What About FSMA?

FDA's Supplemental Proposed Rules for Preventive Controls and Foreign Supplier Verification Programs

Bob Hirst
Vice President, Education, Science and Technical Relations
IBWA

Joe Levitt
Partner
Hogan Lovells

Agenda

- Introduction and Overview
- Key Takeaways
- Key Points from Supplemental Proposed Rules
  - Preventive Controls for Human Food
  - Foreign Supplier Verification Program
- New FDA Inspection Paradigm
- Question and Answer Session

Introduction and Overview

Joe Levitt

Introduction

- FDA first issued proposed rules to implement the FDA Food Safety Modernization Act (FSMA) in 2013
- FDA released four supplemental notices of proposed rulemaking on September 19, 2014
  - Comments on the revised provisions are due December 15, 2014
- FDA is under court order to issue final rules by
  - August 30, 2015 (Preventive Controls)
  - October 31, 2015 (FSVP, Produce Safety, 3 PAC)

Scope of the Supplemental Proposals

- FDA has not issued complete re-proposals of the rules proposed in 2013
- Only those issues contained in the supplemental proposals are open for comment
  - FDA will not accept comment on issues raised in the original proposals but not specifically addressed in the supplemental proposals
- FDA will continue to review comments submitted to the original proposed rules
  - These and issues raised by the supplemental proposals will be addressed in the final rules

Key Takeaways

1. FDA is directly responsive to many requests from the food industry (including IBWA)
2. The revised regulations are more flexible and more risk-based, and tailored to the nature of the food and the facility involved
3. What you see is likely what you will get
4. Devil is in the details
   - Look closely at the text of the regulations and ask: is this workable?
5. Many major issues have been resolved, but others won't be until the final rule
   - e.g., consumer complaints & Part 11 Compliance

Key Takeaways

NOTE: There were virtually no changes in the portion of the proposed preventive controls rule addressing new requirements for Current Good Manufacturing Practices (CGMPs)!

- Previous webinars and seminars on CGMPs are still valid.
- New DRAFT FSMA audit checksheets issued in 2014 for CGMPs are still valid.

Overview of Key Provisions

- Hazard Analysis
  - RLTO has been replaced with "significant hazard"
  - Evaluate "severity" and "probability"
  - Consider economically motivated adulteration (EMA)
- Management of Controls
  - FDA agrees that not all controls should be managed the same way ("Sliding scale" concept)
  - Repeated use of the phrase "as appropriate to the nature of the preventive control"
- Testing
  - FDA proposes specific regulatory language for both product testing and environmental monitoring
  - Nature and extent of testing dependent on the nature of the food and the food safety systems in place in the facility

Overview of Key Provisions (continued)

- Supplier Verification
  - Very detailed requirements, but limited to circumstances where the supplier is controlling any significant hazards
  - Supplier risks taken into account
  - Hybrid approach for onsite audits
    - Confidentiality of audit reports
  - Consistent with FSVP

Overview of Key Provisions (continued)

- Very small business definition
  - $1 million total annual sales of human food
  - $2.5 million total annual sales of animal food
  - → Would be qualified facilities subject to modified requirements
- Revised definitions for "farms," "packing," and "holding"

Preventive Controls

Formerly Known As "HACCP"

Bob Hirst

Contents of the Food Safety Plan

Original Proposed Rule

- Written hazard analysis;
- Written preventive controls;
- Written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls;
- Written corrective action procedures;
- Written verification procedures; and
- Written recall plan.

Supplemental Proposed Rule

- Written hazard analysis;
- Written preventive controls;
- Written supplier program;
- Written recall plan.
  - Must address hazards identified in hazard analysis AND unanticipated hazards
- Written procedures for monitoring the implementation of the preventive controls;
- Written corrective action procedures; and
- Written verification procedures

Contents of the Food Safety Plan

Original Proposed Rule

- Written hazard analysis;
- Written preventive controls;
- Written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls;
- Written corrective action procedures;
- Written verification procedures; and
- Written recall plan.

Supplemental Proposed Rule

- Written hazard analysis;
- Written preventive controls;
- Written supplier program;
- Written recall plan.
  - Must address hazards identified in hazard analysis AND unanticipated hazards
- Written procedures for monitoring the implementation of the preventive controls;
- Written corrective action procedures; and
- Written verification procedures

Hazard Analysis

- FDA proposes to remove the term "reasonably likely to occur" and replace it with "significant hazard":
  - 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 the hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls . . . as appropriate to the food, the facility, and the nature of the control."
- Facilities would evaluate identified hazards by assessing "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 preventative controls."

