

Food Safety, GAPs, FSMA: Coping with New Regulations for Fresh Produce

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NC State University
A&T State University
**COOPERATIVE
EXTENSION**

Empowering People • Providing Solutions

topics

- NC's Model for Education
- Identifying Microbial Risks & Remediation Steps
- GAPs audit
- FSMA
- Resources

NC's Model



- NC Fresh Produce Safety Task Force
- Team Approach
- Tiered-educational initiative
 - Agent-delivery
 - Specialist-delivery

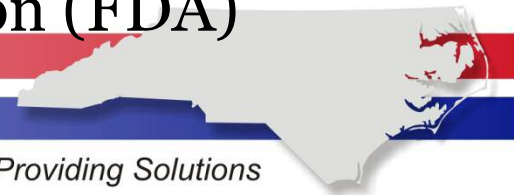
North Carolina Fresh Produce Safety Task Force

- Purpose: to minimize food safety risks and enhance the economic competitiveness of North Carolina's fresh produce industry.
- Goal: To ensure that North Carolina has a competitive, vibrant and safe fresh produce industry supported through the research, teaching and outreach programs of N.C. State University, N.C. A&T State University, North Carolina Department of Agriculture and Consumer Services, Farm Bureau and industry groups.



Unique Partnership

- Individual Growers
- Fresh Produce Brokers/Distributors
- Commodity Groups- Carolina Farm Stewardship Assoc. and others
- N.C. State University
- N.C. A&T State University
- North Carolina Department of Agriculture and Consumer Services – Marketing and Food & Drug Divisions
- NC Farm Bureau
- Carolina Farm Stewardship Association
- United States Food and Drug Administration (FDA)



6 Working Groups

- Education
- Research
- Industry and Policy Relationships
- Networking and Communication
- Small Farms
- Management



Training Aids in the form of Team



Testing your KNOWLEDGE Pre & Post tests developed

- What are you coming in with?
- Use of real-time technology



Break out activities

Top Three Words for....

- “Produce Safety”
- Number off (1,2,3)
- Break into groups
- Present to group



Third-deadliest U.S. food outbreak was preventable, experts say

By **Scott Bronstein** and **Drew Griffin**, CNN Special Investigations Unit
updated 9:21 AM EDT, Thu May 3, 2012

INFO MORE VIDEOS SHARE

<http://www.cnn.com/2012/05/03/health/listeria-outbreak-investigation/index.html>

Mystery surrounds listeria outbreak

Source: CNN

Highlights of Accomplishments

- fresh produce safety tiered educational curriculum (Tier 1-3)
- communication toolkit for agents
- on-line curriculum participant tracking
- certificate of attendance issuance
- searchable database for grower's marketing tool
- social media tools (Website, Blog, news releases, interviews)
- growers tool kits
- fresh produce safety plan template
- risk and liability (2) extension information sheets
- impacts (1) and case studies (3) documents;
- direct market display risk checklist
- needs assessments from agents and growers
- videos including The Produce Lady, risk & liability, educational mock audits
- eight bilingual worker trainings videos (YouTube)

