Food Safety By Design
Focus on FSMA Preventive Controls

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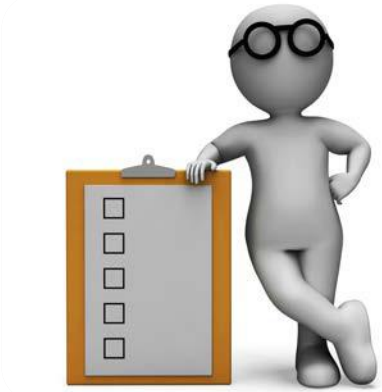
Overview

- Why did FSMA pass Congress
- What is the goal of the Preventive Control Rule
- Approach to building a food safety plan
- Environmental monitoring program
- Supply chain control PC rule and FSVP
- Role of GFSI



Why was FSMA Passed by Congress?

- Series of major outbreaks
  - Spinach - E. coli O157 2006
  - Peanut butter – Salmonella 2007
  - Pet food – melamine 2007
  - Peanut butter – Salmonella 2009
- Desire on multiple fronts to change requirements
  - Consumer organizations
  - Private sector
  - FDA
  - Congress

FDA Expectations

- Identify all the risks pertaining to the food you manufacture, process pack or hold
- Determine which risks need to be controlled to prevent food borne illness
- Understand how to control the risks (in plant and supply chain)
- Make sure that those risks are being controlled
- Track that the systems are working every day

Is FSMA a Bunch of "Busy Work"

- What keeps a food company executive awake at night
  - Regulatory compliance
  - Economic pressures on the company
  - Innovation
  - Recalls

- Protecting the brand
- Risk based preventive controls will protect a brand

Final Preventive Controls Rule Key Principles

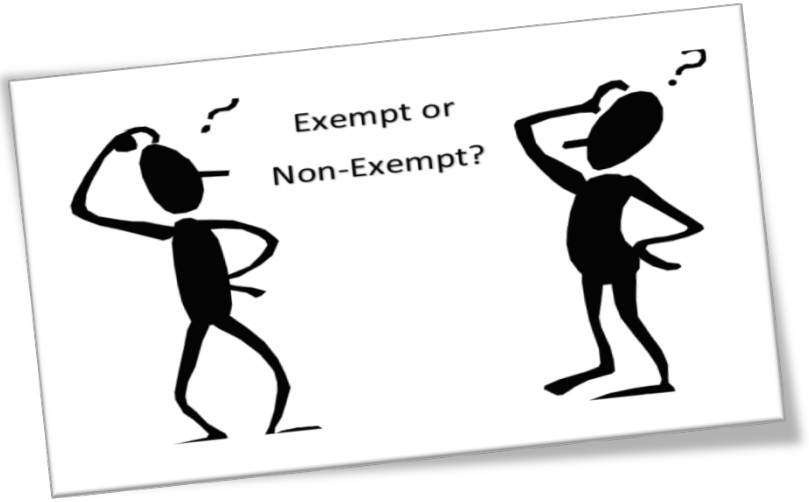
- Risk based
- Focused on prevention
- Each facility would be required to implement a written food safety plan that focuses on preventing "hazards requiring preventive controls"
  - Identify "Hazards Requiring Preventative Control"
  - Implement preventive controls
  - Monitor, verify, validate, corrective actions
  - Keep records
- FDA can inspect your food safety plan
- Food Safety Plan Considered a "Trade Secret" – No FOIA

Facility Registration

- Does your facility manufacture, process, pack, or hold food?
- Then need to register unless exempt
- Next facility registration is due November, 2018

Exemptions

- Alcoholic beverages and food produced at same so long as it is in prepackaged form and constitutes less than 5% overall sales
- Pasteurized Milk Ordinance Regulated Facilities - extended
- Retail
- Restaurants
- USDA
- Seafood HACCP
- Juice HACCP
- LACF for Micro risks
- Farms (primary and secondary)