Hazards to be Considered

Original Proposed Rule

- Biological
- Chemical Physical
- Physical
- Radiological

Supplemental Proposed Rule

- Biological
- Chemical (includes rad.)
- Physical
- Hazards that occur;
  - The hazard may be unintentionally introduced; or
  - The hazard may be intentionally introduced for purposes of economic gain.

Hazards to be Considered

Original Proposed Rule

- Biological
- Chemical Physical
- Physical
- Radiological

Supplemental Proposed Rule

- Biological
- Chemical (includes rad.)
- Physical
- Hazards that occur;
  - The hazard may be unintentionally introduced; or
  - The hazard may be intentionally introduced for purposes of economic gain.

Implementation of Preventive Controls

- Preventive controls would be implemented to SMOP significant hazards
- The regulations would explicitly provide that:
  - Preventive controls include controls other than those at critical control points (CCPs) + CCPs themselves
  - There may not be any controls at CCPs
    - But companies will have to justify
  - Parameters only needed for process controls
    - But closely review regulatory language

Preventive Controls to Include:

- Process controls
- Food allergen controls
- Sanitation controls
- Supplier controls
- Recall plan
- Other controls
  - "Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section."
  - Examples of other controls include hygiene training and other current good manufacturing practices.

Management of Preventive Controls

- Level of oversight for the various preventive controls (referred to as "management components") is flexible based on the nature of the control
- Examples provided in the preamble include:
  - Not all monitoring activities generate records;
  - Not all corrections require records;
  - Not all preventive controls require validation; and
  - Not all corrective actions require verification
- Close review of the actual regulatory language required (e.g., validation, corrections)

Product Testing

- FDA proposes to require product testing as a verification activity ("as appropriate")
- "Product testing" would encompass ingredient testing, in-process testing, and finished product testing
- Product testing procedures would be required to specify the procedures for identifying samples and the procedures for sampling, the test conducted, corrective actions, etc.

Product Testing
(continued)

- Facility corrective action procedures would be required to address the presence of an environmental pathogen or appropriate indicator organism in a ready-to-eat (RTE) product tested through product testing
- FDA is also reopening the comment period for the agency's previous request for comment on how and when product testing programs are appropriate
- Will not likely affect bottled water significantly since we have extensive testing requirements in place.

Environmental Monitoring

- As part of the hazard evaluation, FDA proposes to require an evaluation of environmental pathogens whenever a RTE food is exposed to the environment prior to packaging and the food does not receive treatment
- FDA proposes to require environmental monitoring as a verification activity if contamination of a RTE food with an environmental pathogen is a significant hazard

Environmental Monitoring (continued)

- Environmental monitoring procedures would need to:
  - Identify the locations and sites for routine environmental monitoring;
  - The timing and frequency of monitoring; and
  - Address the presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring
- FDA is also reopening the comment period for the agency's previous request for comment on when and how environmental monitoring programs are appropriate
- IBWA commented on ET already in place (i.e., caps and containers as being sufficient)

Supplier Verification - Scope

- FDA proposes to require a "supplier program" for raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt
  - If you or your customer control the hazards, no SP
- "Suppliers" are establishments that manufacture or process food, raise animals, or harvest food that is provided to a receiving facility without further processing
- "Receiving facilities" manufacture or process raw materials or ingredients that they receive from suppliers
- For bottled water, applies to salts, minerals and packaging materials

Supplier Verification – Scope (continued)

- Facilities that pack or hold food without manufacturing are neither "suppliers" nor "receivers"
- Receiving facilities would be required to establish supplier verification activities if they receive material from a distribution center and they identify a significant hazard in the material that is controlled by the supplier to the distribution facility – i.e., two steps back

Supplier Verification – Scope (continued)

- If a facility receives an ingredient from a supplier, but the hazard is controlled by the supplier's supplier, the receiving facility would conduct supplier verification activities that would include verifying that the supplier has conducted appropriate verification that its supplier has controlled the hazard
  - For example, the receiving facility could review the supplier's food safety records for its supplier program
  - Here, just one step back

Supplier Verification – Scope (continued)

- FDA is seeking comment on how supplier verification activities should address gaps in the system where:
  - Materials pass through more than one facility that would not be required to verify control of hazards; and
  - Raw agricultural commodities such as fresh produce will not be handled by any facilities that would be required to have preventive controls before reaching consumers

