

A Program of NC Cooperative Extension

Module 7: **The Three T's: Transportation, Traceback and Traceforward**

Acknowledgments

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Module 7: The Three T's: Transportation, Traceback and Traceforward

Estimated duration: 2 hours

Instructional overview:

Module 7 will demonstrate the recommended safety practices for the sanitation of transportation facilities and the necessary traceback/traceforward procedures to protect fresh produce effectively.

Instructional objectives:

- Participants will be able to appraise safety conditions during loading, unloading and inspecting of fresh produce in transport.
- Participants will be able to demonstrate knowledge of a traceability system.
- Participants will understand procedures to conduct rapid and effective removal of foods from the marketplace (Recall).

Equipment, supplies and materials needed:

- Laptop and LCD projector
- PowerPoint (PPT) presentation on CD
- Nametags, pens

Preparation needed:

- Review Module 7 and PPT prior to day of the workshop; become familiar with GAPs programming—how each module is an integral part of the other modules.
- Secure a laptop computer with PPT capability and LCD projector. Save a copy of the PPT presentation (on CD) on computer.
- Make copies of workshop activities/handouts, pre-test and post-test (if applicable) for all participants.
- Review the Resource list at end of manual for helpful references.
- Obtain, easels, flip charts, markers if needed.
- Prepare room to accommodate participants and projector. Prepare sign-in sheet and nametags, as applicable.



Learners' Objectives

- Participants will be able to appraise safety conditions during loading, unloading and inspecting of fresh produce in transport.
- Participants will be able to demonstrate knowledge of a traceability system.
- Participants will understand procedures to conduct rapid and effective removal of foods from the marketplace (Recall).

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Module 7

Welcome

Have participants make nametags and introduce themselves

Activity

Participants should be handed the Pre-test.

PPT 7-1: The 3T's: Transportation, Traceback and Traceforward

This module addresses the continuum represented by Good Manufacturing Practices (GMPs) and the Produce Traceability Initiatives present currently in the produce industry. The issues discussed in this module help growers trace produce as it moves through the entire supply chain starting in the field and ending with the consumer.

PPT 7-2: Learners' Objectives No notes



Why Is This Subject Important?

- Important part of the food chain it involves moving produce from field to cooler, packing facility or other distribution terminal market.
- Essential because the pre-transit handling of perishable commodities dictates the product's quality and shelf life AFTER transport.

During Transportation...

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- Cross-contamination from other food or non-food sources is the biggest concern.
- Potential for more exposure to contaminated surfaces during loading, unloading, storage and other necessary operations.
- Shipping (loading) and receiving (unloading).

Photo courtesy of http://ucce.ucdavis.edu/files/filelibrary/6123/40400.jpg and http://barfblog.foodsafety.ksu.edu/lettuce-skull(2).jpg

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PPT 7-3: Transportation Topics

This module will be broken into three topics: Transportation, Traceback and Traceforward, Recall and Mock Audits.

PPT 7-4: Why Is This Subject Important?

Preventing contamination is the first line of defense. Reducing pathogens on produce is essential to reduce food-borne illnesses, but it will also reduce produce spoilage (from other plant pathogens) and improve the overall appearance of produce at the end-markets.

PPT 7-5: During Transportation....

Food surfaces can be contaminated by exposure from other foods or from non-food sources, such as handling by workers.



Preventing Cross-contamination

Items to consider:

- Limiting access from field to catwalks/packing house?
- Making the product flow linear from field to transport?

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- Container/Bin tote cleaning and sanitation?
- Issues of backhauling?

Review of the Packing House

Containers or Bins

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- Should be cleaned and sanitized periodically.
- Reusable bins should be made of materials easy to clean.
- Bins will be inspected for damage; either repaired or replaced.Pallets
 - Pallets should be in good condition/free of loose pieces and debris.
 - Damaged pallets should be repaired or discarded.
- Packing House

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- Should be clean, free of debris and personal belongings.
- Employees and visitors should be free of jewelry and practicing good hygiene practices.

PPT 7-6: Plan the Load—Four Areas

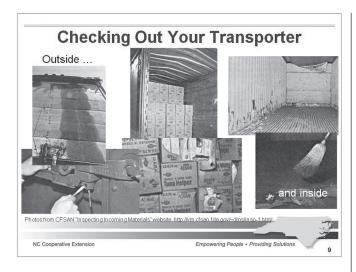
Planning is one important step in prevention. By means of visual inspections and use of checklists, we have less chance of making mistakes and overlooking items.

PPT 7-7: Preventing Cross-contamination

Cross-contamination can take place anywhere along the food supply chain. Making a map of the product flow can be helpful in visualizing all the different parts involved in food safety.

PPT 7-8: Review of the Packing House

While the packing house was covered in more depth in another module, this subject bears repeating in summary form. Again, it is a look at all the potential sources of contamination and good management practices associated with its management.



Check the Trailer

- Do not load a damaged trailer.
- Check records on previous hauling loads/backhauling issues.
- Pre-cool trailer to required temperature.
- Check seals on trailers and other tamper evidence tools?
- · Complete checklist.

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· Keep chart of F and C handy!

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PPT 7-9: Checking Out Your Transporter

These photos indicate the various areas of concern when checking out your transporter.

PPT 7-10: Check the Trailer

These steps should be adopted as normal or standard operating procedures. This will allow the grower and handlers to understand expectations and conform accordingly. The following two handouts can be given to growers. They document visual inspections and provide important references for dealing with temperature conversions.

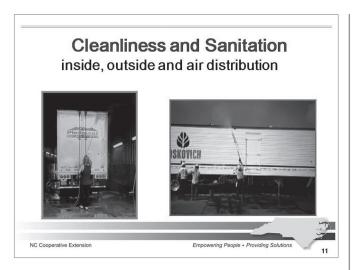
Handout 7-1:

10-Point Checklist for Transportation Handout 7-2:

Celsius to Fahrenheit Conversion Chart

Additional items to check for in the reefer truck :

- Air delivery chute intact?
- Door seal damage?
- Side door seal tight?
- Door damage?
- Wall damage?
- Front bulkhead installed?
- Floor drains open (clean)?
- Floor clean?