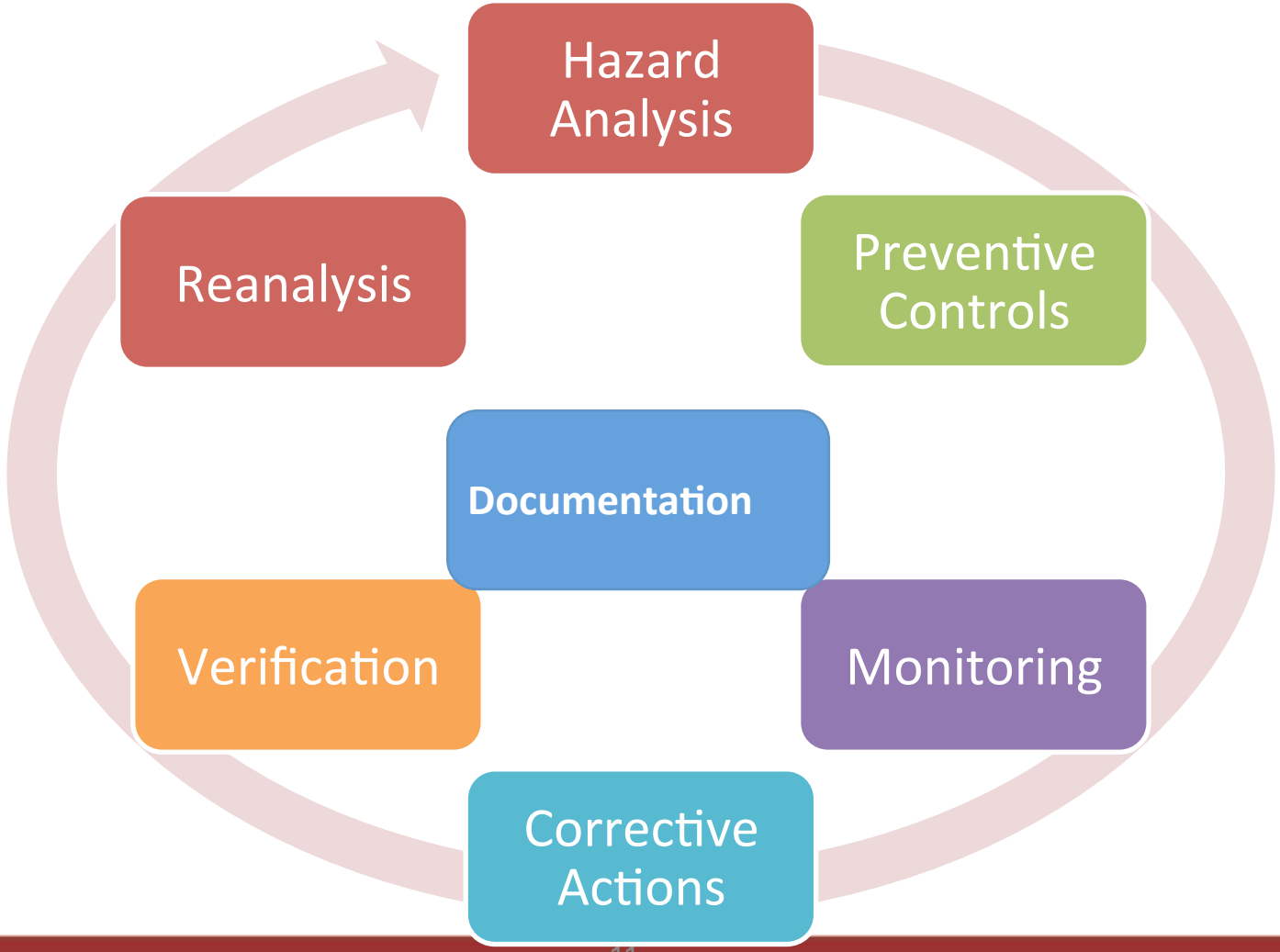
Exemptions- Warehouses

- Solely engaged in the storage of unexposed packaged foods – don't need to comply with C and G unless modified requirements (refrigeration)
- Solely engaged in the storage of RAC's (other than produce) intended for further processing
- Solely engaged in the holding and/or transportation of RAC's (other than produce)

