where appropriate). _____ _____ (*How do you clean your harvesting containers, etc? how often?).* Dirty containers will not be used and broken pallets will be repaired.

_____

_____ *(Once produce is harvested how do you treat it? Where is it taken? Ex: The harvested product is not expected to be stored out of doors in totes, trucks, bins, or other containers, or in bulk on the ground).* Should the harvested product be stored out of doors, it will be covered to protect it from contamination.

Any equipment used for hauling the produce is kept in good condition (such as being clean and odor-free). Trailers and equipment are inspected before produce is loaded. Fertilizers, pesticides, meat, poultry, fish and other products are not mixed in with produce handling and transport. When produce is loaded into the trailer, damage and contamination are minimized. If load shifting is an issue, care is taken to prevent it.

(If) ice or cold water is used for cooling the produce, the water source must be potable and the ice/cold water is manufactured, transported, and stored under sanitary conditions. The ice production and storage facilities are regularly cleaned and sanitized by _____ (*How?)*. Sanitary conditions are maintained in all areas where ice is manufactured, transported, or stored. _____ (*If ice is not used on you farm, where do you cool produce? Refrigerated facilities, not refrigerated until sold at markets?)*

(*If)* refrigeration systems are used to store produce, the temperature should be maintained at the recommended temperature, _____ (*What temperature?).* **This temperature should be checked regularly and recorded in a log, which is attached to this binder.** The thermometer used to take the temperature is checked for accuracy _____ (*How often?).*

*This sample plan was adapted from a NY extension doc.

Documentation for the MDA GAPs Audit

Included in this packet are sample logs that may be used for documenting compliance with the MDA GAPs audit. These exact logs do not have to be used, they are provided as samples.

Note that this does not cover all documentation; records are still required for the following audit points:

9. Pesticide applicators license.

13, 15, 30, 33. Water quality test results.

*The logs and records in this packet have been adapted from the Cornell National GAPs program.

Worker Training Log

Name of operation: **Date:**

Trainer:

Training material (Please attach any written materials to this log with a staple):
Please see the food safety plan for overall Worker Training procedures.

	Employee Name (please print)	Employee Signature
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		

Reviewed by: Title: Date:

***Pertains to Question 1 on the MDA audit.**

Surface Water Testing Log

Name of operation:

Please see the food safety plan for overall information on surface water testing.
Save any document providing information on test methods and test results from your laboratory.

Date	Surface water location/name	Laboratory	Results	Corrective actions if necessary	Initials

Reviewed by: Title: Date:

***Pertains to Question 12 in the MDA audit.**

Field Pest Monitoring Log

(examples may include deer, groundhogs, birds, rodents, rabbits, etc.)

Date	Field	Crop Grown	Type and # of Animals	Control Taken

***Pertains to Question 19 on the MDA GAPs audit.**

Manure Applications log

Name of operation:

Please see the food safety plan for overall manure application procedures.

Date	Field Applied	Rate	Manure Type	Incorporated (Yes or No)	Supplier	Crop Planted (Type and Date)	Crop Harvested (Date)	Initials

Reviewed By: Title: Date:

***Pertains to Question 21, option B, a. in the MDA audit.**

Packinghouse Water Treatment Log

Name of operation:

Please see the food safety plan for overall water treatment procedures.

Date	Water pH Level	Type of Chemical Used	Amount Added	Type of Produce Being Run	Initials

Reviewed by: **Title:** **Date:**

***Pertains to Question 34 on the MDA audit.**

Processing / Packing Line Log

Name of operation:

Please see the food safety plan for overall processing/packing line water control procedures.

Date	Cleaning List (check each)					Date Cleaned	Treatment	Cleaned By (name)
	Contact Surface	Dump Tanks	Flumes	Wash Tanks	Hydro Cooler			

Reviewed by: Title: Date:

*** Pertains to Question 35 on the MDA audit.**

Pest/Rodent Control Log (in the Packinghouse)

Name of operation:

Please see the food safety plan for overall Pest/Rodent control procedures.

Company Used* or self	Date of Service or action taken	Type of Pest	Type of Control**	Location of Traps	Traps Checked (date)	Checked by (name)	Disposal means

*If using a company for service, attach report or receipt of service for each of their visits.
**List type of control methods used such as exclusion, traps, poison, repellants, etc.

Reviewed by: Title: Date:

***Pertains to Question 41 on the MDA audit.**

Cooler Temperature Log

Name of operation: **Date of Thermometer Calibration:**

Cooler number: **Thermometer number:**

Please see the food safety plan for overall temperature control procedures and thermometer calibration instructions

Date	Thermometer calibrated date	Recorded temperature		Corrective actions if necessary:	Result of corrective actions and date accomplished	Initials
		AM	PM			

Reviewed by: Title: Date:

***Pertains to Question 42 on the MDA audit.**

A note on calibration of your thermometer

This information on thermometer calibration is brought from “Food Store Sanitation”, 1998, Sixth Edition, Gravani, Robert B., Rishoi, Don C., Cornell University Food Industry Management Distance Education Program, Lebhar-Friedman Books, Chain Store Publishing Corp.

Melting point of ice method

1. Place ice in a container and let it melt.
2. Stir to make sure that the temperature in the ice/water mixture is uniform throughout the container.
3. When the ice is partially melted and the container is filled with a 50/50 ice and water solution, insert the thermometer and wait until the needle indicator stabilizes. The thermometer should be 32ºF (0ºC).
4. If the thermometer is not reading 32ºF (0ºC), it should be adjusted by holding the head of the thermometer firmly and using a small wrench to turn the calibration (hex) nut under the head until the indicator reads 32ºF (0ºC).

An important item to remember as you are calibrating your thermometer using the melting point of ice method is to never add tap water to ice because this will *not* be 32ºF (0ºC) but will be at a higher temperature. The calibration will be much more accurate if you use melting ice.

Food Safety Modernization Act

PRODUCE SAFETY RULE

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Deanna Baldwin
Program Manager, Food Quality Assurance

The Food Safety Modernization Act (FSMA)

- FSMA includes:
  - **Produce Safety Rule**
  - Preventive Controls for Human Food
  - Preventive Controls for Animal Food
  - Foreign Supplier Verification Programs
  - Accreditation of Third-Party Auditors/Certification Bodies
  - Sanitary Transportation of Human and Animal Food
  - Prevention of Intentional Contamination/Adulteration
- Focused on prevention of food safety issues – Farm to Fork

Produce Rule Five Year Cooperative Agreement with FDA

- FDA has recognized regulation of the growing and harvesting of produce is different than regulation of manufactured food
  - Most Health Departments that conduct manufactured food inspections are not familiar with agricultural practices
  - Regional differences in available water, climate and growing practices
  - State Departments of Agriculture know regional differences and agricultural practices
- FDA requested proposals for the states to enter into an agreement to provide a “State Produce Safety” Program

Maryland Produce Safety Program

- MDA was awarded a funded agreement with FDA to develop and implement a "Maryland Produce Safety Program"
  - FDA oversight
    - Ensure that MDA's Program is equivalent to the federal rule
  - Must meet the same standards as the FDA Produce Safety Rule
  - MDA has partnered with University of Maryland Extension, University of Maryland Plant Sciences and University of Maryland Agricultural Law Initiative to develop and implement the Program

Produce Rule Five Year Cooperative Agreement with FDA

- Inventory - MDA
  - Used to determine resources needed for training, technical assistance, and inspection
  - MDA required to share information with FDA
    - Information on sales and other commercial confidential information will not be released under Maryland Public Information Act
  - Growers can expect mailings from MDA requesting:
    - Contact information for the farm
    - Information that would establish categories (exempt, qualified exempt, fully covered) and compliances dates for the farm
      - Gross sales of Food
      - Types of Crops (Potatoes vs. Tomatoes)
      - Crops destined for further processing with pathogen reduction step