Proper Cleaner Selection and Disinfection

- · Pre-rinse/pre-clean
- Adequate contact time
- Proper cleaner selection
- Adequate mechanical disinfection
 - 6-8 gpm; 650-850 psi; 130-150°F
 - Clean water rinse; 60-80 psi; 130-150°F
- Cleaning air distribution system



PPT 7-12 (continued)

Cleaning air-distribution systems is essential, too:

- Remove air delivery plenum.
- Remove return air bulkhead.
- Clean evaporator outlets & inlets.
- Clean return air bulkhead.

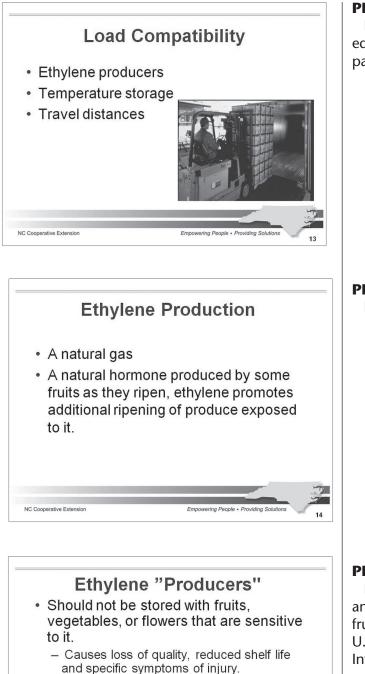
More in-depth information on cleaning and sanitizing equipment can be found at:

University of Maryland—Improving the Safety and Quality of Fresh Fruits and Vegetables: Good Manufacturing Practices for Handling, Packing, Storage and Transportation of Fresh Produce (http://jifsan.umd.edu/pdf/gaps_en/III_Good_Manufacturing_Pra.pdf).

PPT 7-11: Cleanliness and Sanitation We should be looking at the transporter from both the inside and outside for cleanliness.

PPT 7-12: Proper Cleaner Selection and Disinfection

What does it really mean to be "clean"? Prerinsing the surface will remove most of the organic debris. Remember: potable water must be used in this process because there is a potential for food contact. Some sanitizers lose their effectiveness when they come in contact with organic matter or when they are exposed to air, light or metals. Choosing the appropriate cleaning agents to match the type of cleaning surface can make a difference in truly cleaning and disinfecting a surface. For instance, a moderately alkaline cleaner with corrosion inhibitors should be used on aluminum panels and floors. For wood panels, polyphosphates plus a surfactant should be sufficient.



- Examples of ethylene effects:
 - Increased ripening and softening of mature green tomatoes.
 - Symptoms resulting from putting bananas or avocados in a brown paper bag.

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PPT 7-13: Load Compatibility

Now that the transporter is clean and disinfected, we need to make sure that the load is compatible with the transporter.

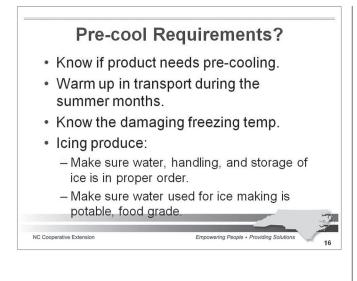
PPT 7-14: Ethylene Production No notes

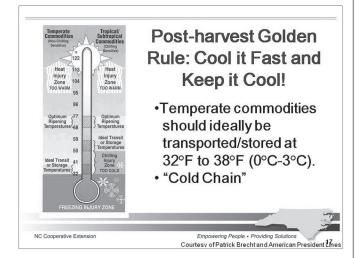
PPT 7-15: Ethylene "Producers"

More detailed information about properties and recommended conditions for storing fresh fruits and vegetables can be found on the website U.C. Davis Postharvest Technology, Research & Information Center http://postharvest.ucdavis. edu/Produce/Storage/Properties-english.pdf (last updated November 2001).

Recommend that presenters download and present to audience.

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Recording Thermometers

• Usually placed to measure discharge air temperature.

- Microprocessors

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- Provide documentation of refrigeration ("reefer") unit performance.
- Newer types have probes to record product temperatures, too.
- · Calibrate the temperature sensors!

PPT 7-16: Precool Requirements?

Temperature can have an effect on horticultural commodities. All products are harmed by exposure to excessively high and low temperatures. Tropical and subtropical products must be transported at higher temperatures to avoid chilling injury. If ice is used to cool produce or produce container, ice must be made with potable water. Currently, no regulation requires a truck to be refrigerated when transporting fresh fruits and vegetables.

PPT 7-17: The Postharvest Golden Rule: Cool It Fast and Keep It Cool!

Transportation is a very important food-safety link between grower and consumer. "Cold chain" refers to an uninterrupted series of temperaturecontrolled activities in the storage and distribution supply chain.

PPT 7-18: Recording Thermometers

Some trucking agencies are using microprocessors. Microprocessor controllers are an important asset because they:

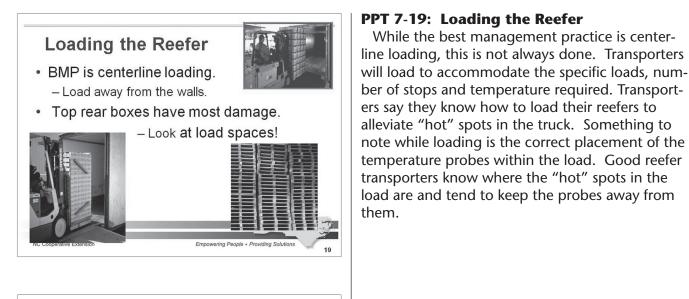
- Measure and control discharge and return air temperatures
- Document refrigeration unit performance.

Optional features include:

- Cargo temperature recording
- Upper/lower set-point limits
- Atmosphere management

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Receiving a Load

- · Inspect the transport vehicle.
- Check the load.

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- Look for evidence of insects/rodents/ bird activity.
- Take random samples of food containers.
- Document with an Incoming Inspection Report.

Authority for Sanitary Food Transportation Practices

- 2005 Sanitary Food Transportation Act
 - Amends the Federal Food, Drug, and Cosmetic Act (FDCA) 402.
 - Shifts authority from Dept. of Transportation to U.S. Food and Drug Administration (FDA).
 - $-\operatorname{As}$ of 2008, no rules have been developed.