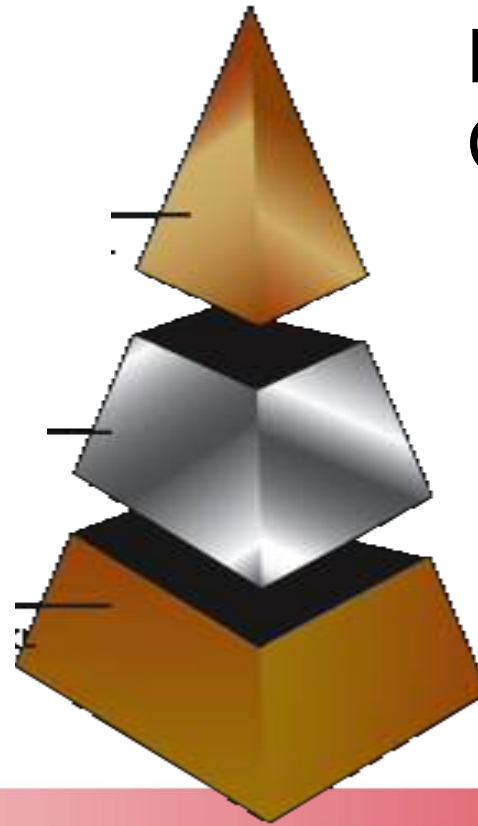
NC Fresh Produce Safety Initiative



Tier 3

Tier 2 - Traceability and Risk Mgmt

Tier 1- Basic Level



Farmers Market Curriculum

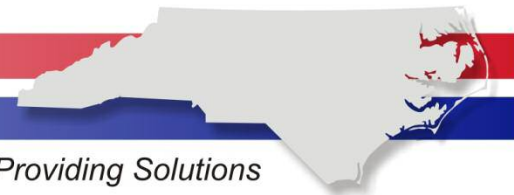
Small Farms Focus



Basic Training - Every Grower Should Know

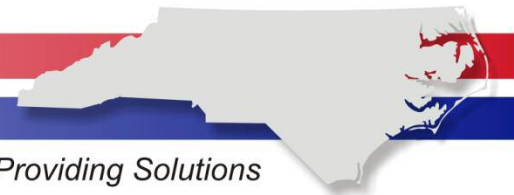
TIER 1

- **Module 1:** [Fresh Produce Safety Introduction](#)
- **Module 2:** [GAPs Field Practices](#)
- **Module 3:** [Packing Facility Sanitation](#)
- **Module 4:** [Health and Hygiene](#)
- **Module 5:**
[Animals, Animal Byproducts, Biosolids & Site Selection](#)
- **Module 6:** [Water Quality](#)



TIER 2

- **Module 7: The 3 Ts: Transportation, Traceback and Traceforward**
- **Module 8: Managing Liability and Risk**
- **Module 9: Dealing with Controversies and Crises: Working with News Media**
- **Case Study: Bagged Spinach Outbreak**
- **Validation Techniques (hands-on)**
- **SSOP, SOP, and food safety plan**



Food Safety Principles

Personnel Health &
Hygiene

Sampling

GOOD FARMER'S MARKET PRACTICES

Food Safety Culture

Commodity-Specific Risks

Training program

Preparation, Storage, Sanitation

Eight Principles of Good Agricultural Practices

1. Prevent microbial contamination
2. Start program of GAPs
3. Human/animal feces
4. Water
5. Animal manure
6. Worker hygiene/sanitation
7. Follow all applicable laws
8. Traceback/recordkeeping/documentation

FDA: Transmission Routes for Microbial Contaminants in Fresh Produce

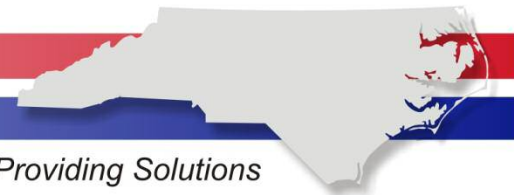
The four “W”s

1. Water

2. Worker

3. Waste

4. Wildlife



One year ago

- Food Safety Modernization Act signed into law by President Obama January 4
 - Phased-in implementation over next three years
 - Requires at least 12 new regulations from FDA

**FDA FOOD SAFETY
MODERNIZATION ACT**



FSMA One-Year Progress Report*

- Mandatory Recall Authority
- Administrative Detention of Foods
- Prior Notice of Imported Food
- Authority to Suspend the Registration of Food Facilities
- Fees (for certain domestic and foreign facility reinspections and for failure to comply with recall orders)
- Product Tracing Pilots Launched (tomatoes)
- Established the Produce Safety Alliance and the Food Safety Preventive Controls Alliance

***www.fda.gov/fsma**



FSMA focuses on prevention

- Six major preventive control rules:
 - Food preventive controls (GMP modernization)
 - Feed preventive controls
 - Prevention of intentional contamination
 - Sanitary transportation
 - Foreign supplier verification
 - Produce safety