The Food Safety Plan

- You must prepare, or have prepared, and implement a written food safety plan.
- The food safety plan must be prepared, or its preparation overseen, by one or more **preventive controls qualified individuals.**
- ***REMINDER !*** *Preventive controls qualified individual* means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

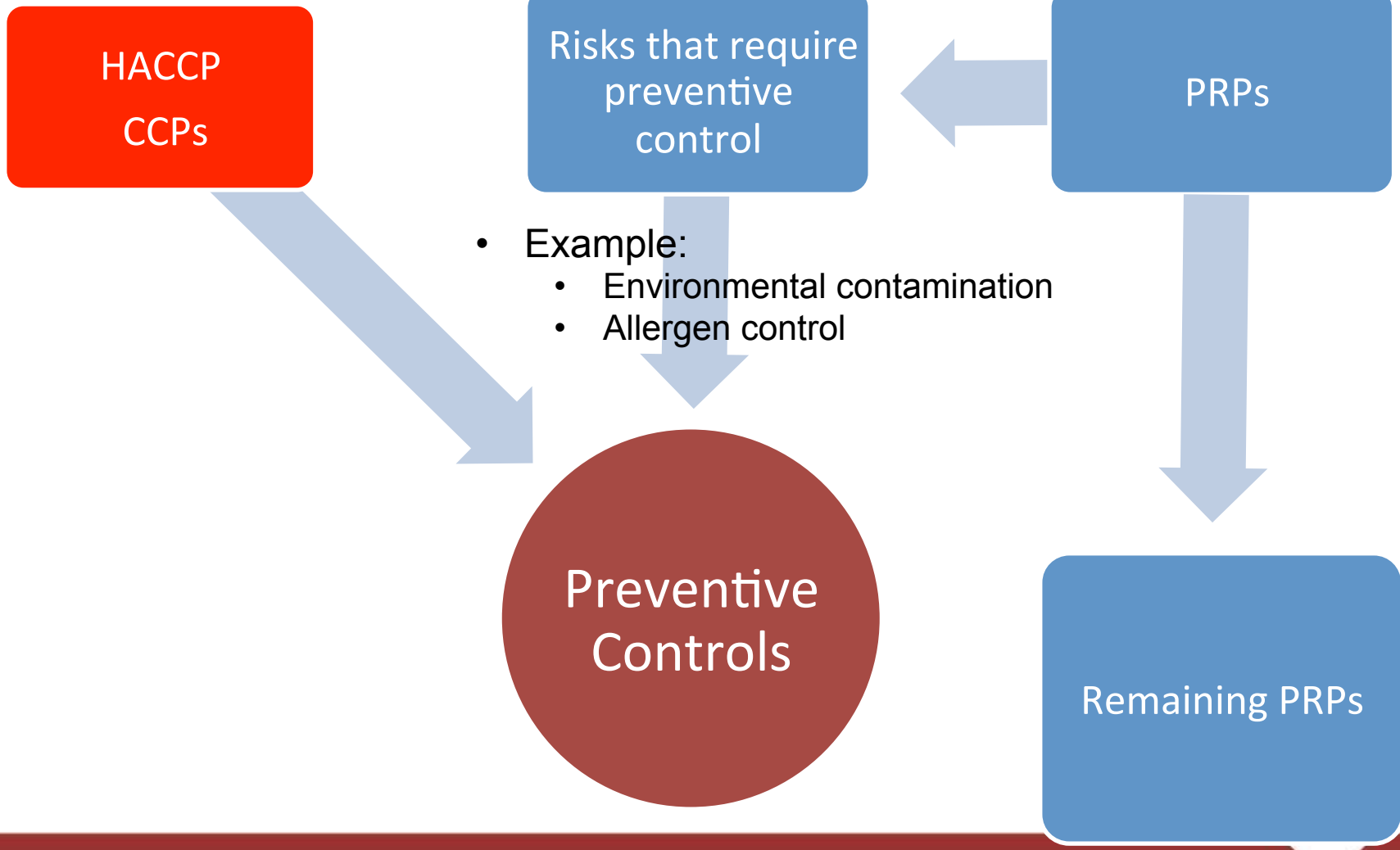
The Food Safety Plan



More than HACCP

- Think of all the food safety risks in the facility
- Which ones rise to the level of a “risk that requires a preventive control”
- How do you control those risks
  - With a CCP e.g. cooking
  - With a prerequisite program e.g. environmental control
  - With hand washing
  - Other ways – supply chain control
- Do all these identified risks require a CCP

HACCP vs. HARPC vs. PRPs



Hazard Analysis

- Conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held
- Which hazards require a preventative control
  - Must consider biological, chemical (radiological), and physical
  - Consider hazards that:
    - Occur naturally
    - Unintentionally introduced
    - Intentionally introduced for economic gain
- Consider
  - Severity of the illness
  - Probability of illness or injury if the hazard is not controlled
  - Must include an evaluation of environmental pathogens

Hazard Analysis

- Must consider
  - Formulation of the food
  - Condition, function and design of the facility
  - Transportation practices
  - Manufacturing/processing procedures
  - Packaging and labeling activities
  - Storage and distribution
  - Intended or reasonably foreseeable use
  - Sanitation including employee hygiene
  - Any other relevant factors (e.g. weather related)

Hazard Analysis

- What are "Hazards requiring a preventive control"
  - A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would …….
    - based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls),
  - establish one or more preventive controls to significantly minimize or prevent the hazard

Preventive Controls

- Identify and implement preventive controls to provide assurance that the hazard is significantly minimized or prevented to avoid adulteration
  - May be CCPs
  - May be controls other than CCPs
- Must be written
- May be process controls
  - Include the nature of the process control
  - Identify the maximum or minimum value to which the parameter should be controlled