Verification Activities

- FDA provides flexibility for facilities to determine the appropriate verification activities based on:
  (1) the severity of the hazard;
  (2) where the preventive controls for those hazards are applied;
  (3) the supplier's food safety practices;
  (4) the supplier's compliance with FDA food safety regulations;
  (5) the supplier's food safety performance history; and
  (6) any other factors, such as storage and transportation
  → Supplier risks considered

Appropriate Verification Activities

- Based on the risk evaluation factors, facilities would determine, conduct, and document verification activities
- Potential verification activities would include:
  - Onsite auditing;
    - Conducted by a qualified auditor
  - Sampling and testing food;
    - Could be conducted by the supplier or the receiver
  - Reviewing the supplier's food safety records; or
  - Additional risk-based verification activities

Appropriate Verification Activities (continued)

- SAHCODHA Hazards (N/A to bottled water)
  - Initial onsite audit and annually thereafter
    - *unless* the facility documents its determination that other verification activities and/or less frequent audits provide adequate assurance
- Special suppliers
  - Facilities could conduct alternative verification activities for materials received from
    - qualified facilities
    - a farm not subject to requirements under the produce safety rule

Appropriate Verification Activities (continued)

- Instead of onsite audit, FDA proposes to allow the receiving facility to rely on results of an inspection of the supplier by FDA or food safety authority of a country whose food safety system FDA has recognized as comparable
  - Inspection must have been within 1 year of the date that onsite audit would have been required
  - Facility would need to document inspection results relied upon

Verification Activities Approved Suppliers

- FDA proposes to require verification activities, as well as documentation, to ensure materials are received only from approved suppliers
  - No "list" required
  - When necessary and appropriate, materials could be received on a temporary basis from unapproved suppliers whose materials the receiving facility subjects to adequate verification activities before acceptance for use

Related Activities

- Facilities also would need to:
  - Review verification records
  - Take corrective actions when needed and document those actions

Documentation of Supplier Verification

- FDA proposes minimum requirements for:
  - Records documenting an audit;
    - But the underlying audit report would remain confidential
  - Records of sampling and testing;
  - Records documenting review of the supplier's relevant food safety records; and
  - Documentation of alternative verification activities for suppliers that are qualified facilities or farms not subject to the produce rule
- FDA explains that it would expect many of the records to be accessible during facility inspections because they would be in electronic form

Supplier Programs and Deemed Compliance with FSVP

- Deemed compliance with FSVP
  - If an importer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer is in compliance with those requirements
  - If an importer's customer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer annually obtains written assurance that its customer is in compliance with those requirements

Supplier Verification
(continued)

- FDA is reopening the comment period for its previous request for comment on when and how supplier programs are appropriate
- FDA is also seeking comment on whether it should include requirements to address conflicts of interest for individuals conducting supplier verification activities and the scope of such requirements

Economically Motivated Adulteration (EMA)

- FDA proposes to require the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain
  - Focus is on adulterants that are reasonably likely to cause illness or injury in the absence of their control
  - Not focused on adulterants that solely affect quality and value
- FDA suggests it is practicable to determine whether EMA is reasonably foreseeable by focusing on circumstances where there has been a pattern of adulteration in the past
- Moved from proposed IA rule.

Additional Changes to Definitions

- Activities performed incidental to packing a food would be "packing" activities
  - This definition would apply to all establishments that pack food
- Activities performed incidental to holding a food would be "holding" activities
  - This definition applies to all foods and all facilities that hold food

Very Small Business

- FDA proposes to define a "very small business" as a business that has less than $1 million in total annual sales of human food
- A company's status as a "very small business" impacts the compliance date for those facilities and the exemption for qualified facilities
- The proposed revision would essentially make "very small business" and "qualified facility" synonymous