Courtesy of Donald W. Kraemer, Acting Deputy Director Center for Food Safety and Applied Nutrition, nFDA



Highlights of Two

Produce Safety Regulation

- Growing, harvesting, post-harvest handling of produce (e.g., trimming, washing, grading)
- Packing of produce, where exempt from BT Act registration

Food Preventive Controls Regulation

- Packing of produce, where subject to BT Act registration
- Processing of produce (e.g., fresh cut)
- Warehousing, shipping, receiving of produce

Courtesy of Donald W. Kraemer, Acting Deputy Director Center for Food Safety and Applied Nutrition, nFDA



Bioterrorism Act (Bt)- Registered Food Facilities



- [Public Health Security and Bioterrorism Preparedness and Response Act of 2002](#), otherwise known as the **Bioterrorism Act**
- Both domestic and foreign farms do not need to register if they fall within the following criteria established by FDA:
 - Facilities that pack or hold food, provided that all food used in such activities is grown, raised or consumed on that farm or another farm under the same ownership.
 - Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.
- By this definition, packing houses that pack foods other than those owned by them need to register. The Bioterrorism Act makes failure to register a prohibited act.

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm>





FDA U.S. Food and Drug Administration

Reportable Food Registry(RFR) for Industry Effective September 2009

electronic portal to report when there is reasonable probability that an **article of food** will cause serious adverse health consequences.

Applies to **registered food** facilities that manufacture, process, pack, or hold food for human or animal consumption

Applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula.

<http://www.fda.gov/food/foodsafety/foodsafetyprograms/rfr/default.htm#about>

FSMA homepage

<http://www.fda.gov/fsma>

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

What's New | How to Participate | Main Topics

- Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues July 2011
- FDA Meeting FSMA Food Safety A Consumer Update on the imp July 5, 2011
- FDA Progress Report on Impler 2011 July 5, 2011
- Anti-Smuggled Food Strategy F July 3, 2011

More on What's New...

Implementation Timeline


July 2011 Issued a joint anti-smuggling strategy	July 2011 Issued draft guidance for the dietary supplement industry	August 2011 2012 User Fees
On July 5, FDA issued an anti-smuggling strategy that was developed by the Department of Health and Human Services (HHS) in coordination with the Department of Homeland Security. (SEC. 309)	On July 5, FDA issued draft guidance for the dietary supplement industry that clarifies for industry its expectations regarding new dietary ingredients. (SEC. 113)	On August 1, FDA published, through a Federal Register Notice, the fiscal year (FY) 2012 fee schedule for certain domestic and foreign facility reinspections, failure to comply with recall orders, and certain importer reinspections. (SEC. 107)

Food Safety Modernization Act (FSMA)

was signed into law by President Obama on food supply is safe by shifting the focus of attention to preventing it.


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the FDA Food Safety Modernization Act for his since President Obama signed the FSMA



FSMA Blog

The US and on Food Sa by Michael F Deputy Cor



and Drug Administration to meet with our Mexican counterparts. The trip was part of a larger, proactive strategy to reach out to stakeholders, both domestic and foreign, to explain the background and implementation strategies for the new Food Safety Modernization Act (FSMA) and importantly, to listen to issues raised by stakeholders. [MORE>](#)

Recently Posted Consumer Updates


- FDA Meeting FSMA Food Safety Goals
- Fish Hazards and Controls
- Food Bill Aims to Improve Safety

More Consumer Updates related to FSMA...

NC Coopera

For more blog postings, visit the FSMA Blog page.