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food safety. Before shipping ever begins, it is important to have a policy in place that spells

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important to have a policy in place that spells out the acceptable conditions and costs for shippers if these conditions are not met. Fresh fruits and vegetables are perishable products, and the timeliness of deliveries is essential to produce quality and food safety.

If a reefer comes in dirty, growers' choices are: refuse the load or clean it themselves. By notify-

ing the contractor of the unsatisfactory condi-

tions, growers can renew the commitment to

PPT 7-20: Receiving a Load

PPT 7-21: Authority for Sanitary Food Transportation Practices

The 2005 Sanitary Food Transportation Act (SFTA) raises several issues for the food industry with respect to the transportation of food and food products. Transportation cleanliness is an important component of fresh produce food safety. Transportation providers need to know the responsibilities and standards that they are being expected to meet.

The 2005 SFTA amended FDCA 402 to render unsanitary transport "adulteration," and added a new FDCA section 416 concerning "sanitary transportation practices." Such regulations will apply to shippers, motor vehicles and rail carriers, receivers and any other person engaged in the transportation of food. In addition, section 416

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PPT 7-21 (continued)

mandates the FDA's forthcoming sanitary food transportation regulations that prescribe appropriate record-keeping. Failure to comply with the new regulations is deemed a prohibited act under the FDCA and may subject offenders to criminal prosecution and seizure of affected shipment. We will have to keep an eye on this Act for forthcoming regulations.

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 Set lowest acceptable temperatures for each commodity carried (heats up in transport).
 Use recording thermometers with probes to monitor product temperature.
 Maintain records of reefer performance and maintenance.
 Regularly inspect and sanitize trucks and containers.
 Maintain records of prior cargoes and equipment cleaning.

PPT 7-22: Recommendations

In summary, cool produce, keep it cool and clean during transport and RECORD your efforts. Some useful definitions in transportation are included below for your convenience:

Due Diligence. Using "Due Diligence" can go a long way in protecting you and your produce from meritless claims!

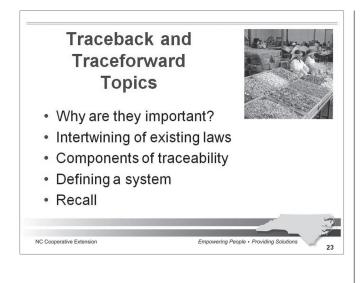
Transportation providers need to have temperature and diagnostics records from the refrigerated unit, plus equipment maintenance records to protect themselves.

• The burden of proof of a loss shifts to the transporter when the shipper has good records and the transporter has few or none.

PPT 7-22 (continued)

Suitable Shipping Condition (SSC). SSC applies only to F.O.B. sales, and means that the produce, at time of shipment, is in a condition which if handled under normal transportation conditions will assure delivery at the agreed destination without abnormal deterioration.

F.O.B. The commodity is placed "free on board" the carrier at the shipping point in "Suitable Shipping Condition," and the buyer assumes all risks of loss and damage in transit not caused by the seller. This means, for example, that if the load is wrecked or stolen in transit, the buyer must pay the invoice price to the seller and pursue a claim against the carrier to recover damages.



PPT 7-23: Traceback and Traceforward

Revisit the objective:

- Participants will be able to demonstrate knowledge of a traceability system.
- Participants will understand procedures to conduct rapid and effective removal of foods from the marketplace (Recall).

Or.....One step back One step forward

- "Who/Where did I get it from and Who/Where is it going."
- A traceback investigation is the method used to determine and document the distribution and production chain, and the source(s) of a product that has been implicated in a food-borne illness investigation, quickly and accurately.

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Why Is This Documentation Important?

- Quickly & accurately = locate foods in the distribution system
- Quickly & accurately = prevent illnesses and possible deaths
- Quickly & accurately = allow for integration of other existing program requirements

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 Quickly & accurately = less economic impact to growers

The Consumer Speaks.... Food scares erode confidence in food safety. 46 percent worry about getting sick from food. 52 percent have only some or little confidence in the food inspection system. Consumers support traceability solutions. 86 percent support labeling produce so it can be tracked. 80 percent support federal safety standards for produce. 92 percent support COOL.

PPT 7-24: Or.....One Step Back, One Step Forward

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, also called the Bioterrorism Act (2002), instructed the U.S. Food and Drug Administration (FDA) to require this one-step-back and one-step-forward documentation. 21CFR part 1, subpart J prescribes the establishment and maintenance of records for persons who manufacture, process, pack, transport, distribute, receive, hold or import food in the U.S. *"Generally, everybody in the supply chain must be able to trace one step back and one step forward."*

PPT 7-25: Why Is This Documentation Important?

Traditionally, the food industry has resisted stronger tracing requirement. But after the recent *Salmonella* outbreak and estimates of losses amounting to \$250 million for tomato growers alone, ideas are starting to change. (This does not account for the pepper growers' losses!) Growers are starting to realize that these outbreaks have the potential to shut down the whole industry, and that it may be to their advantage to enable traceback investigations that focus on the source of contamination.

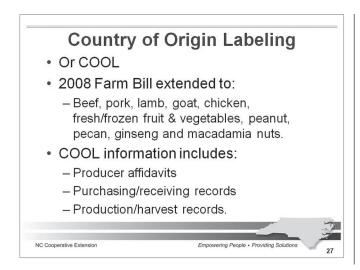
PPT 7-26: The Consumer Speaks

Why is traceability important? Consumers demand it as well as industry, and now the U.S. Congress thinks it's important! This slide represents cumulative summaries from two consumer surveys on food safety.

- Sources: AP-Ipsos poll July 18, 2008; Harvard School of Public Health poll June 12, 2008.
- Consumer Reports survey July 10, 2007.