Produce Rule Five Year Cooperative Agreement with FDA

- Outreach Activities – MDA, UMD, UME
- Make Maryland produce growers aware of the Produce Rule and Resources available
  - MDA website FSMA page http://mda.maryland.gov/fsma
  - Mail and email informational flyers to farmers
  - Training for Extension Agents
  - Presentations at Grower meetings

Produce Rule Five Year Cooperative Agreement with FDA

- Education, Training, Assistance
  - MDA, UMD, UME
  - Provide formal and informal training
    - Produce Safety Alliance Curriculum
    - Supplemental training to assist with implementation of practices
  - Provide technical assistance to produce growers
  - Provide Readiness Reviews prior to mandated inspections
    - Joint non regulatory inspections by MDA Inspectors/UMD/UME
    - Identify any areas that may not be in compliance
    - UMD and UME can assist growers with correcting these areas
  - Identify cost share, low cost loans, grants and other assistance for growers to implement food safety practices

Produce Rule Five Year Cooperative Agreement with FDA

- Inspection and Enforcement – MDA
  - Adopt regulations that are equivalent to the FSMA Produce Rule
  - Prioritize and conduct inspections based on compliance dates and risk
    - MDA will conduct inspections – not FDA
  - Enforcement Actions
    - Severity based on public health risk of non compliance
  - Produce and /or Environmental Sampling
    - Only conducted when implicated in an outbreak or inspection indicates high risk of contamination

Worker Health, Hygiene and Training

- All workers that handle or contact covered produce or supervise covered activities must be trained
  - Managers, farm workers, office staff, volunteers, interns, family members
  - Training Programs must include:
    - Principles of food hygiene and food safety
    - Personal hygiene and it's relationship to food safety
    - Supervision by a qualified person
    - Appropriate instruction relevant to the person's duties
    - Documentation of date, names of those trained and topics that were covered
    - One person on the farm must attend FDA recognized training curriculum
      - Produce Safety Alliance Produce Safety Rule
- Visitors must be made aware of the farm's food safety
  - Practices they are responsible for doing
  - How to report food safety risks they see

Workers Must

- Maintain personal cleanliness
- Avoid contact with animals (other than working animals)
- Maintain gloves in a sanitary condition, if used
- Wear clean clothes each day/clean footwear
- Be provided with a sufficient number of toilets and sinks
- Remove or cover hand jewelry that cannot be cleaned
- Not eat, chew gum, or use tobacco in an area used for a covered activity
- Not work in contact with food when ill
- Wash their hands

Biological Soil Amendments

- Human waste is prohibited unless it meets EPA regulation for biosolids
- Untreated biological soil amendments of animal origin considered high risk
  - Minimum Application Interval - Current 90/120 days prior to harvest
  - Treat to reduce risk
    - Compost
    - Heat/drying
    - Records – Treatment process or record from seller of treatment storage process
- Designate specific equipment and tools for handling soil amendments
- Sanitize equipment and tools that contact soil amendments and fresh produce
- Direct traffic (foot/equipment) to minimize cross-contamination
- Store to minimize runoff, leaching and wind drift

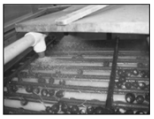
Wildlife, Domesticated Animals, and Land Use

- **Wildlife**
  - **During the growing season:**
    - Monitor for feces and evidence of intrusion
    - Evaluate the risk of fecal contamination on produce (e.g., tree vs. root crop)
  - **Immediately prior to harvest**
    - Monitor for fecal contamination, signs of animal activity (e.g., trampling, rooting, feeding, tracks)
    - Assess risks and decide if the crop or a portion of the crop can be safely harvested
- **Domesticated Animals**
  - Exclude and control animals from entering produce fields
  - Minimize cross contamination from grazing areas and produce
- **Records – Worker Training**

Agricultural Water

- **Production Water**
  - Water used in contact with produce during growth
  - Irrigation, fertigation, foliar sprays, frost protection

- **Postharvest Water**
  - Water used during or after harvest



Agricultural Water Quality

- All agricultural water must be safe and of adequate sanitary quality for its intended use
  - Applies to water used for Production and Postharvest Water

Water Quality Criteria for Water Used During Growing Activities

- Apply to water used with a direct water application method to covered produce
- Each source of production water must be tested to evaluate whether its water quality profile meets the following criteria:
  - **126 or less** colony forming units (CFU) generic *E. coli* per 100 mL water geometric mean (GM)

    AND
  - **410 or less** CFU generic *E. coli* per 100 mL water statistical threshold value (STV)

Agricultural Water Requirements 4 years from compliance date

- Inspect Water Sources and Water Distribution Systems
  - Make repairs/prevent contamination
- Build an initial microbial water quality profile
- Production Water
- Use alternative methods if water source does not meet the requirements
  - Allow die off time between irrigation/harvest
  - Water treatment
  - Drip irrigation (unless it is a root crop)

Water Quality Criterion for Harvest and Postharvest Activities

- Water used post harvest must have no detectable generic *E. coli* per 100 mL sample
- Treatment not mandated
- Change water as necessary to reduce cross contamination risks
- Only use sanitizers according to the label
- Keep records of water quality/water treatments

Harvest and Postharvest Practices

- No produce destined for fresh market that is contaminated with feces or dropped covered produce
- Worker health and hygiene practices
- Building must be suitable size, construction and design to facilitate maintenance and sanitary operations
- Clean and Sanitize Food Contact Surfaces
  - Record of cleaning, sanitizing of tools, equipment and containers is required
- Packing containers – new single use or cleaned reusable
- Pest Control
- Vehicles must be cleaned prior to hauling produce

Break area for eating/drinking

Produce Rule
Crop Exemptions

- Exempt from compliance with growing, harvesting, packing and holding requirements
  - Produce that is not a raw agricultural commodity
  - Produce that is rarely consumed raw
    - Examples: White potatoes, Sweet potatoes, Sweet Corn
  - Food grains
  - Produce that receives commercial processing that adequately reduces the presence of human pathogens

Produce Rule
Farms with Exemptions/Modified Requirements

- Farms that have an average annual value of produce sold during the previous three years of $25,000 or less are exempt
- Only grow produce that receives commercial processing that adequately reduces the presence of human pathogens are exempt except for the following requirements:
  - Must annually obtain from the customer that they or an entity the conducts the processing for them has established and follows a process that adequately reduces the presence of human pathogens
  - Documents accompanying the produce to the customer and to anyone else that is conducting the process for the customer must state "The food is not processed to adequately reduce the presence of microorganisms of public health concern.

Produce Rule
Farms with Exemptions/Modified Requirements

- **Qualified Exemption**
  - **Gross Food Sales** averaging less than $500,000 annually during the previous three years
    - FDA Definition of food includes non covered produce, animal feed (including growing grain, hay, etc.), livestock, poultry, processed food (includes contract production)
  - Direct food sales to consumers and/or to restaurants and retailers in the same state or not more than 275 miles away must exceed sales to all others combined
  - Modified requirements
    - Provide the name and complete business address of the farm where the produce was grown either on a label or at the point of purchase
    - Farm must maintain sales records subject to inspection to verify exemption status
      - » Records are not required to be submitted to MDA or FDA
      - » Will be inspected on site
    - Farm must review sales records and document the review annually to verify they still meet the Qualified Exemption requirements
  - Exemption can be revoked
    - Active investigation of food borne illness linked to farm
    - If determined necessary to protect public health
  - Unlikely that retailers will buy from Qualified Exempt Growers unless they are in compliance

Produce Safety Rule Compliance Dates

- Very small businesses with $25,000 to $250,000 in average annual produce sales during the previous three year period: January 26, 2020
- Small businesses with more than $250,000 and up to $500,000 in average annual produce sales during the previous three year period: January 26, 2019
- Qualified Exemption:
  - Labeling requirements: January 1, 2020
    - Name and address of grower must be on label or posted on sign
  - Retention of records supporting eligibility:
    - Over $250,000 in food sales – January 26, 2016
    - $25,000 to $250,000 in food sales – January 26, 2017
- Businesses with more than $500,000 in produce sales: January 26, 2018
  - Inspections have been delayed until 2019
  - Produce Growers are still required to be in compliance with the Rule
  - Cause inspections will be conducted (implicated in food borne illness outbreak)
- Compliance with certain aspects of the water quality standards and related testing and recordkeeping provisions – By four years beyond the compliance dates for the rest of the final rule

What do I do now?