- Allergen controls
  - Protection against cross contact contamination
  - Labeling/label verification

Preventive Controls

- Sanitation Controls for microbial and allergen risks
  - Cleanliness of food contact surfaces
  - Prevention of allergen cross contact and cross-contamination
- Supply chain controls (details in Subpart G)
- Recall plan
- Other controls as needed (hygiene training and cGMPs)

Monitoring (§ 117.145)

- As appropriate for the nature of the preventive control
  - Written procedures including frequency
  - Adequate frequency to provide assurance that they are consistently performed
  - Record keeping
    - Must document in accordance with verification and records review
  - Exception records
    - E.g. time/temperature control when records show loss of temperature control
    - May be adequate in other circumstances too
    - Verses affirmation records

Corrective Actions (§ 117.150)

- As appropriate to the nature of the hazard and the nature of the preventive control
  - Must be written and to be taken if preventive controls are not properly implemented including procedures to address as appropriate
    - Presence of a pathogen or appropriate indicator in RTE product
    - Presence of environmental pathogen or indicator
  - Procedures must describe the steps
    - Identify and correct the problem
    - Reduce the likelihood that the problem will recur
    - All affected food is evaluated for safety
    - All affected food is prevented from entering commerce

Corrective Actions (§ 117.150)

- Corrections (avoids the need for a corrective action)
  - You take action in a timely manner to identify and correct conditions and practices that are not consistent with allergen controls or not consistent with sanitation controls
  - A minor problem that does not directly impact product safety
- Records
  - All corrective actions (and where appropriate corrections) must be documented.
  - Subject to verification and records review

Verification (§ 117.155)

- Must include
  - Validation in accordance with § 117.160
  - That monitoring is being conducted appropriately
  - That appropriate decisions are made about corrective actions
  - Verification of implementation and effectiveness of the preventive controls
  - Reanalysis is done appropriately
  - Fully documented

Validation (§ 117.160)