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PPT 7-27: Country of Origin Labeling

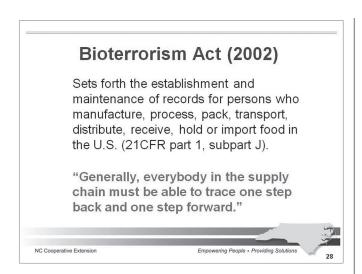
Building the case for traceability, a mandatory Country of Origin Labeling (COOL) became effective on September 30, 2008 for fresh/frozen fruits and vegetables under the 2008 Farm Bill which went into final effect on March 16, 2009 (http:// www.ams.usda.gov/AMSv1.0/cool). The intent of COOL is to provide consumers with additional information on which to base their purchasing decisions. With a heavy interest and demand for "local food" this could result in increased sales of apples grown in North Carolina.

PPT 7-27 (continued)

Who Must Label: Anyone licensed as a retailer under the Perishable Agricultural Commodities Act (PACA) must provide COOL labeling. The Perishable Agricultural Commodities Act (PACA) of 1930 required the documentation and retention of records that covered produce lot identity and all transfers and transactions between shipping point and destination receiver. It is the responsibility of those in the business of supplying fruit and vegetables to a retailer to provide the information needed to comply with this law. It will be required by those to whom you are selling a majority of your fruit through wholesale markets. If you are selling all of your fruit through local food stands, this will not affect you.

Information Needed: The information needed is the country in which the fruit has been grown. When required to provide this information, you can provide this information on the product itself, on the box or bin in which the products are delivered, or in another document associated with the transaction (example: bill of sale). Other examples of perishable agricultural commodities documents can be found at: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3103377

Exemptions: Restaurants and other food-service establishments, along with food stands are exempt and processed foods are excluded. COOL verifications for fruits and vegetables can include: producer affidavits, purchase/receiving records, production, harvest records or bills of lading/invoice. Program oversight and implementation is the responsibility of USDA's Agricultural Marketing Service.



PPT 7-28: Bioterrorism Act (2002)

The Bioterrorism Act requires domestic and foreign facilities to register with FDA if they manufacture, process, pack or hold food for human or animal consumption in the U.S. The purpose of registration is to provide FDA with sufficient and reliable information about food and feed facilities. Examples of FDA-regulated foods include fruits and vegetables, fish and seafood, and dairy products and shell eggs.

Both domestic and foreign farms do not need to register if they fall within the following criteria established by FDA:

PPT 7-28 (continued)

- 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. In August 2006, FDA published a revised Compliance Policy Guide (CPG).

More information about the Bioterrorism Act can be found at: www.ncfreshproducesafety.org. Click on Good Agricultural Practices or directly at http://frwebgate.access.gpo.gov/cgi-bin/getdoc. cgi?dbname=107_cong_public_laws&docid=f:publ188.107.pdf.

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Traceback Components

- A documented traceback program has been established.
- Finished product is traceable to:
 - the packing house
 - a group of growers/the specific grower
 - a group of orchards or fields/to the specific orchard or field

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- a group of harvest dates/a specific harvest date
- a packing date.

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 The operation has performed a "mock recall" that was proven to be effective.

Internal + External = Whole-Chain Traceability

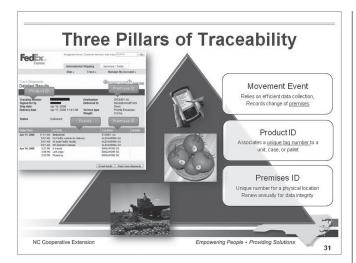
- Internal = confidential or proprietary data and processes companies use within their own span of operations to track/trace product (e.g. packer).
- External = the data exchange and business processes that take place between trading partners to track/trace product (grower => packer => retailer).

PPT 7-29: Traceback Components

While integrating the necessary information for a traceability system, lot integrity needs to be maintained throughout the commodities distribution life. Ideally, for lot integrity all of the commodities should be from the same field and the same grower. For example, with incomplete boxes of tomatoes, it has been common practice to "top off" the box with others from various boxes. This compromises the lot integrity if the boxes are from different growers or fields. A traceability system enables compliance with existing laws like the COOL and Bioterrorism Act.

PPT 7-30: Internal + External = Whole-Chain Traceability

Whole-Chain Traceability means being able to trace the physical movement of food from field to fork. A recent push from industry for Whole-Chain Traceability is called the Produce Traceability Initiative (http://www.producetraceability.org/ www.produce).



Define a System

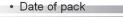
- Grower
 - Uniquely identify all growers in a value chain
 - Machine readable (barcode or RFID)
 - And human readable (growers name, address)
- Specific Field location (Premises ID)
 - Coordinates (get a map of your fields online)

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- Use the Farm Service Agency numbers
- Assign a Product ID for each commodity
- · Identify each picker or group of pickers
- Date of harvest (and time of day)



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Define a System (cont'd)
Movement codes (harvest, pack, ship...)
Receipt date
Ship date
Personnel health records linkage
Documentation for fresh produce needs to be kept for at least one year.

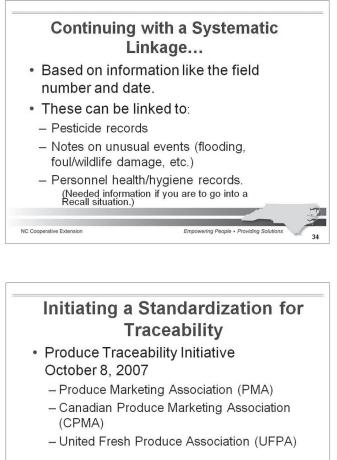
PPT 7-31: Three Pillars of Traceability

Graphically shown, there are three three pillars of traceability. Premise ID links the products originating in production fields with the grower's contact information. Product ID enables this product to be identified regardless of how many times it moves or where it ends its journey. The final pillar is the ability to track movement of the product electronically throughout the food chain. This ensures accurate records are kept of the events involved with moving a particular product from field to retail establishment. These three pillars characterize a true traceability system.

PPT 7-32: Define a System

Documentation for fresh produce traceability needs to be kept for at least one year. (RFID = Radio-Frequency Identification.)

PPT 7-33: Define a System (continued) No notes





PPT 7-34: Continuing with a Systematic Linkage

As mentioned in an earlier slide, personnel health records along with other records such as pesticide usage and unusual events should all be linked in your food-safety plan under traceability.