- Required by Produce Safety Rule
  - Attend a Produce Safety Alliance Produce Safety Rule Training for Growers
    - Keep your Association of Food and Drug Officials Certificate in a safe place
  - If you think you meet the Qualified Exemption standard, keep records of:
    - Dollar value of food sales
    - Dollar value of produce sales
    - Where produce was sold (location and type of business)
    - Produce that was sent for further processing with a kill step
  - Start implementing compliant practices
    - Worker Health, Hygiene and Training
    - Begin Testing Agricultural Water to determine if you need to make changes
- Not Required by Produce Safety Rule (will assist with compliance)
  - Attend a Basic/Advanced GAP training
  - Write and Implement a Food Safety Plan
  - Consider GAP certification
  - Request a Readiness Review
  - Request technical assistance through UMD or UME
- Check the MDA FSMA web page for updates

Additional Resources for Produce Growers Maryland GAP Program

- Food Safety Plan that covers:
  - Water Quality
  - Biological Soil Amendments
  - Worker Health and Hygiene
  - Domestic and Wild Animals
  - Sanitation of harvest and post harvest tools, equipment, baskets
  - Meeting standards would be compliant with Produce Safety Rule
- MDA/UMD/UME offer
  - Basic & Advanced GAP Training
  - Assistance with Food Safety Plan Writing
- No cost MDA GAP Inspections
- No Cost MDA GAP Certification
- Cost Share for USDA GAP/GHP and USDA Harmonized Audit Fees ($108 per hour)

Upcoming Food Safety Training
Check the MDA website for registration

- January 10, 2018 On-farm Food Safety and Recall Readiness Training for CSA Operators Cecilton
- January 16, 2018 Basic GAP Cockeysville
- January 19, 2018 On-farm Food Safety and Recall Readiness Training for On-Farm Market
- January 25, 2018 On-farm Food Safety and Recall Readiness Training for Agritourism Operators
- February 5, 2018 Basic GAP Queenstown
- February 12, 2018 Produce Safety Rule/Preventive Controls for Human Food Salisbury
- March 12, 2018 Advanced GAP (Emphasis on Water Quality/Testing and Distribution Systems) Annapolis
- Two other Produce Safety Alliance Produce Safety Rule trainings are being planned for February/March – Frederick and Baltimore County

Food Quality Assurance Program

Contact Information
Deanna Baldwin
410-841-5769
Deanna.Baldwin@maryland.gov

Molly Gillingham
410-841-5769
Molly.Gillingham@maryland.gov

Justine Beaulieu
301-405-7543
jbeauli1@umd.edu

http://mda.maryland.gov/fsma

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NORTHEAST SARE Sustainable Agriculture Research & Education

Agritourism Food Safety Risks & Recommendations

January 25, 2018



Forrest Hall Farm, Mechanicsville, Maryland

Agriculture Law Education Initiative

The Agriculture Law Education Initiative (ALEI) is a partnership of the Francis King Carey School of Law at the University of Maryland, Baltimore (UMB); the College of Agriculture & Natural Resources at the University of Maryland (UMCP); and the School of Agriculture and Natural Sciences at the University of Maryland Eastern Shore. ALEI is an initiative of the University of Maryland: *MPowering the State*, a strategic alliance between UMB and UMCP created in 2012 to significantly expand research collaboration, business development, and student opportunities at both universities.

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Food Safety Risks of an Agritourism Operation

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- According to the 2012 Census of Ag, farms with agritourism rose by 42% percent from 2007 with just over 33,000 of the nation's 2.1 million farms offering agritourism and recreational activities.
- Agritourism operations differ but all involve inviting customers to the farm.
- Understanding the risks and how taking preventive steps is the best way to protect your operation.

Food Safety Planning & Prevention

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- Conduct a comprehensive assessment of potential risks on the farm (see checklist)
- Identify these risks and steps to minimize them in a farm safety plan
- Educate & train employees
  - Maintain a record of employee training.
- Communicate risks & expectations to visitors
- Establish emergency response procedures

Food Safety Risks of an Agritourism Operation

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Agritourism food safety risks stem from a variety of sources:

- Harvest & Handling
- Worker/Farmer Hygiene
- Customers
- Farm animal displays
- PYO fields
- Farm store
- Bathrooms

Harvest and Handling

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To prevent product contamination during harvest and handling GAP and FSMA procedures should be followed.

- Farm should have a written food safety plan that is updated annually.

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Harvest & Handling

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- Everything that comes in contact with a produce item should be cleaned prior to and after use.
  - Harvest tubs, distribution crates, tables, and delivery containers.
- Cleaning:
  - 1. Rinse or brush off soil or other residue. 2. Wash with soap and water (be sure water is from a clean source). 3. Rinse to remove any remaining residue and detergent.
- Sanitizing:
  - 1. Apply a fine spray of the sanitizer (at the appropriate concentration). 2. Allow to air dry, do not wipe or rinse off, unless instructions advise wiping.

Worker/Farmer Hygiene Risks & Recommendations

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- Workers should be trained on how pathogens are spread.
- Workers should wash hands before handling produce, after using the bathroom, after eating, emptying the trash, handling untreated compost, using pesticides/cleaning chemicals and/or handling animals.
- Workers should only eat/drink in designated areas
- Workers should not work when sick or with an open cut.
- Workers handling cash transactions should not touch produce to prevent cross-contamination from currency.

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Consumer Contamination Risks & Recommendations

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- The potential for customers causing contamination needs to be considered and managed.
  - Customers should be informed of food safety procedures and the need to wash hands after going to the bathroom and/or touching animals and not consuming any food before it is washed.
    - Procedures should be posted.
  - Areas of the farm (production areas) off limits to customers should be cleared marked.
  - Pets should not be allowed in and around areas where food is to be consumed.

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Farm Animal Displays Risks & Recommendations

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- Animals should be excluded from areas where food is being grown, prepared for sale and/or sold.
- Handwashing stations should be positioned at exits of animal display areas.
- Signage should be posted informing customers of importance of washing hands after touch animals.
- Consumers should be prohibited from eating in animal display areas.

Worker/Farmer Hygiene Risks & Recommendations

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- Farmers need to maintain proper hygiene to prevent being the source of risks.
  - Farmers should follow same hygiene routine as workers to set a good example and reduce risks.
  - Farmers should not bring four legged friends to work.
  - Farmers should maintain a first aid kit so that worker injuries can be properly addressed.

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PYO Risks & Recommendations

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- Encourage and inform customers to wash their hands before they pick.
- Provide a handwashing station at entrance to PYO fields.
- Provide a bathroom near PYO fields and service regularly.
- Regularly clean and sanitize PYO containers.
- No pets should be permitted in the PYO fields (exception- service animals).
- If you have a petting zoo and a PYO encourage customers to PYO first.

PYO Risks and Recommendations

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- Inform customers not to pick produce that has fallen to the ground.
- Don't sell produce at retail picked by customers.
- Fields off limits to picking because of recent spraying or compost application need to be clearly marked.
- Label any non-potable water sources.
- If applicable, inform customers to refrigerate produce when they get home.

Farm Store Risks & Recommendations

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- Food should be stored off of the floor of the cooler and not in direct contact with cooler walls.
- Condensation should be prevented from dripping on food.
- Coolers should be regularly cleaned and sanitized.
- Lighting fixtures should be covered to prevent contamination if a fixture breaks.