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Growing Market Demand for GAPs certification

- Market-driven, not required by law
 - Food Safety Modernization Act (FSMA)
- Fresh Produce for schools- required
- Commodity-specific state/agreements- required
- Multiple Buyer requirements for different 3rd Party Auditors

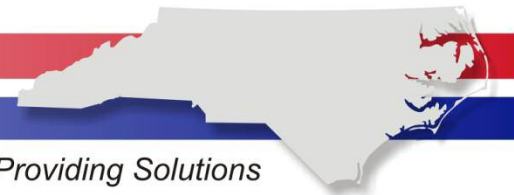


GAPs Certification

- Annual Certification (365 days) with Passing Score
 - an unannounced surveillance review during year
- Costs
 - Certification, testing, equipment, change of process, additional facilities/equipment, etc.
- 3rd Party Auditors has to see the entire scope of activities “in operation” in order to audit (e.g production/harvesting activities)
 - Assess, manage, and demonstrate risk reduction

GAPs Certification Process

- Education
- Integrated policies and procedures into a food safety program/plan
- Train management & employees
- Decide on 3rd Party Auditor/checklist
- Schedule Audit



Education

- Risk Assessment
 - Self Certification – no cost way of going through the process of food safety on the farm to identify priority risk areas
- Understand your Market requirements
- Training to all staff, management – risks and understand reasons why
- Auditor Questions/ Matrix

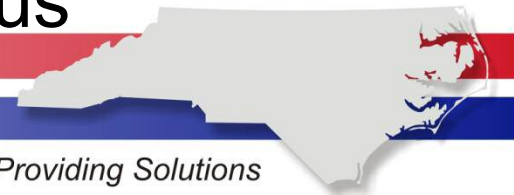
3rd Party Auditors

An independent, impartial party hired to perform surveillance audits (ALL GENERAL EXCEPT AS NOTED)

- NSF Davis Fresh
- Primus
- Scientific Certification Systems (SCS)
- USDA
- Florida Dept. of Agric & CS (Tomatoes)
- Calif. Dept of Food & Drug/Leafy Green Marketing Agreement (CDFA/LGMA)
- Canadian Hort. Council (CHC)/ On-Farm Food Safety (OFFS)
- Georgia GAP

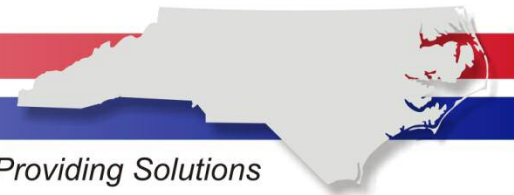
Choose Auditor

- Consider all Market requirements
 - Each market may have different needs in an audit
 - Audit may be commodity specific
- Can you combine Market needs by adding writers to one audit to accomplish all market needs?
 - Example: GA GAPs and Primus Audit



3rd Party Auditors Matrix

- Decide what part of the audit you will be doing
 - Field, Operation & Harvesting (Orchard)
 - Packhouse
- Download the checklists and expectation Manual
 - Includes actual questions
 - Understand the requirements from the questions from expectation
 - ASK QUESTIONS
- Understand Payment regime for Auditor
 - Hourly or part of audit
 - Travel expenses



General Questions

Implementation of a Food Safety Program

Questions		Points	Yes	NO	N/A	Doc
P-1	A documented food safety program that incorporates GAP and/or GHP has been implemented.					D
P-2	The operation has designated someone to implement and oversee an established food safety program. Name _____					D

Traceability

Questions		Points	Yes	NO	N/A	Doc
G-1	A documented traceability program has been established.	15				D
G-2	The operation has performed a "mock recall" that was proven to be effective.	10				R

Worker Health & Hygiene

Questions		Points	Yes	NO	N/A	Doc
G-3	Potable water is available to all workers.	10				R
G-4	All employees and all visitors to the location are required to follow proper sanitation and hygiene practices.	10				P
G-5	Training on proper sanitation and hygiene practices is provided to all staff.	15				D
G-6	Employees and visitors are following good hygiene/sanitation practices.	15				

Total Points earned for General Questions =

Total Possible = 180 *The total number of points possible for this section.*

Subtract "N/A" = *Enter the additive number of N/A points (+points) here.*

Adjusted Total = *Subtract the N/A points from the Total possible points*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the*
Passing Score

Passing Score =

Pass **Fail** **(please mark one)**

This program is intended to assess a participant's efforts to minimize the risk of contamination of fresh fruits, vegetables, nuts and miscellaneous commodities by microbial pathogens based on the U.S. Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," and generally recognized good agricultural practices.