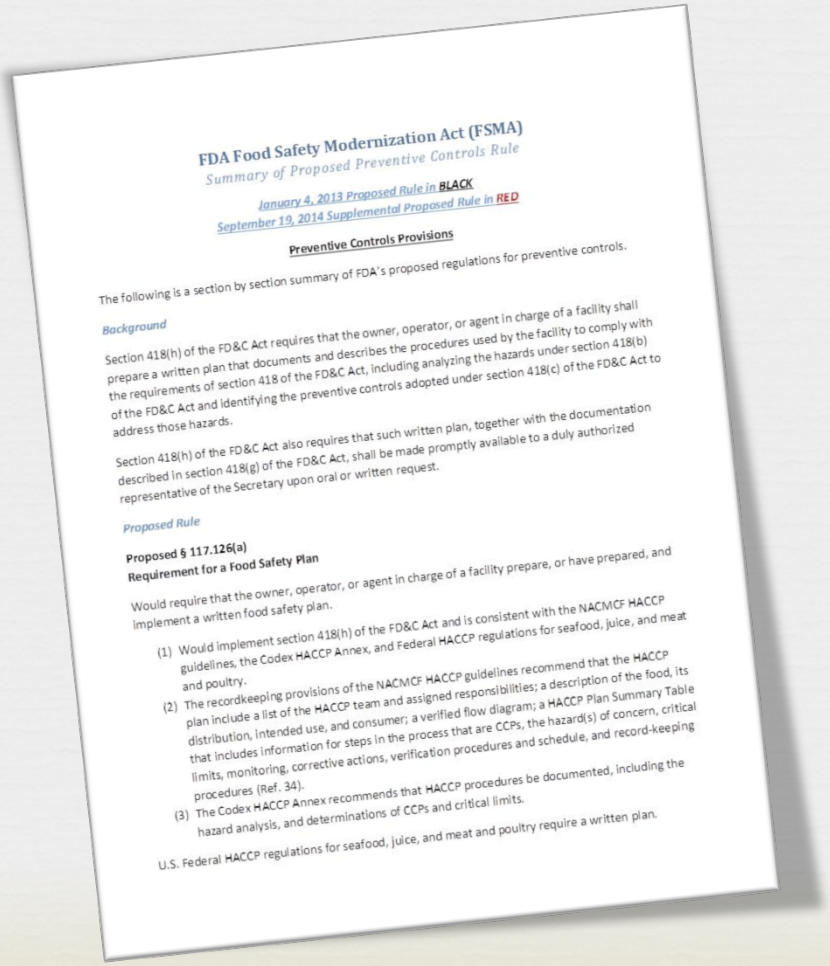
Withdrawal of Exemption for Qualified Facility

- Under FSMA, "qualified facilities" are exempt from preventive control requirements and are subject to modified requirements
  - Exemption may be withdrawn:
    - (1) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the facility; or
    - (2) if FDA determines it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak
- FDA proposes to add certain due process elements to the regulations providing for the withdrawal of an exemption

Withdrawal of Exemption (continued)

- FDA proposes:
  - To include specific regulatory actions the agency must take before issuing an order to withdraw an exemption, including notifying the facility in writing of the circumstances that may lead FDA to withdraw the exemption
  - To provide an opportunity for the facility to respond in writing within 10 days
  - To consider the corrective actions taken by the facility
  - To allow facility 10 days to appeal and 120 days to come into compliance
  - To provide for reinstating an exemption

For More Information… FSMA Summary of PC Rule



FDA Food Safety Modernization Act (FSMA)

Summary of Proposed Preventive Controls Rule

January 4, 2013 Proposed Rule in **BLACK**

September 19, 2014 Supplemental Proposed Rule in **RED**

Preventive Controls Provisions

The following is a section by section summary of FDA's proposed regulations for preventive controls.

Background

Section 418(h) of the FD&C Act requires that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards under section 418(b) of the FD&C Act and identifying the preventive controls adopted under section 418(c) of the FD&C Act to address those hazards.

Section 418(h) of the FD&C Act also requires that such written plan, together with the documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

Proposed Rule

Proposed § 117.126(a)
Requirement for a Food Safety Plan

Would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, and implement a written food safety plan.