Farm Store Risks & Recommendations

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- Market buildings should be monitored for pests and pests should be controlled.
- Food should be stored off of the floor of the market (6 inches) and when in cooler not in direct contact with cooler walls.
- Condensation in cooler should be prevented from dripping on food.
- Lighting fixtures should be covered to prevent contamination if a fixture breaks.

Farm Store Risks & Recommendations

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- Produce should be stored separately (and never under) high risk (meat/poultry) and allergenic foods (milk, eggs & soy).
- Melting ice should be allowed to drain to prevent food from sitting in water.

Farm Store Risks & Recommendations

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- Reused containers can contain bacteria and spread pathogens.
  - Storage crates need to be cleanable if they are to be reused (food grade bins)and sanitize them between uses). Broken crates should be disposed.
  - Label storage containers as harvest and post-harvest to avoid cross contamination.
  - Cardboard boxes should be treated as single use containers for fresh produce.
  - Bags given to customers should be new and free of chemicals/debris that can contaminate food.

Farm Store Risks & Recommendations

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- Product sampling
  - Produce should always be washed with potable water before cut for samples
  - Handle samples with freshly washed hands or single-use gloves.
  - Avoid the potential for multiple handlings by customers by inserting a toothpick into each piece or by serving samples in an individual serving cup. A utensil such as tongs can also be available for the customers to select a sample without touching product with their hands.
  - Record and keep track of how long samples have been on the display table. To avoid presenting produce that doesn't look fresh, discard any cut samples that have been sitting out for more than two hours.
  - Have a waste basket nearby to discard used sample litter (i.e., plates, toothpicks, cups, and spoons).

Bathroom Risks & Recommendations

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- If indoor bathroom's are not available, portable bathroom facilities should be located in a convenient location but far enough from fields or the farm store to prevent contamination in the case of a spill.
- There should a hand washing station near the portable bathroom and signage regarding the importance of hand washing.
- Portable bathrooms and indoor bathrooms should be stocked with soap/towels, etc. and cleaned regularly and a cleaning log should be kept.

Questions/Thanks

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Feel free to contact me with any questions.

Sarah Everhart
severhart@law.umaryland.edu
410-458-2475

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NORTHEAST SARE Sustainable Agriculture Research & Education

Recall Planning

Sarah Everhart, Esq.



On-Farm Food Safety and Recall Readiness Workshop

Recall Planning

- All Maryland farmers, large or small, have a shared goal: to grow safe food for consumers.
- However, foodborne illness outbreaks happen.
- When an outbreak occurs and can be traced to the source, it is may be followed by a recall of the product.
- A recall can result in substantial financial damage to the grower involved and have a negative impact on the entire industry.
- A recall plan will lessen confusion, delay, and financial repercussions.

What is a Recall Plan?

- A recall plan is a documented, systematic plan outlining how a grower will track and recall products.
- Plans can vary in specificity, but at a minimum a good recall plan should include the "who, what and how"
  - Who in the operation will do each task;
  - What steps should be taken; and
  - How the recall procedures will be implemented.

How to Prepare a Recall Plan?

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- This may seem like a daunting task.
- Break it down into these 10 parts:
  - 1. Prepare for recall
  - 2. Identify the concern
  - 3. Initiate the recall
  - 4. Notify the regulatory agencies
  - 5. Identify and trace affected products
  - 6. Notify affected parties
  - 7. Control and dispose of recalled products
  - 8. Determine the recall's effectiveness
  - 9. Terminate the recall
  - 10. Remedy the recall's cause and restore operations

Prepare for the Recall

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- Best way to prepare is to keep good records.
  - Customer/Buyer Contact list
    - Appendix A of Model Recall Plan
  - Recall Team contact list (assign each staff member a role in the recall process)
    - Appendix B of the Modell Recall Plan
      - Be sure to fill in your county health department phone number

Prepare for the Recall

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- Recall Team Roles:
  - ***Recall Team Leader*** - has the authority to initiate a recall and make critical decisions quickly.
  - ***Recall Team Coordinator*** - oversees the complaint investigation, tracks recalled products, and coordinates the recall team.
  - ***Government Liaison*** - contacts the regulatory agencies and provides necessary information.
  - ***Media/Customer Spokesperson*** - disseminates information to the media and customers, handles press releases, social media, etc.
  - ***Legal Counsel*** - provides legal advice has previously reviewed the plan.
  - ***Insurance Agent***- provides coverage information.

Prepare for the Recall

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- Produce Traceability Plan
  - Does your farm have a traceability system that allows you to trace your products throughout the chain (suppliers, customers, etc.)?
  - Do you keep records of agricultural inputs including soil amendments, fertilizers, seeds/transplants, and agricultural chemicals so that you can link them with each of your crop types and ultimately, if necessary, to the buyer(s)?
  - Do you label your products with a traceability code (lot number) based on harvest date, crop, and field number?
    - Appendix C to Model Recall Plan

Prepare for the Recall

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- Mock Recall Exercises
  - Conduct them annually to test traceability and the recall plan itself.
  - Inform the buyer you are conducting an exercise.
  - Attempt to trace a lot sold to a buyer and see if you could recall a product if needed.
  - Afterwards, make necessary updates to the traceability procedures and recall plan.
    - Appendix D to the Model Recall Plan

Identify the Concern

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- A recall may be initiated in several ways:
  - 1) Consumer complaint;
  - 2) Notification by a regulatory agency of a food safety issue, such as a foodborne disease outbreak, or
  - 3) An internal discovery indicating a potential food safety issue.

Identify the Concern

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- Do you have a procedure for recording consumer complaints?
- Train your staff to take consumer complaints seriously.
- Consumer complaint information will be very important if a recall is required.
- Have a consumer complaint form for staff to use to get all information.
  - Appendix E to Model Recall Plan

Initiate the Recall

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- Not every complaint will result in a recall but every complaint should be reviewed.
  - Maryland law defines a foodborne disease outbreak as two or more related cases of illness following consumption of a common food item.
  - If you receive two complaints you should contact the county health department and the MDA (Food Quality Assurance).

Initiate the Recall

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If you decide to initiate a recall:

- Assemble the Recall Team
- Contact your legal counsel and your insurance carrier.
- Use the Recall Checklist, Appendix F to Model Recall Plan, to keep things on track.

Notify the Regulatory Agencies

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- If a grower suspects their product caused or may cause a foodborne illness based on an internal discovery:
  - Call the county health department and the MDA (Food Quality Assurance).
  - MDA and Maryland Dept. of Health (MDH) will coordinate on recall process.
  - If recall is interstate, FDA will get involved.
  - If the issue is serious or life-threatening, call the FDA's 24-hour emergency line at 1-866-300-4374 or 301-796-8240 should be called.
  - You don't need to make the decision to initiate a recall alone, use the experts at regulatory agencies to help you.
    - Health Hazard Questionnaire- Appendix G to Model Recall Plan

Notify Regulatory Agencies

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- If a consumer is treated by a physician for foodborne illness, the physician will report the illness to the Maryland Department of Health and an investigation that may lead to a recall will commence.
- A recall can also be initiated by the state or federal government.
  - For example, a state or federal regulatory agency may sample a farm's products and find them to be unsafe which can lead to a recall.

Notify Regulatory Agencies

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- If a farmer is implicated in an outbreak, the county health department, the MDH, and the MDA will assist the farmer in notifying consumers and removing the product from circulation.
- The goals of the state agencies during a foodborne illness outbreak are to provide support to the farmer and to protect the public health.
- To achieve these goals, however, it is vital that the regulatory agencies are notified as soon as practicable of a potential food safety threat.