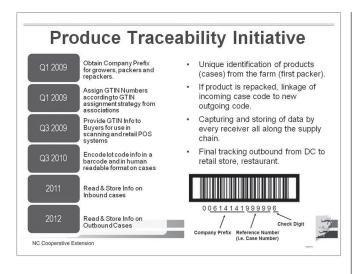
PPT 7-35: Initiating Standardization for Traceability

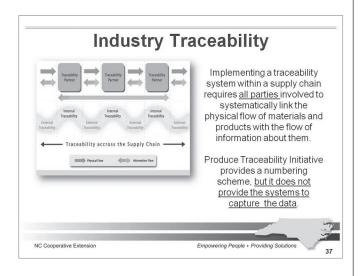
A look at what is being proposed on a national level needs to be incorporated in our discussions of traceability. Current sentiment in the marketplace indicates that producers are guilty by association until proven otherwise. In an effort to address this sentiment and limit the impact of product recalls, the Produce Traceability Initiative began with standardization of case-level identification as the simplest first step. The initiative brings together the Produce Marketing Association (PMA), Canadian Produce Marketing Association (CPMA) and United Fresh Produce

PPT 7-35 (continued)

Association (UFPA) to incorporate existing technology, standards and information used in the produce industry. Examples of this include the use of bar codes, GS standards, lot or batch numbers and case-level identification (GTINs). At the heart of the standardization is the GS1 coding, using the system's Global Trade Item Number (GTIN), which is similar to the U.S. UPC coding but allows for more information. Identifying commodities by numerical coding rather than description is critical because word-based descriptions can vary significantly, while, like a UPC code, each attribute in a numerical code can have a specific meaning that is recognizable worldwide.

More information on the Produce Traceability Initiative can be found at http://www.producetraceability.org.







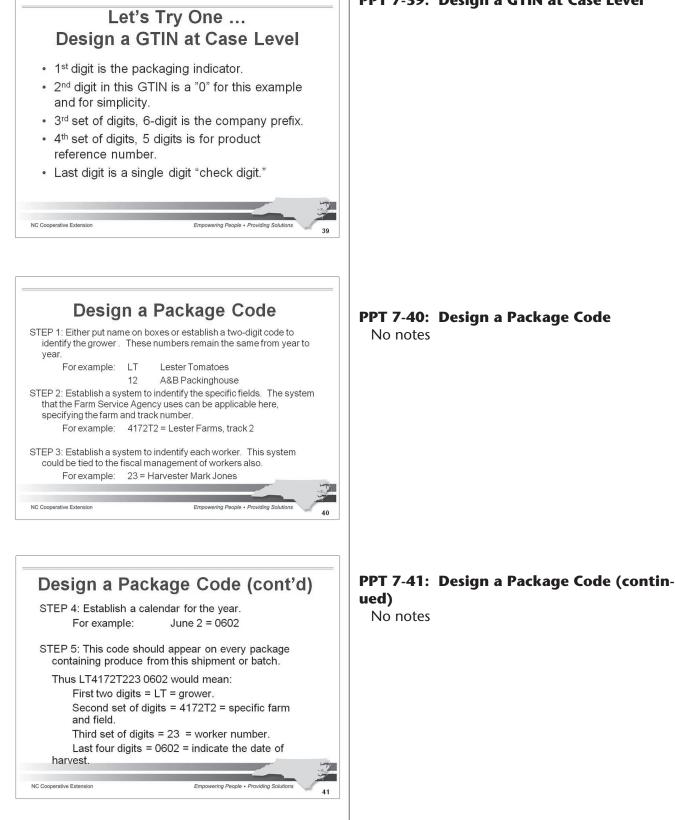
PPT 7-36: Produce Traceability Initiative

The Produce Traceability Initiative recommends a timeline for industry's process of traceability. Remember, we are looking at both an internal and external traceability. This means that we need to think about lot integrity and how this will be traced electronically. How do growers start looking at managing records for quick and easy access? This timeline with recommended practices addresses the steps that the initiative set forth to reconcile these thoughts and questions. It was designed to help the industry maximize the effectiveness of current traceback procedures while developing a standardized industry approach to enhance the speed and efficiency of traceability systems for the future.

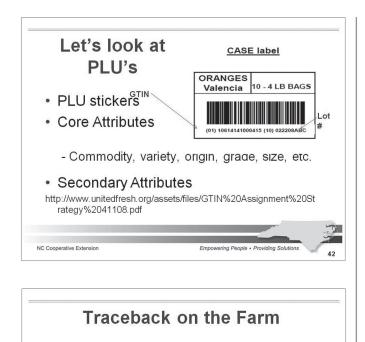
PPT 7-37: Industry Traceability

No notes.

PPT 7-38: Technology already exists for tracing fruit and vegetables throughout their supply chain history. Consumers see this every time they shop.



PPT 7-39: Design a GTIN at Case Level



- Produce Traceability Initiative system designed to case level (First Packer).
- Important to have a system defined from the farm level that identifies
 - Grower
 - Lot number (attached to harvested field)
 - Harvest/Pack date.



PPT 7-42: Let's Look at PLU's

Now that we have a design package code known as a GTIN, we need to look at how it can be incorporated into the PLU (Price Look Up) stickers currently employed in industry.

(Create a handout and go through SCENARIO 1.)

PPT 7-43: Traceback on the Farm

The current recommendations coming out of the Produce Traceability Initiative are guidelines for traceback systems to the case level at the first packer level. Two scenarios can apply:

 If the packer is representing growers for sales and marketing, then the packer is the brand owner and responsible for getting the GS1. This would indicate that the packing facility would be responsible for securing a company pre-fix (GS1) and establishing the GTINs, recording and maintaining specific grower information including lot number and harvest/ pack date. It is important to understand that the grower using this system would still

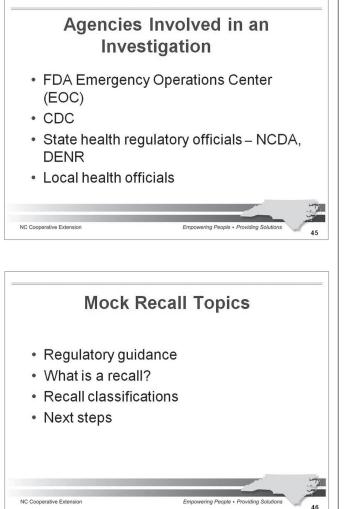
need to give information of grower details, lot number and harvest/pack date to the packer for incorporation into the whole-chain traceability system.