How to get the most for your \$

- Have documents prepared
 - Do a mock audit internally
- Reframe from side conversations with Auditor
 - Have these before audit begins
- Schedule Audits as far in advance as possible
- Share travel time of auditor to your region
 - Association or market broker can assist
- Apply for the cost-share \$
- Look to reduce number of different auditor demands from markets



Resources

- Websites
- Videos
- Curriculums
- People!

Hand-washing Units Summary

NCSU Commercial Unit



*Cost: \$2,000
 Application: Commercial-scale fields
 Capacity: 125 gallons
 System: Gravity-fed with knee valves

*Minus the trailer

NCSU Farmers Market Unit



*Cost: \$2,000
 Application: Farmers markets, Events, etc.
 Capacity: 125 gallons
 System: Pump

*Minus the wagon

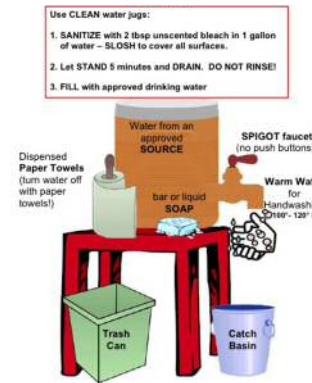
“Use-Yer-Foot” Unit



*Cost: \$139 (rentals available, \$15/day)
 Application: Farmers markets, Events, etc.
 Capacity: 10 gallons
 System: Gravity-fed with foot pedals

*N.C. residents add state sales tax, shipping not included

Quick & Easy Unit #1



Cost: <\$100
 Application: Farmers markets, Smaller fields, Events, etc.
 Capacity: 5-10 gallons
 System: Gravity-fed with valve faucet (no push buttons)

Quick & Easy Unit #2



Cost: <\$100
 Application: Farmers markets, Smaller fields, Events, etc.
 Capacity: 5 gallons
 System: Gravity-fed with valve faucet (no push buttons)

N.C. State Hand-washing Stations

- **Rod Gurganus**, director of N.C. MarketReady, the N.C. Cooperative Extension outreach of N.C. State's Plants for Human Health Institute, and **Dr. Gary Roberson**, extension specialist in biological and agricultural engineering, developed two hand-washing station prototypes for producers.
- Took into account producer feedback, construction costs, functionality and used widely available materials like water tanks and plumbing parts to give producers room for customization.
- Construction costs are estimated around \$2,000 for both units, minus the support trailer or wagon, but will vary depending on brands, accessories, etc.
- Custom additions can include waste receptacles, steps/ ramps, towel racks and soap dispensers.



(L-R) Dr. Gary Roberson and Rod Gurganus, N.C. State University, developed two hand-washing station prototypes for producers.



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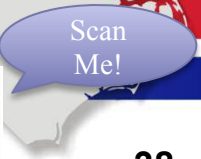
Construction guidelines and photos are available at:
<http://ncsu.edu/enterprises/ncfreshproducesafety/hand-washing-unit/>

N.C. State Commercial Unit

Background



- This facility has a 125gal capacity and is intended for commercial use in fields.
- Gravity-fed system: top tank holds clean water (125gal), bottom tank collects waste water and should have double the capacity of the top tank (250gal).
- Designed for six people to wash their hands (can be customized). Operated by knee valves that control water flow when pressed with the leg (reduces contamination risks from faucets).
- Frame must be able to support the water supply tank when full (1,000lbs). Trailer weight capacity should be 3,000lbs. min.
- Construction costs will vary, but this unit cost about \$2,000, minus the trailer.
 - Water tanks: \$600/pair
 - Plumbing: \$600
 - Support frame: \$500
 - Sinks: \$300/pair



N.C. State Farmers Market Unit



Background

- Producer feedback highlighted a need for a smaller hand-washing facility for use at farmers markets, one that would be easier to deploy and involve fewer costs.
- This unit holds two 125gal tanks and is operated by a water pump system.
- The sinks fold up and latch for easy transport and storage.
- Construction costs will vary, but this unit cost around \$2,000, minus the wagon.
 - Water tanks: \$600/pair
 - Pump system (pump, accumulator tank, electrical): \$500
 - Plumbing: \$400
 - Sinks: \$300/pair
 - Accessories (soap dispenser, etc.): \$100
- A solar panel could be added to the electrical box for more efficient charging.