Identify and Trace Affected Products

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- Once a recall is initiated it is crucial for a grower to identify any unsafe products and track which items in the supply chain are affected.
  - Traceability Plan
  - Clean break before and after lots
  - Good records will narrow down the search for affected products and reduce the amount of product that will need to be recalled.
  - Keep a traceability log to record which products have been found.
    - Traceability Log- Appendix H to Model Recall Plan

Notify Affected Parties

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- During a recall a grower will work with regulatory agencies to notify all parties in the distribution chain as well as affected consumers.
  - Keep a communications log to record all notifications.
    - Appendix J to Model Recall Plan.
  - The regulatory agencies overseeing the recall will assist the grower with crafting and executing a press release to communicate the recall to consumers.

Control and Dispose of Recalled Products

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- The grower will need to document, control and properly dispose of recalled products.
  - Product Retrieval Log, Appendix K to Model Recall Plan.
- All affected products in the grower's possession or control should be segregated and clearly marked to prevent the products from entering the commerce stream.
- Consult with regulatory agencies on disposition of products.
  - Use a product retrieval log to track which products have been retrieved.

Determine the Recall Effectiveness

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- It is a grower's responsibility to determine and document, through effectiveness checks, that all known, affected customers were notified about a recall and have taken appropriate action.
  - This is why communications, tracing and retrieval of affected products needs to be documented.

Terminate the Recall

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- The final decision when a recall may be terminated lies with the overseeing regulatory agency.
- A recall is considered complete after all possible customer responses indicating receipt of notice of the recall have been received and it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned or destroyed.

Are the cow's ever going to come home ?

Remedy the Cause and Restore Operations

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- A Plan should include remedying the cause of the recall and restoring operations.
  - Restoring physical operations and trust (public, consumers and supply chain partners).
  - Best way to survive a recall?
    - Be prepared and proactive

Wrap up

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- Although no one likes to imagine distributing an unsafe food product, such a situation should be anticipated.
- Having a recall plan in place ensures a more organized recall experience and eliminates mistakes made under stress when determining what actions to take.

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Thank you

Sarah Everhart
Severhart@law.umaryland.edu
410-458-2475

Agritourism Operation Food Safety Preventive Measures Checklist

Harvest and Handling Preventive Measures	**Yes**	**No**	**N/A**
The farm has a written food safety plan and follows Maryland GAP/FSMA.			
The farm has a system to regularly clean and sanitize: harvest tubs, sorting and display tables, and refrigerators.			
Worker/Farmer Hygiene Preventive Measures			
All farm workers are trained in food safety, eat and drink only in designated areas and records of annual trainings are maintained.			
Workers wash hands before handling produce, after using the bathroom, after eating, emptying the trash, handling untreated compost, using pesticides/cleaning chemicals and/or handling animals.			
Workers do not work when sick or with an open cut.			
Workers handling cash transactions do not touch produce for sale to prevent cross-contamination from currency.			
Farmer Hygiene Preventive Measures			
The farmer follows the same hygiene procedures as the workers.			
The farmer maintains a first aid kit so that worker injuries can be properly addressed.			
Consumer Contamination Preventive Measures			
Farm visitors are informed of food safety procedures and procedures are posted.			
Pets (except service animals) are not allowed in and around produce to be consumed.			
Contamination from customers to bulk items is prevented by providing utensils such as tongs, or deli tissue, to use for picking up items			
Areas of the farm (production areas) off limits to visitors are cleared marked.			
Farm Animal Contamination Preventive Measures			
Animals are excluded from areas where food is being grown, prepared			

for sale and/or sold.			
Handwashing stations are positioned at exits of animal display areas.			
Signage is posted informing customers of importance of washing hands after touch animals.			
Consumers are prohibited from eating in animal display areas.			
Pick-Your-Own Contamination Preventive Measures			
Customers are encouraged and informed to wash their hands before they pick.			
A handwashing station or bathroom with handwashing sink is provided at entrance to PYO fields.			
PYO containers are regularly cleaned and sanitized.			
Pets are excluded from PYO fields (exception- service animals).			
Customers are informed not to pick produce that has fallen to the ground.			
Fields off limits to picking because of recent spraying or compost application are clearly marked and all non-potable water sources are also labelled. To limit the risk of contamination, produce picked by customers is not sold to public.			
Market Building Contamination Preventive Measures			
Market buildings are monitored for pests and pests are controlled.			
Food is stored off of the floor of the market (6 inches) and when in cooler not in direct contact with cooler walls.			
Refrigerators are regularly cleaned and sanitized and food is not stored under condensers or against the walls of the refrigerator.			
Lighting fixtures are covered to prevent contamination if a fixture breaks.			
Produce is stored separately (and never under) high risk (meat/poultry) and allergenic foods (milk, eggs & soy).			
Melting ice is allowed to drain to prevent food from sitting in water.			
Storage crates are cleaned and sanitized if they are reused (food grade bins) and broken crates are disposed. Cardboard boxes are treated as single use unless a plastic liner is used.			
Storage containers are labelled as harvest and post-harvest to avoid cross-contamination.			
Bags given to customers are new and free of chemicals/debris that can contaminate food.			
Food Demonstration/Sample Contamination Preventive Measures			
Produce is washed with potable water before cut for samples.			

Samples are handled with freshly washed hands or single-use gloves.			
Customer contamination is reduced by inserting a toothpick into each piece or by serving samples in an individual serving cup and a wastebasket is nearby			
A record is kept to track how long samples have been on a display table and any cut samples that have been sitting out for more than two hours are discarded.			
Bathroom Contamination Preventive Measures			
Portable bathroom facilities are located in a convenient location but far enough from fields/market, etc. to prevent contamination in the case of a spill.			
There is a hand washing station near the portable bathroom and signage regarding the importance of hand washing.			
Portable bathrooms and indoor bathrooms are stocked with soap/towels, etc. and cleaned regularly and a cleaning log is kept.			

EXTENSIONBULLETIN

Model Recall Plan

SEPT. 2017 | EB-429

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UNIVERSITY OF MARYLAND EASTERN SHORE

UNIVERSITY OF MARYLAND EXTENSION

Table of Contents

Disclaimer: This model plan is intended to provide general information and should not be construed as providing legal advice.

Introduction

This is the recall plan for _____ Farm. This plan does not address recall provisions related to meat or egg products. This plan will be periodically updated.

Recall Policy

In the event of a food safety issue related to our products, _____ Farm will protect the public health by efficiently identifying and removing unsafe food from the distribution chain and informing consumers of potentially hazardous food in the marketplace. This plan will be tested annually through a mock recall to ensure it functions effectively.

Preparing for a Recall

CUSTOMER/BUYER CONTACTS

Appendix A contains a list with the names and available contact information for all customers/buyers of our products. _____ Farm will use this list to contact customers in the event of a recall and will update the list as needed.

RECALL TEAM

The list in Appendix B describes the various roles of the Recall Team, the staff members assigned each role, and the contact information for the regulatory agencies involved in a recall. The Recall Team is responsible for coordinating all aspects of a product recall. The roles and responsibilities of each Recall Team member are as follows:

- ***Recall Team Leader*** – has the ultimate authority to make the decision to initiate a recall, make critical decisions quickly, and designate team members as needed.
- ***Recall Team Coordinator*** – oversees the complaint investigation and the trace-back process, and coordinates the recall team to address the issues at hand.
- ***Government Liaison*** – contacts the regulatory agencies, is knowledgeable about the farm's traceability procedures, and is prepared to provide the necessary information, as well as able to access related records and documents
- ***Media/Customer Spokesperson*** – disseminates information about the recall to the media and customers, and handles press releases, social media, etc.
- ***Legal Counsel*** – provides legal advice in the event of a recall or food safety event, is familiar with our farm, and has reviewed this recall plan.
- ***Insurance Agent*** – provides information relating to insurance coverage.

TRACEABILITY PLAN

Appendix C contains a copy of our traceability plan. Being able to effectively trace products is a key component of a recall. Our farm utilizes a system that allows us to trace products one step forward and one step back. We keep records of all our agricultural inputs including soil amendments, fertilizers, seeds/transplants, and agricultural chemicals so we can link them with each of our crop types and ultimately to our buyers. We also assign our products a traceability code (lot number) based on harvest date, crop, and field number.