- Must validate the preventive controls
- Validation must:
  - Be performed or overseen by a PCQI
  - Be done prior to the implementation of the food safety plan
  - Be performed as necessary to demonstrate control measures can be implemented as designed:
    - Within 90 days after production of the applicable food begins OR
    - Within a reasonable timeframe with justification
  - Must be preformed if there are changes that may impact control of the hazard
  - Must be performed if a reanalysis indicates the need for it

Finished Product Testing

- Product testing which must be
  - Be scientifically valid
  - Identify the test microorganism(s) or other analyte(s)
  - Specify the procedures for identifying samples, including their relationship to specific lots of product;
  - Include the procedures for sampling, including the number of samples and the sampling frequency
  - Identify the test(s) conducted, including the analytical method(s) used;
  - Identify the laboratory conducting the testing
  - Include corrective action procedures

Environmental Monitoring

- Environmental monitoring would be required
  - Where RTE product is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed.
- Routine testing does not have to be conducted by an accredited lab, the test method must be scientifically valid, and results do not need to be sent to the FDA

Verification (§ 117.165)

- Environmental monitoring must
  - Be scientifically valid;
  - Identify the test microorganism(s);
  - Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring.
    - The number and location of sampling sites must be adequate to determine whether preventive controls are effective
  - Identify the timing and frequency for collecting and testing samples.
    - Must be adequate to determine whether preventive controls are effective;
  - Identify the test(s) conducted, including the analytical method(s) used
  - Identify the laboratory conducting the testing
  - Include the corrective action procedures

Reanalysis (§ 117.170)

- Once every 3 years
- As needed
  - When a significant creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;
  - When you become aware of new information about potential hazards associated with the food
  - Unanticipated food safety problem
  - Whenever you find that a preventive control is ineffective
- When FDA tells you need to

FSMA Approach to Supply Chain Control

- Preventive Controls Rule (Human and Animal Food)
  - Registered firms must assess supply chain risk
  - If suppliers are responsible for controlling risk, the customer must verify that the risk is being controlled
- Foreign Supplier Verification Program
  - Shift the burden of ensuring safe food to importers
  - Importers required to perform risk-based activities to verify that food imported into the U.S. is to the same food safety standards as those required of U.S. producers.

FSMA Approach to Supply Chain Control

- Do you need to comply with the PC rule?
  - Need supply chain control as part of PC requirement

- Are you an importer of food that does not need to be compliant with the PC rule
  - Need to be compliant with FSVP

FSMA Approach to Supply Chain Control

- Hazard analysis
- Evaluate the risks – who is controlling the risk
- Supplier verification that risk are being controlled
- Use only approved suppliers
- Document corrective actions
- Build a program and keep records

FSMA Preventive Control Rules – Supply Chain Program

- The receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control
- Program must be written
- When applied by an entity other than the receiving facility's supplier facility must
  - Verify the supply-chain-applied control; or
  - Label food as not having the risk controlled; and,
  - Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment

Importers Responsibilities

- Determining the hazards reasonably likely to cause illness or injury with each food
- Evaluating the risk posed by a food, using the results of the hazard analysis, and evaluating the foreign supplier's performance
- Conducting supplier verification activities. In general, importers must establish and follow written procedures to ensure they only import foods from foreign suppliers they have approved

Exemptions

- Certain juice, fish, and fishery products under the current HACCP rules
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages
- Food that is transshipped
- Food imported for processing and future export
- Food exported from and returned to the United States without manufacturing/processing in a foreign country
- Certain meat, poultry, and egg products regulated by the U.S. Department of Agriculture (USDA)

Supply Chain Program - Verification

- If the hazard is being controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans:
  - The appropriate supplier verification activity is an onsite audit of the supplier; and
  - The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter

Supply Chain Program - Verification

- Onsite audit must be performed by a qualified auditor
- If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (*e.g.,* Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan)

- Various substitutions for onsite audit
  - Written results of an appropriate inspection by FDA, by other Federal Agencies or by State, local, tribal or territorial agencies
  - If foreign may be FDA or country recognized by FDA

FSMA and GFSI (§ 117.330)