• However, if growers represent themselves to the wholesale/retail/food service, and thus they own their brand name, then they would be responsible for the guidance recommendations starting with the GS1 as stated above for the packer.



PPT 7-44: Traceback Investigation Conducted

If a traceback investigation is conducted, as we have seen recently with studies on *E.coli* on bagged spinach (2006) and more recently *Salmonella* on tomatoes/peppers (2008), it will be important to have quick and easy access to information that is pertinent to the particular commodity, including such items as are available in the traceback system outlined previously. Setting up a traceability system is the beginning of a recall program which we will see on the next slides.



Regulatory Guidance

- 21 CFR Part 7, Subpart C: Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibility <u>http://www.access.gpo.gov/nara/cfr/waisidx_0</u> <u>4/21cfr7_04.html</u>
- U.S. Food and Drug Administration (FDA) has authority over most other foods.
- USDA Food Safety and Inspection Service (USDA/FSIS) has authority over meat and poultry products.

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PPT 7-45: Agencies Involved in an Investigation

Once a traceback investigation begins, any one of these agencies could be involved, simultaneously or otherwise.

PPT 7-46: Mock Recall Topics

Part of your traceability system is a check on that system for effectiveness. This is a mock recall. Once your traceability system is defined, your next step is to develop a Case Scenario that you can run your company though. Talk to N.C. Cooperative Extension to help come up with a scenario—it will help to have outside personnel evaluate your system, and it could be fun!

The following set of slides will outline the regulatory structure and give you some definitions and resources to help you as you continue developing your traceability system.

PPT 7-47: Regulatory Guidance

Although we are talking about a mock recall, in the real world, recalls are increasing in frequency. This slide gives you the regulatory agency responsible for recalls, the areas that they are responsible for and the code of federal register pages to back up this authority.

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SS 🔊 http://www.fda.gov/		✓ 🏓 Go Lin
FDAS U.	S. Food and Drug Administration	n Kealth and Health and Human Services
Search GO		Food Industry Register a Facility Prior Notice of Imports
Powered by Google A-Z Index Site Map	FDA NEWS Marketing of MS Drug Tysabri Suspended Illegal SciFit Procut Dietary Supplements Seized	FDA employees and areas of regulation. Flu Information PPA Losing Weight Cell Phones
Products FDA Regulates Food Foodborne Illness, Nutrition, Dietary Supplements	New-Product Approved to Treat Smallpox Vaccination Complications New Improvements in FDA's Drug Safety Monitoring Announced Cellular, Tissue and Gene Therapies Advisory Committee to Meet March 3-4	 Imported Drugs Counterterrorism Bioterrorism Act Buying Medicines Online Counterfeit Drugs More Hot Topics
Drugs Prescription, Over-the-	Recalls, Product Safety	FDA Activities About FDA

Situations Prompting Recalls

- · Allergens
- Bacterial /chemical contamination
- Communicable disease
- Company-generated information
- Foreign objects
- Illnesses identified by State Health Dept. Or CDC
- In-house sabotage
- Misbranding

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- Packaging defects
- Real or fraudulent consumer claims
- Scientific reports
- Suppliers' notification
- Tampering and tampering threats
- Undeclared ingredients

What Is a Recall?

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- Recalls are the procedures conducted to identify and recover potentially adulterated, misbranded, and/or hazardous foods from trade and/or consumer channels effectively.
- · Voluntary actions by manufacturers.
- FDA does have the authority to seize adulterated products or to acquire an injunction against distribution or may initiate recall process by informing firm that an adulterated product in commerce has been identified.



PPT 7-48: U.S. FDA Website

This website (http://www.fda.gov/Safety/Recalls/default.htm) from FDA gives us the up-todate information on a recall produce. If you want to know what is official on a recall, the FDA or Centers for Disease Control and Prevention (CDC) websites are your best choices.

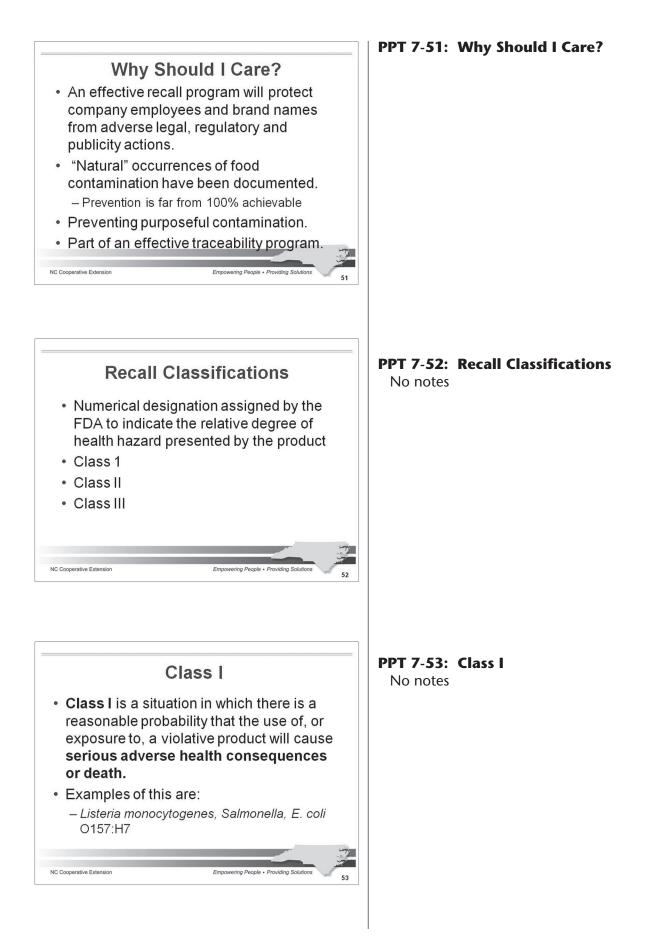
General FDA Site: http://www.fda.gov/ CDC: http://www.cdc.gov/

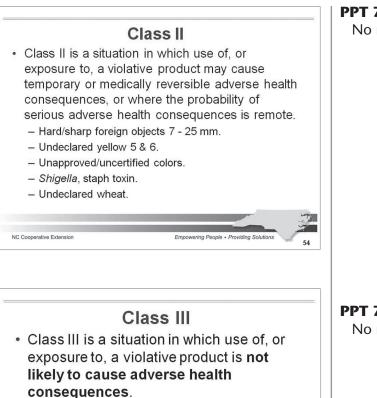
PPT 7-49: Situations Prompting Recalls No notes

PPT 7-50: What Is a Recall?