Mock Recall

Once during each growing season, we conduct a mock recall for our farm and markets which mimics the process of an actual recall. We use mock recalls to determine whether the recall plan and procedures are capable of 1) identifying and quickly controlling a given lot of potentially affected product and 2) reconciling the quantities produced, in inventory, and distributed. A mock recall will help us evaluate the effectiveness of our plan and procedures by identifying potential problems and ensuring employees are familiar with recall procedures. Appendix D lists the materials used during a mock recall. If problems are identified during the mock recall, this plan will be amended.

Recall Procedures

In the event of a recall, the Recall Team Leader will take the following steps to ensure successful retrieval of products, communication with all necessary parties, and restoration of normal business.

IDENTIFY THE CONCERN

A recall may be initiated in a few ways: 1) consumer complaint(s); 2) notification by a regulatory agency of a food safety issue; or 3) an internal operations discovery or laboratory report indicating a potential food safety issue.

We take all consumer complaints related to our products very seriously and record them on a Consumer Complaint Form in Appendix E. The employee who takes the call should ask all questions on the Consumer Complaint Form and record all pertinent information. As soon as possible after receiving the complaint, the employee is required to inform the owner/manager of _____Farm and/or the Recall Team Leader.

After receiving a consumer complaint, notification by a regulator of a food safety issue, or an internal discovery of a condition that could create a food safety risk, the owner/manager of _____ Farm and/or the Recall Team Leader will assess the severity of the issue. If the consumer complaints are related to adverse health effects caused by the farm's products, we will use the Health Hazard Evaluation Questionnaire in Appendix G to assess the concern. In addition, _____ Farm will also assess the concern by consulting the Maryland Department of Agriculture's (MDA) Food Quality Assurance Department at 1-410-841-5769 or after hours at 443-223-9408.

The speed with which the health hazard must be evaluated will depend on the nature of the alleged violation or defect. The more serious the potential health effects, the greater the need for an urgent response. If _____ Farm receives more than one consumer complaint about adverse health effects caused by one of our products, we will consider the situation to be a potential foodborne disease outbreak and will contact the local health department.

When contemplating a recall, the owner/manager of _____ Farm and/or the Recall Team Leader will also contact legal counsel for advice pertaining to the applicable legal standards before deciding to initiate a recall.

If no risk is found after a thorough investigation, a consumer complaint may be handled internally and no further action may be necessary. If the investigation determines there may be a minimal risk associated with a product which is not likely to cause adverse health consequences (such as improper labeling), the product will be removed from the market and the issue corrected. However, if _____ Farm finds a potential risk of adverse health consequences from one of our products or that a product is adulterated or misbranded, a recall will be initiated. In the case of a potential recall, the owner/manager

of _____ Farm and/or the Recall Team Leader must document all information available to support the decision—either to recall, or not.

If _____ Farm is notified by the county health department, the Maryland Department of Health, the MDA, or the federal Food and Drug Administration (FDA) that our products could be implicated in a foodborne illness outbreak, we will make a record of the communication, assemble the recall team, contact our legal counsel and insurance agent, if applicable, and start an internal investigation in coordination with the agencies.

INITIATE THE RECALL

After the decision to initiate a recall, the Recall Team will assemble, notify regulatory agencies (if not previously notified), and determine the recall's scope. To determine the class and scope of the recall, _____ Farm will consider 1) whether any disease or injuries have already occurred from use of the product; 2) the seriousness of the health hazard; 3) the immediate and long-range consequences; and 4) the ability to identify and quantify the defective product in the marketplace.

_____ Farm will use the following FDA class levels of recall:

- ***Class I:*** A situation where serious (possibly even fatal) health consequences may result if the product is consumed. Examples include Listeria or Salmonella in food. A public alert is usually issued.
- ***Class II:*** A situation where a health hazard might exist but the probability is remote. A public alert may be issued. An example is a food containing an undeclared allergen.
- ***Class III:*** A situation where a food violates federal regulations, but is unlikely to cause adverse health consequences, and where a public alert is not usually issued. An example is a food with a minor labeling issue.
- ***Market Withdrawal:*** A situation where a food has a minor violation that is not in violation of any food safety laws. The products may be withdrawn from the market without initiating a recall.

The Recall Team will use the Recall Plan Checklist in Appendix F to stay on track of all necessary steps in the recall process.

Notify the Regulatory Agencies

When the decision to initiate a recall based on consumer complaints is made, the Government Liaison member of the Recall Team will contact the county health department. If the issue is serious or life-threatening, the Government Liaison will call the FDA's 24-hour emergency line at 1-866-300-4374 or 301-796-8240. If the Recall Team initiates a recall because of an internal discovery, the Government Liaison will also contact the MDA's Food Quality Assurance Department at 1-410-841-5769 or after hours at 443-223-9408. The federal, state, and local regulatory agencies will work with _____Farm on the recall process. Appendix B lists the contact numbers for the regulatory agencies.

Identify and Trace Affected Products

Identifying and tracking affected products are crucial during a recall and will be done in accordance with _____ Farm's traceability plan. The Recall Team Coordinator will initiate trace-back procedures to determine the products, number of units, units of measure, farm, harvest date, and lot numbers involved. All information pertaining to the trace back will be recorded in the Traceability Log found in Appendix H. The Coordinator will also collect all pertinent documentation regarding the affected product such as inputs and outputs of the field associated with the lot number, harvesting methods, and any other details that could aid in the investigation (for example: ill employees). The Government Liaison will work with the Coordinator to make sure the required information is provided to the overseeing regulatory agencies throughout the investigation.

Notify Affected Parties

The Media/Customer Spokesperson member of the Recall Team will work with the overseeing regulatory agencies to send out all press releases and customer notifications. If the products pose a significant health hazard and the recalled products are in the hands of consumers, a press release is usually appropriate.

_____ Farm will notify all wholesale, retail, and direct customers as soon as possible about the recall. Notifications will be done through a telephone call, in person, or in writing (the preferred form of notification). If produce was distributed at a farm-owned retail stand, a notice will be posted there. See Appendix I for a form to use for recall notification by telephone.

The notification must include:

- A complete description of the product and any codes used to identify the product,
- A description of the problem and any potential associated health hazards,
- The scope of the recall (wholesale, retail, or user level),
- Clear instructions regarding removing the product from sale, ceasing distribution, sub-recalling (if appropriate), returning the product, or modifying the product, and
- A return response form for all written notifications so that customers can indicate they received the notification and followed the instructions.

Links to model press releases and recall notifications can be found in Appendix I. _____ Farm will retain evidence of all communications. We will record all communications during the recall in the Communications Log found in Appendix J.

Control and Dispose of Recalled Products

The Recall Coordinator or a designated member of the Recall Team is responsible for ensuring all recalled products are controlled and disposed of appropriately. _____Farm will make all reasonable efforts to remove affected products from the commerce stream.

All affected products still in the control of _____ Farm (e.g., inventory located onsite, in transit, in off-site storage, and in off-site distribution) will be detained and segregated to prevent reentry into the commerce stream. The Team will document all quantities and identification codes to help with

reconciling product amounts and will clearly mark all affected product "not for sale or distribution." _____ Farm will work with the overseeing regulatory agencies to decide on the appropriate disposition of recovered recalled products. Products deemed unsafe for human consumption may be returned, destroyed, and disposed of by appropriate means. No products will be destroyed without first notifying the regulatory agencies. The team will quarantine all returned products until the recall ends. The Recall Coordinator or another member of the Recall Team will document quantities, identification codes, and disposition on the Product Retrieval Log in Appendix K.