- To the extent that an existing HACCP plan or GFSI-compliant food safety plan includes all required information, a facility can use such plans to meet the requirements of this rule.
- Relying on existing records, with supplementation as necessary to demonstrate compliance with the requirements of the human preventive controls rule, is acceptable.
- Could be a set of documents kept in different locations within the facility, with a list of the relevant documents (e.g. Table of Contents).
  - Leverage PRPs as needed

Areas of Difference

- GFSI is HACCP focused
  - CCPs and prerequisite programs
- FSMA is HARPC focused
  - Risks that require a preventive control
  - Avoids creating CCPs for all risks
- When implemented properly both will protect the food supply

GFSI Schemes

- The Acheson Group has compared several GFSI schemes with FSMA Preventive Control Rules
  - SQF
  - BRC
  - FSSC
- All match up well and are essentially either comparable or exceeding FSMA.

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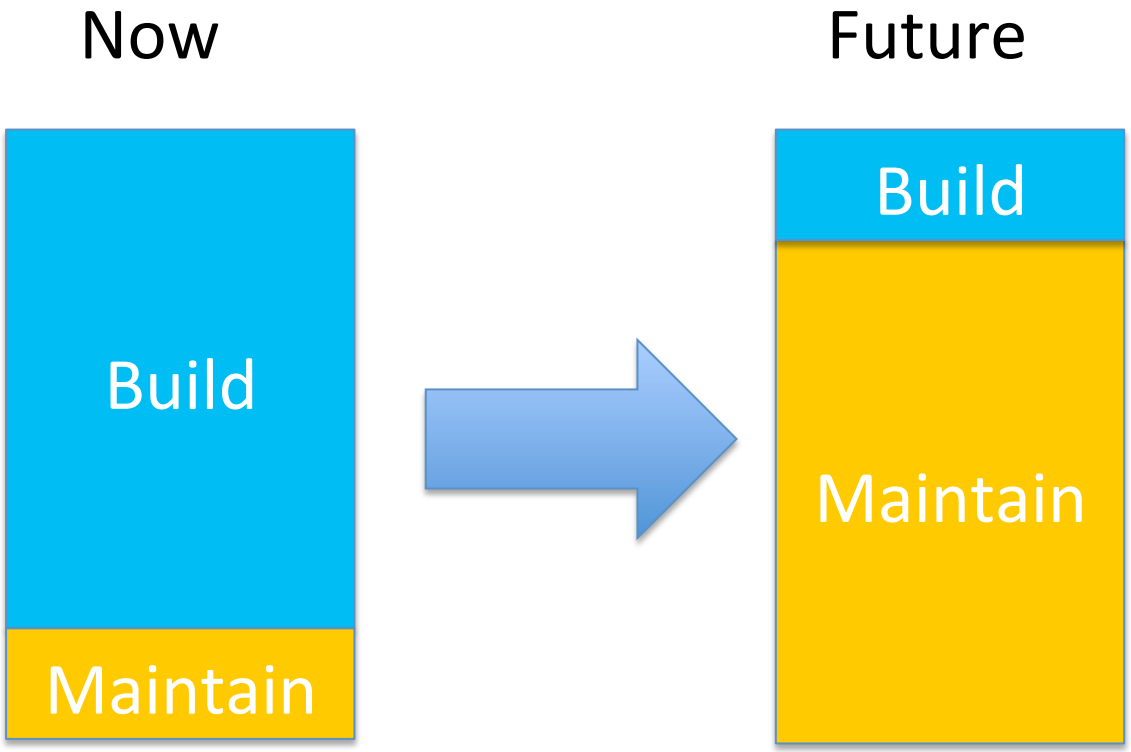
Future FSMA Challenges



Summary

- Compliance with FSMA Preventive control rules will reduce brand risk
  - Supply chain risk control
  - Environmental control programs
- Record keeping is critical
- Maintain the program don't just build it and walk away
- Being GFSI compliant is a good start to FSMA compliance

Thank You
Questions?