Many situations can prompt a recall. Most often, the local or state agency will be the first to notify the grower or industry. It is important to have a group of individuals trained in what a recall will mean for the particular company. Traceability is only part of the recall scenario. It is a great deal more involved. The following slides only touch on the topic, giving the framework for recalls.

The University of Florida IFAS has a comprehensive resource for growers wanting more information and worksheets for them to develop. http:// edis.ifas.ufl.edu/FS108





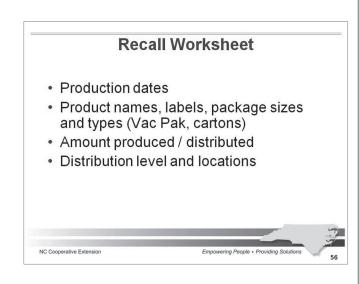
- Mold, yeast, lactobacillus.

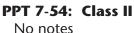
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- Hard/sharp foreign objects less than 7 mm.
- Off odor/off taste from contaminant at levels not likely to pose a hazard to health.

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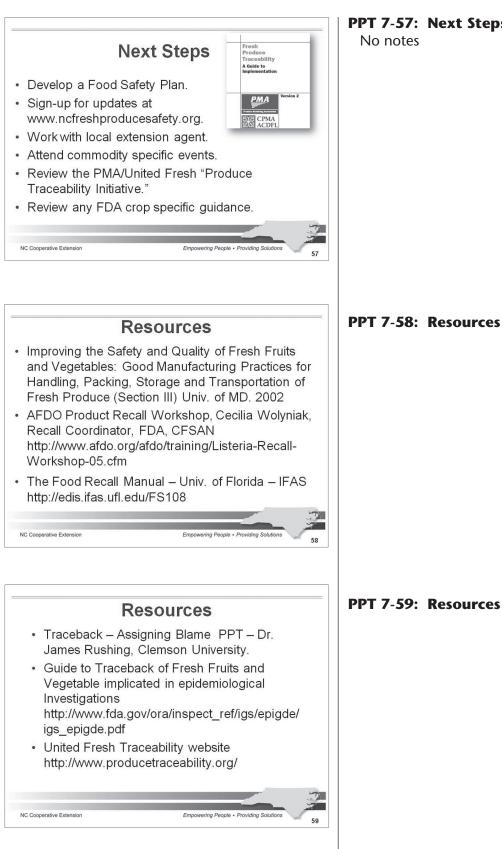




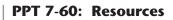
PPT 7-55: Class III No notes

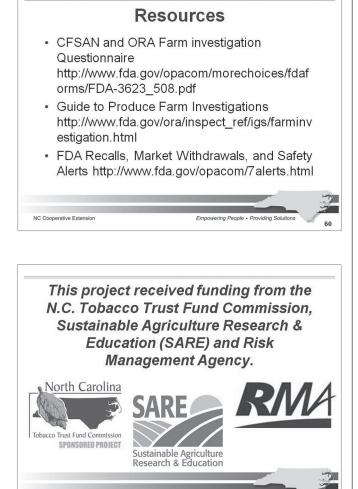
PPT 7-56: Recall Worksheets

A recall can be a very scary occurrence for growers. Growers will be asked to supply information to the regulatory agencies that they feel might be helpful. This is a partial list to help growers understand that a systematic approach to food safety is recommended. Building a traceability system provides an essential part of the wholechain food safety system.



PPT 7-57: Next Steps





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Resources and Contacts

21 CFR Part 7, Subpart C: Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibility. http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr7_04.html

AFDO Product Recall Workshop, Cecilia Wolyniak, Recall Coordinator, FDA, CFSAN. http://www.afdo. org/afdo/training/Listeria-Recall-Workshop-05.cfm

Traceback – Assigning Blame PPT, Dr. James Rushing, Clemson University.

Guide to Traceback of Fresh Fruits and Vegetable implicated in epidemiological Investigations. http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075005.htm

CFSAN and ORA Farm Investigation Questionnaire. http://www.fda.gov/opacom/morechoices/fda-forms/FDA-3623_508.pdf

Guide to Produce Farm Investigations. http://www.fda.gov/ora/inspect_ref/igs/farminvestigation. html

FDA Recalls, Market Withdrawals, and Safety Alerts. http://www.fda.gov/opacom/7alerts.html Sanitation During Transportation PPT, Jeffrey K. Brecht, Ph.D. Horticultural Sciences Department, University of Florida, Gainesville.

Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables – Sanitation and Traceback. December 2000 K. L. B. Gast and K. Holt. http://www.oznet.ksu.edu/library/hort2/mf2482.pdf

U.S. FDA, Center for Food Safety & Applied Nutrition, Inspecting Incoming Food Materials, Jan. 1999. http://www.cfsan.fda.gov/~dms/insp-toc.html

Good Manufacturing Practices for Handling, Packing, Storage and Transportation of Fresh Produce, Sect. III UM. http://www.jifsan.umd.edu/PDFs/GAPS_English/III__Good_Manufacturing_Pra.pdf Trevor Suslow PPT

N.C. Fresh Produce Safety 10-Point Checklist for Transportation

Ins	pect for the following:	Yes	No	Comments
Pre	-load conditions			
1.	Has the transport vehicle been previously used to transport live animals or other harmful substances like chemicals or fertilizers that could contaminate fresh produce?			
2.	Is all water utilized in these steps potable?			
3.	Are all the transport vehicle and equipment (such as conveyors and pallets and containers) free from odor and moisture, clean and in good repair before loading the product?			
4.	Are all personnel who have come in contact with produce at the transport process practicing good personal hygiene practices ?			
5.	Is refrigeration equipment working properly and are the transporters aware of produce temperature requirements?			
6.	Is a Pre-cooling truck necessary? Record temperatures below. Use temperature recorder for trip, if available.			
Loa	ding conditions:			
7.	Upon visual inspection, does all equipment used to pack, load and stabilize produce have physical integrity and are they free from organic debris?			
8.	Is fresh produce loaded in trucks or trailers to minimize physical damage to the product, reduce the potential for contamination during transport and maximize flow of cold air?			
9.	Has the product been inspected at the point of shipping for damage, temperature abuse and code dates? Record the product status on shipping log or other documentation.			
10	Are all documents verified and corrective actions taken?			