Determine the Recall's Effectiveness

The Recall Team will need to determine the level of the recall's effectiveness. To do so, the team will perform and document effectiveness checks of the recall to prove that all known, affected customers were notified of the recall and have taken appropriate action. See links to model effectiveness check documents in Appendix I.

Terminate the Recall

For the recall to be terminated, the Recall Team will need to evaluate whether all possible customer responses have been received and if it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed. The overseeing regulatory agencies will notify _____ Farm when the recall is terminated.

Remedy the Cause and Restore Operations

As soon as the Recall Team identifies the reason for the recall, it will take corrective and/or preventative measures to remedy the issue. After the recall, the team will update, revise, and make all necessary amendments to this plan. Finally, _____ Farm will focus on fully restoring operations. _____ Farm will not only remedy the physical issues associated with the cause of the recall but will also focus on rebuilding public trust in our products. Upon completion of a recall, the Media/Customer Spokesperson member of the Recall Team will craft a statement announcing the end of the recall to advise customers that they may once again enjoy our products.

Following a recall, _____ Farm will assess what changes, if any, need to be made to this plan to make it more efficient and effective.

Appendix A: Customer/Buyer Contact list

Customer/buyer name	Address	Email	Business phone	Mobile phone	Product sold

Source: Diane T. Ducharme, Draft Recall Plan Workbook, March 2016, North Carolina State University, (Adapted for UVM by Ginger Nickerson) https://www.uvm.edu/~susagctr/whatwedo/producesafety/GAPsResources/gapresRTSampleRecallPlanMarch62016GNRevised.docx.

Appendix B: Recall Team Contact List

Role	Name	Business Phone	After Hours Phone	Responsibilities During Recall
Recall Team Leader				• Serves as recall team leader • Makes final decisions on recovery of products • Reassigns team members
Recall Team Coordinator				• Oversees complaint investigation • Coordinates the recall team actions
Government Liaison				• Communicates with regulatory agencies and works with legal counsel and provides information to regulatory agencies
Media/Customer Spokesperson				• Handles all media and customer communication • Works with regulatory agencies on press releases and customer letters
Legal Counsel				• Handles liability questions • Advises government liaison on regulatory responses
Insurance Agent				• Addresses insurance coverage issues
Local Health Dept. (Contact info for Md. health departments: http://dhmh.maryland.gov/Pages/departments.ASPX)				
MD Dept. of Ag.		410-841-5769	443-223-9408	• Oversees recalls for food distributed intrastate
MD Dept. of Health	State of Maryland Rapid Response Team	410-767-8400	410-795-7365	• Oversees recalls for food distributed intrastate
FDA Baltimore District Office	Recall Coordinator	410-799-5414		• Oversees all product recalls for FDA-regulated product within the Baltimore District (MD, D.C., VA, WV)
FDA Emergency		1-866-300-4374	301-796-8240	

Appendix C: Produce Traceability Plan

Trace back records: Our farm uses a traceability system allowing us to trace a product one step forward and one step back. We keep records of all our agricultural inputs including soil amendments, fertilizers, seeds/transplants, and agricultural chemicals so that we can link them with each of our crop types and ultimately, if necessary, to the buyer(s).

[DESCRIBE YOUR SYSTEM HERE – THIS IS AN EXAMPLE – YOUR SYSTEM AND THE INFORMATION YOU RECORD MAY BE DIFFERENT]

1. All products produced by the farm will be assigned a traceability code (lot number) based on harvest date, crop, and field number.
2. Harvested product will be tagged, stamped, or labeled by marketing unit (examples: bin, box, case, pallet, bag, etc.) to show the following information:
    a. The type of crop
    b. The name and address of our farm
    c. The field the crop was grown in [IF APPLICABLE]
    d. The harvest date [OR PACK DATE- WHICHEVER YOU USE ON YOUR LABELS]
    e. The lot number [IF USED]
3. All product is invoiced as it is shipped from the farm.
4. Invoices include: farm name and information, buyer name and information, and inventory amounts transferred/exchanged.
5. Invoice should be signed or initialed by the customer (receiving party) when product is delivered.
6. All unused/unsold inventories are accounted for including quantity, date, and method of disposal.

We use a lot number system which identifies the harvest date and field (example: 072417-2 means harvested on July 24, 2017 from field 2. Add any other information you use in your lot tracking system.) When we make a sale, the invoice includes information on boxes shipped, to whom, the date of shipment, and the harvest date and field code number. We keep copies/have electronic copies of all invoices so that the buyer and our farm have the same information. If a product is comingled during or after harvest, the above label information for EACH crop type and block of land is provided to the buyer.

Source: Diane T. Ducharme, *Draft Recall Plan Workbook*, March 2016, North Carolina State University, (Adapted for UVM by Ginger Nickerson) https://www.uvm.edu/~susagctr/whatwedo/producesafety/GAPsResources/gapresRTSampleRecallPlanMarch62016GNRevised.docx.

Appendix D: Mock Recall Exercise

Once during each growing season, we conduct a trace forward/mock recall exercise to verify that we can match each lot sold to the specific buyer and that we can recall a product if needed. As part of the exercise, we contact a buyer to identify a load received from our company. **Make sure to inform the buyer that this is a mock recall exercise!** We ask how much of the product has been sold, how much they have in inventory, and if any has been disposed of for other reasons (fell on floor, etc.). This information is recorded on our Mock Recall form and kept on file. After a selected lot is sold and shipped, we go through our records to verify that we can match each box shipped to the destination buyer.

Our goal is to achieve 100% effectiveness of reconciliation of product to recipients within ___ hours. The percent effectiveness of the recall is calculated in the following way:

A = total amount of product

B = amount still in inventory

C = amount delivered to customers

D = incidental usage if any (e.g. product dropped on ground, etc.…)

(B+C+D) / A x 100 = % effectiveness of recall

The gwoal of the exercise is to demonstrate that we have open communication with our buyers and if necessary, we can work with them to remove any of our shipped products from their inventory.

Mock Recall Log

Date			Buyer/customer name				Buyer contact info		
Product	ID/ Lot #	Harvest date	Ship date	Amt. shipped, PO #, & container type	Date & time of buyer contact	Amt. of product remaining in buyer possession	Amt. of product sold by buyer & to whom	Amt. of product returned/ destroyed	Initials
	Comments: Determine the percent effectiveness of the (mock) recall. The total amount of suspect product must equal the sum of the product shipped and the amount still in inventory. $\frac{B + C + D}{A} \times 100 = \%\ \text{Effectiveness}$ A – Total amount of product produced B – Amount still on inventory C – Amount delivered to customers D – Incidental usage (product dropped on ground, etc.)								

Source: Diane T. Ducharme, Draft Recall Plan Workbook, March 2016, North Carolina State University, (Adapted for UVM by Ginger Nickerson) https://www.uvm edu/~susagctr/whatwedo/producesafety/GAPsResources/gapresRTSampleRecallPlanMarch62016GNRevised.docx.

Appendix E: Consumer Complaint Form

Name of person who received call: _____

Date and time of incoming call: _____

Name of person calling: _____

Contact phone number for person calling: _____

Name/contact information of person ill or injured, if not caller: _____

Age of person ill or injured: _____

Allergies or pre-existing conditions of consumer: _____

Description of the consumer's complaint (odor, color, taste, allergic reaction, object in food, illness, etc.:

_____

Injured person's symptoms: _____

Date and time symptoms occurred: _____

Date the consumer saw a doctor, if any: _____

Doctor's name and contact information:_____

Doctor's diagnosis: _____

Description of the product the consumer is complaining about (include specific packaging info/product codes, etc.)

_____

Amount of the product consumed: _____

Names of other consumers of the product: _____

Symptoms of other consumers, if any: _____

Date and location of product purchase: _____

Storage of the product before consumption: _____

Use of or preparation of the product before consumption: _____

Other agencies/persons the consumer has notified_____ Contact information _____

_____

Status of any remaining product _____ If there is remaining product, tell the injured person not to dispose of the product and ask if the farm could retrieve the product for testing.