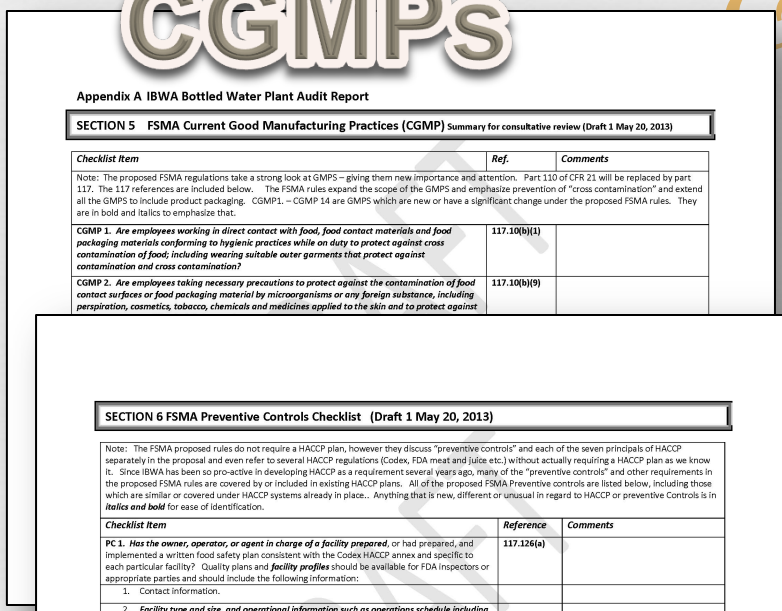
(1) Would implement section 418(h) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry.

(2) The recordkeeping provisions of the NACMCF HACCP guidelines recommend that the HACCP plan include a list of the HACCP team and assigned responsibilities; a description of the food, its distribution, intended use, and consumer; a verified flow diagram; a HACCP Plan Summary Table that includes information for steps in the process that are CCPs, the hazard(s) of concern, critical limits, monitoring, corrective actions, verification procedures and schedule, and record-keeping procedures (Ref. 34).

(3) The Codex HACCP Annex recommends that HACCP procedures be documented, including the hazard analysis, and determinations of CCPs and critical limits.

U.S. Federal HACCP regulations for seafood, juice, and meat and poultry require a written plan.

2014 Supplemental Audit Checksheets

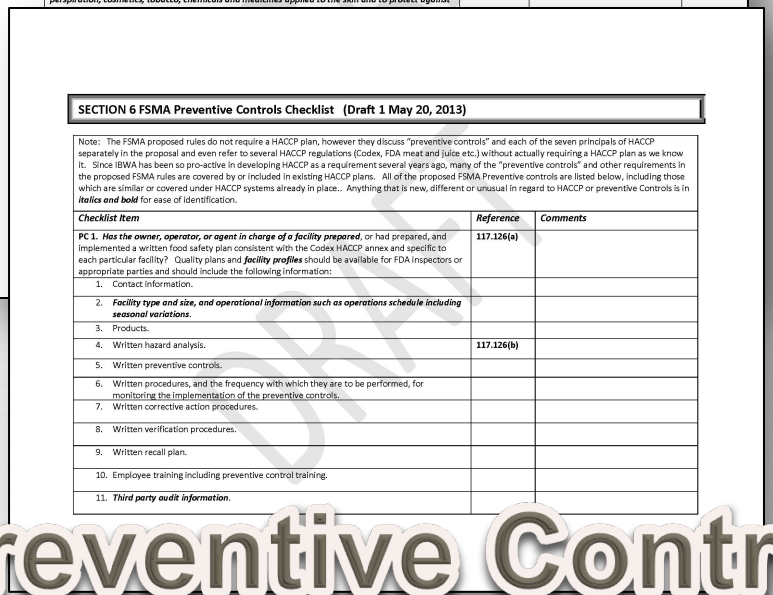


CGMPs

Appendix A IBWA Bottled Water Plant Audit Report

SECTION 5 FSMA Current Good Manufacturing Practices (CGMP) Summary for consultative review (Draft 1 May 20, 2013)

Checklist Item	*Ref.*	*Comments*
Note: The proposed FSMA regulations take a strong look at GMPS – giving them new importance and attention. Part 110 of CFR 21 will be replaced by part 117. The 117 references are included below. The FSMA rules expand the scope of the GMPS and emphasize prevention of "cross contamination" and extend all the GMPS to include product packaging. CGMP1. – CGMP 14 are GMPS which are new or have a significant change under the proposed FSMA rules. They are in bold and italics to emphasize that.		
CGMP 1. ***Are employees working in direct contact with food, food contact materials and food packaging materials conforming to hygienic practices while on duty to protect against cross contamination of food; including wearing suitable outer garments that protect against contamination and cross contamination?***	**117.10(b)(1)**	
CGMP 2. ***Are employees taking necessary precautions to protect against the contamination of food contact surfaces or food packaging material by microorganisms or any foreign substance, including perspiration, cosmetics, tobacco, chemicals and medicines applied to the skin and to protect against***	**117.10(b)(9)**	