Temperature at time of checklist completion:______Temperature at time of loading:______

Signatures:		
Company Representative	:Date:	
Transport Driver:	Date:	

N.C. Fresh Produce Safety Celsius to Fahrenheit Conversion Chart

°C	°F	°C	°F	°C	°F	°C	°F
50	122.0	27	80.6	4	39.2	-19	-2.2
49	120.2	26	78.8	3	37.4	-20	-4.0
48	118.4	25	77.0	2	35.6	-21	-5.8
47	116.6	24	75.2	1	33.8	-22	-7.6
46	114.8	23	73.4	0	32.0	-23	-9.4
45	113.0	22	71.6	-1	30.2	-24	-11.2
44	111.2	21	69.8	-2	28.4	-25	-13.0
43	109.4	20	68.0	-3	26.6	-26	-14.8
42	107.6	19	66.2	-4	24.8	-27	-16.6
41	105.8	18	64.4	-5	23.0	-28	-18.4
40	104.0	17	62.6	-6	21.2	-29	-20.2
39	102.2	16	60.8	-7	19.4	-30	-22.0
38	100.4	15	59.0	-8	17.6	-31	-23.8
37	98.6	14	57.2	-9	15.8	-32	-25.6
36	96.8	13	55.4	-10	14.0	-33	-27.4
35	95.0	12	53.6	-11	12.2	-34	-29.2
34	93.2	11	51.8	-12	10.4	-35	-31.0
33	91.4	10	50.0	-13	8.6	-36	-32.8
32	89.6	9	48.2	-14	6.8	-37	-34.6
31	87.8	8	46.4	-15	5.0	-38	-36.4
30	86.0	7	44.6	-16	3.2	-39	-38.2
29	84.2	6	42.8	-17	1.4	-40	-40.0
28	82.4	5	41.0	-18	-0.4	-	-

Prepared from: http://www.ncdc.noaa.gov/oa/climate/conversion/tempconvert.html

SCENARIO 1:

Step 1: Jack's Grocer submits a purchase order with GTIN 00123456000014.

- Step 2: Supplier receives the purchase order and determines the buyer to be Jack's Grocer.
- Step 3: The system searches for the profile for Jack's Grocer.
- Step 4: The profile for Jack's Grocer has an entry for GTIN 00123456000014, indicating that Jack's Grocer wants the Sierra label, and therefore the Exception Code of 001 is appended to the GTIN.
- Step 5: Supplier routes order to shipping facility with the Exception Code of 001 appended to the GTIN (00123456000014_001). In this example, the Exception Code is appended to the GTIN using an "_".
- Step 6: Shipping facility notes that the "Sierra" label of Fuji apples should be shipped to Jack's Grocer.
- Step 7: After the product is shipped, the supplier strips the Exception Code off of product in their system before generating the invoice.
- Step 8: Invoice is created using just the primary GTIN 00123456000014 (thus matching what was on the purchase order).
- Step 9: Jack's Grocer receives case with GTIN 00123456000014 appearing on the case.

Step 10: Receipt of product matches purchase order which matches the invoice.

NOTE: If an item does not require any Exception Codes, there is no need to include it in the buyer's profile.

Module 7: The Three T's: Transportation, Traceback and Traceforward

Pre-Test/Post-Test

ID Nur	nbei	r/Name: Date:
		ontamination from other food or non-food sources is the biggest concern during storage and transportTrue or False
2. Pota	ble	water does not need to be used when washing transporters
		nperature for storage/transport of most commodities is between degrees F True or False
	e so	hod used to determine and document the distribution and production chain, urce of the product implicated in a food-borne illness is called: A Food-Chain investigation A Confidence investigation A Traceback investigation
5. CO(tands for: County of Original Labeling Country of Origin Labeling Commodity Organic Label
6. The from:	esta	blishment of requirements for tracing commodities one step back and one step forward is
nom.		Country of Origin Labeling Bioterrorism Act Sanitary Food Transportation Act
7. Con	sum	er studies show support for traceability solutions
8. The data exchange and business process that take place between trading partners to trace is called:		
is calle		Internal traceability External Traceability Whole-Chain Traceability
9. "Na	tura	I" occurrences of food contamination have not been documented True or False
	l cau	tion in which there is a reasonable probability that the use of or exposure to a violative prod use serious adverse health consequences or death is considered a recall classification of: Class I

- Class II
- Class III

Module 7: The Three T's: Transportation, Traceback and Traceforward

Pre-Test/Post-Test Answers

1. Cross-contamination from other food or non-food sources is the biggest food-safety concern during storage and transport True or False
2. Potable water does not need to be used when washing transportersTrue or False
 Ideal temperature for storage/transport of most commodities is between and 45 degrees F

4. The method used to determine and document the distribution and production chain, and the source of the product implicated in a food-borne illness is called:

- □ A Food-Chain investigation
- □ A Confidence investigation
- ✓ A Traceback investigation
- 5. COOL stands for:
 - County of Original Labeling
 - ✓ Country of Origin Labeling
 - Commodity Organic Label

6. The establishment of requirements for tracing commodities one step back and one step forward is from:

- □ Country of Origin Labeling
- ✓ Bioterrorism Act
- □ Sanitary Food Transportation Act

7. Consumer studies show support for traceability solutions. True or False

8. The data exchange and business process that take place between trading partners to trace produce is called:

- Internal traceability
- ✓ External Traceability
- Whole-Chain Traceability

9. "Natural" occurrences of food contamination have not been documented...... True or False

10. A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death is considered a recall classification of:

- ✓ Class I
- Class II
- Class III