Any specific requests from the consumer: _____

_____

Source: Douglas L. Archer, Keith R. Schneider, Ronald H. Schmidt, W. Steve Otwell, Renee M. Goodrich, and Chris Thomas, The Food Recall Manual, The University of Florida, http://edis.ifas.ufl.edu/pdffiles/fs/fs10800.pdf.

Appendix F: Recall Plan Checklist

BEFORE A RECALL:

- ☐ Create a Customer/Buyer Contact list (Appendix A). Update names, phone numbers, and emails annually or as needed.
- ☐ Create a Recall Team Contact list (Appendix B) including names and phone numbers of recall team and regulatory agencies.
- ☐ Create an effective Produce Traceability Plan and Mock Recall exercises (Appendices C & D).

ONCE A PROBLEM IS IDENTIFIED:

- ☐ Collect information and consider the health hazard evaluation factors:
  - Document consumer complaints using Consumer Complaint Form (Appendix E).
  - Consider the health hazard evaluation factors using Health Hazard Evaluation Checklist (Appendix G).
- ☐ Consult with the county health department if we have received more than one consumer complaint about adverse health effects caused by one of our products.
- ☐ Consult with the Maryland Department of Agriculture's Food Quality Assurance Department.
- ☐ Consult with legal counsel.
- ☐ Determine actionable items: Is this a recall? Market withdrawal? Or handled internally by correction (repairing, relabeling, or other adjustments to product)?

RECALL DECISION:

- ☐ Activate the Recall Team
- ☐ Contact the proper regulatory agencies and provide information
- ☐ Perform trace-back procedures to determine the product(s), number of units, units of measure, farm, harvest date, and lot numbers involved (one commodity, or one day, all commodities, etc.) (Appendix H).
- ☐ Collect pertinent documentation regarding the affected product.
  - Inputs and outputs of affected field associated with the lot number such as notes on harvesting methods, wildlife activity, ill employees, manure application, etc.
- ☐ Work with regulatory agencies to initiate necessary recall notice, customer notifications, and press release (Appendix I).
- ☐ Record all communications related to the recall (Appendix J).
- ☐ Track, remove, and dispose of recalled products (Appendices H & K).
- ☐ Determine the percent effectiveness of the recall.
- ☐ Determine if the recall is over/terminate.
- ☐ Update the recall plan if necessary.
- ☐ Restore operations.

Source: Diane T. Ducharme, Draft Recall Plan Workbook, March 2016, North Carolina State University, (Adapted for UVM by Ginger Nickerson) https://www.uvm.edu/~susagctr/whatwedo/producesafety/GAPsResources/gapresRTSampleRecallPlanMarch62016GNRevised.docx.

Appendix G: Health Hazard Evaluation Questionnaire

To perform the health hazard evaluation, work through all questions below and attach all supporting documentation.

1. What is the nature of the violation or defect—adulterated product (physical, chemical, or microbial contamination), misbranded product, improperly labeled product, etc.?

2. What illnesses or injuries have already occurred from use of the product?

3. What documentation is there to support the association of the illnesses or injuries with the use of the product?

4. Was the product used in conformance with its labeled directions for use? If so, were the illnesses or injuries due to a) product quality (contamination); b) inadequate directions for use; or c) other known or unknown causes?

5. Are there any existing conditions that could contribute create a health hazard? If so, name the specific conditions (ex. unsafe irrigation water) and explain how these conditions could contribute to a health risk. Document harvest dates, irrigation water source, use of biological soil amendments, mechanical or machine harvest, field pack or packing house, water used post-harvest, or any other processes which could result in product contamination to adequately evaluate existing conditions.

6. What segments of the population— children, elderly, expectant mothers, persons with compromised immune systems, etc. — could be exposed to the affected product? What is the degree of seriousness of this hazard to these specific population segments?

7. What is the degree of seriousness of the health hazard to which the population at risk would be exposed (life threatening, severe, moderate, limited, or none)? Express in terms of:

A. Life threatening: death could occur

B. Severe: permanent significant disability

C. Moderate: transient but significant disability; permanent minor disability

D. Limited: transient minor disability; annoying complaints

E. None: no disability or physical complaints anticipated

8. What is the likelihood of occurrence of the hazard? What is the frequency of illness or injuries or other adverse reactions which have already occurred? If no illnesses or injuries have occurred yet, what is the likelihood of occurrence in each segment of the population at risk?

9. What are the immediate or long-term consequences of occurrence of the hazard?

For more information see, 21 C.F.R. 7.41- Health Hazard and Recall Classification.

Appendix H: Traceability Log

SHIPPED TO						
Product	**Lot number/ code/date**	**Lot quantity**	**Name/location**	**Date shipped**	**Quantity left on-farm**	**Quantity shipped and requiring recovery**
					TOTAL =	0

Source: Diane T. Ducharme, Draft Recall Plan Workbook, March 2016, North Carolina State University, (Adapted for UVM by Ginger Nickerson) https://www.uvm.edu/~susagctr/whatwedo/producesafety/GAPsResources/gapresRTSampleRecallPlanMarch62016GNRevised.docx.

Appendix I: Communication Document Links

MODEL PRESS RELEASES (FDA)

Allergens: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129262.htm

Clostridium botulinum: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129273.htm

E. coli 0157:H7: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129287.htm

Listeria monocytogenes: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129267.htm

Salmonella: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129275.htm

MODEL NOTIFICATION LETTERS/ENVELOPE

Envelope: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214973.pdf

Letter: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214960.pdf

Return Response Form: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214967.pdf

MODEL EFFECTIVENESS LETTERS

Check Letter: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214958.pdf

Effectiveness Check Questionnaire: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214971.pdf

Check Response Format: http://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM214963.pdf

Appendix J: Communications Log

Quantity shipped and requiring recovery	Date/ time	Person contacted	Quantity recovered or destroyed	Quantity remaining with contact	Action taken and description (e.g., picked up, returned, destroyed, etc.)	Quantity recovered
					TOTAL = 0	

Source: Diane T. Ducharme, Draft Recall Plan Workbook, March 2016, North Carolina State University, (Adapted for UVM by Ginger Nickerson) https://www.uvm.edu/~susagctr/whatwedo/producesafety/GAPsResources/gapresRTSampleRecallPlanMarch62016GNRevised.docx.

Appendix K: Product Retrieval Log

Company or organization	Contact	By phone	By letter	In person	Recall team-member	Copy on file	Reason or description

Source: Diane T. Ducharme, Draft Recall Plan Workbook, March 2016, North Carolina State University, (Adapted for UVM by Ginger Nickerson) https://www.uvm.edu/~susagctr/whatwedo/producesafety/GAPsResources/gapresRTSampleRecallPlanMarch62016GNRevised.docx.

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Md. Code Regs. 10.06.01.09B (2017).

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Winifred W. McGee & Lynn F. Kime, Penn State Extension, Proactive Recall Plans, http://extension.psu.edu/business/farm/management/risk/my-food-venture-risk-management-plan/proactive-recall-plans.

Sample Recall Plan, California Department of Public Health, https://archive.cdph.ca.gov/pubsforms/Documents/fdbRIgde23.pdf.

Authored By:

Ashley Ellixson
*Vice President of Legal & Environmental Affairs, United Dairymen of Arizona**

Sarah Everhart
Legal Specialist

Photography by:
Edwin Remsberg

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FatCat Studios

**This publication was written while Ashley Ellixson was an Extension Legal Specialist with University of Maryland.*

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University of Maryland College of Agriculture and Natural Resources
Department of Agricultural and Resource Economics
2200 Symons Hall
College Park, MD 20742
(301) – 405-3541

University of Maryland
Francis King Carey
School of Law
500 West Baltimore St.
Baltimore, MD 2120
(410) 706- 7377

www.umaglaw.org
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