Visit <http://ncsu.edu/enterprises/ncfreshproducesafety/hand-washing-unit/small-station/> for construction guidelines.

NC Cooperative Extension

Funding from the N.C. Rural Economic Development Center's Agricultural Advancement Consortium made this project possible.

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Scan Me!



On-Farm Food Safety Project

About | [How to Get Food Safety Certified](#) | [Create a Food Safety Manual](#) | Forms/Training Materials | Resources | Press | Sponsors

Need Help Creating a Food Safety Plan?



The On-Farm Food Safety Project is a comprehensive national program that offers fruit and vegetable farmers, food safety professionals and agricultural extension specialists technical assistance to utilize and teach best practices in food safety.

This website includes the bulk of these resources including a free online tool, based on a comprehensive risk based framework, which generates customized on-farm food safety plans based on user input. The tool is

designed for use by small to mid-scale fruit and vegetable growers and provides a full set of record keeping tools to document their food safety program and to provide training to their employees

**PROJECT LAUNCH:
Washington DC Press Conference
with Kathleen Merrigan**

**Learn About Food Safety and
Start Your Plan:**

[How to Get Food Safety Certified](#)

[Create a Food Safety Manual](#)

create-manual-button



We are grateful that many leaders in food safety contributed to the development of

www.ncfreshproducesafety.org

NC STATE UNIVERSITY

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Fresh Produce Safety Portal



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The N.C. MarketReady team has compiled valuable resources and materials on this Fresh Produce Safety Web portal, including information on traceability, postharvest quality, cost share opportunities, Good Agricultural Practices (GAPs) and more.

For more information about Fresh Produce Safety in North Carolina, contact:

Diane Ducharme
Extension associate & GAPs
program coordinator
704-250-5402

Rod Gurganus
Director, N.C. MarketReady
252-793-4428

James Oblinger
Professor, Dept. of Food,
Bioprocessing and Nutrition
Sciences
704-250-5447

Search for Growers Trained in Fresh Produce Safety

N.C. Cooperative Extension agents have been conducting Tier 1 trainings throughout the state using the N.C. MarketReady Fresh Produce Safety GAPs Training curriculum.

[Search the GAPs Grower Directory >>>](#)

Program Updates

Fresh Produce Safety Trainings Make an Impact in 2010

The N.C. MarketReady Fresh Produce Safety – Field to Family Good Agricultural Practices (GAPs) Training Curriculum is bearing fruit for the nearly 300 growers and more than 120 Extension agents who have completed the training. Read more to find examples of the impacts the training is having on N.C. farms.

[See Previous Program Updates >>>](#)

Trainings & Events

N.C. MarketReady Fresh Produce Safety – Field to Family GAPs Training Calendar

N.C. Cooperative Extension agents conduct the N.C. MarketReady Fresh Produce Safety – Field to Family GAPs training curriculum at N.C. Cooperative Extension offices and other locations across the state. The curriculum trains growers on how to minimize food safety risks. Review the list of recent and upcoming trainings in the calendar.

Fresh Produce Safety Symposium 2010

September 9, 2010

This symposium is targeted to growers, industry, academics, policymakers, regulators and Extension agents. The primary focus will be on professional recommendations for Good Agricultural Practices (GAPs) and Good Handling Practices (GHPs) for fresh produce safety and protection of public health. Speakers will relay the details of fresh produce and food safety initiatives and research in their states, providing both regional and national perspectives.

Featured Resource



Food Safety Modernization Act Webinar

The N.C. Fresh Produce Safety Task Force (NCFPSTF) and N.C. Farm Bureau (NCFB) present a webinar regarding the recent Food Safety Modernization Act. The webinar is moderated by Diane Ducharme, with NCFPSTF and N.C. MarketReady, and Debbie Hamrick, with NCFPSTF and NCFB.

Recalls