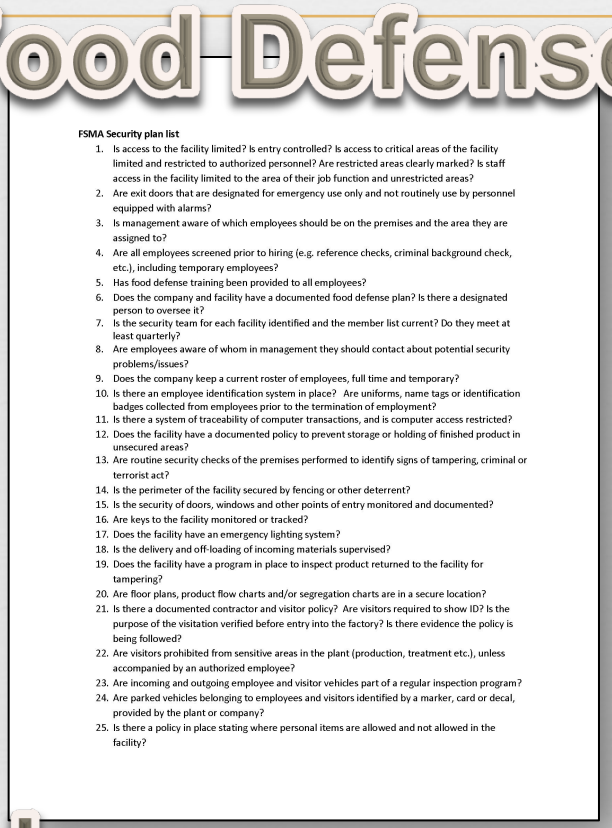


SECTION 6 FSMA Preventive Controls Checklist (Draft 1 May 20, 2013)

Note: The FSMA proposed rules do not require a HACCP plan, however they discuss "preventive controls" and each of the seven principals of HACCP separately in the proposal and even refer to several HACCP regulations (Codex, FDA meat and juice etc.) without actually requiring a HACCP plan as we know it. Since IBWA has been so pro-active in developing HACCP as a requirement several years ago, many of the "preventive controls" and other requirements in the proposed FSMA rules are covered by or included in existing HACCP plans. All of the proposed FSMA Preventive controls are listed below, including those which are similar or covered under HACCP systems already in place.. Anything that is new, different or unusual in regard to HACCP or preventive Controls is in ***italics and bold*** for ease of identification.

Checklist Item	*Reference*	*Comments*
PC 1. ***Has the owner, operator, or agent in charge of a facility prepared***, or had prepared, and implemented a written food safety plan consistent with the Codex HACCP annex and specific to each particular facility? Quality plans and ***facility profiles*** should be available for FDA inspectors or appropriate parties and should include the following information:	**117.126(a)**	
1. Contact information.		
2. ***Facility type and size, and operational information such as operations schedule including seasonal variations.***		
3. Products.		
4. Written hazard analysis.	**117.126(b)**	
5. Written preventive controls.		
6. Written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls.		
7. Written corrective action procedures.		
8. Written verification procedures.		
9. Written recall plan.		
10. Employee training including preventive control training.		
11. ***Third party audit information.***		

Preventive Controls



Food Defense

FSMA Security plan list

1. Is access to the facility limited? Is entry controlled? Is access to critical areas of the facility limited and restricted to authorized personnel? Are restricted areas clearly marked? Is staff access in the facility limited to the area of their job function and unrestricted areas?
2. Are exit doors that are designated for emergency use only and not routinely use by personnel equipped with alarms?
3. Is management aware of which employees should be on the premises and the area they are assigned to?
4. Are all employees screened prior to hiring (e.g. reference checks, criminal background check, etc.), including temporary employees?
5. Has food defense training been provided to all employees?
6. Does the company and facility have a documented food defense plan? Is there a designated person to oversee it?
7. Is the security team for each facility identified and the member list current? Do they meet at least quarterly?
8. Are employees aware of whom in management they should contact about potential security problems/issues?
9. Does the company keep a current roster of employees, full time and temporary?
10. Is there an employee identification system in place? Are uniforms, name tags or identification badges collected from employees prior to the termination of employment?
11. Is there a system of traceability of computer transactions, and is computer access restricted?
12. Does the facility have a documented policy to prevent storage or holding of finished product in unsecured areas?
13. Are routine security checks of the premises performed to identify signs of tampering, criminal or terrorist act?
14. Is the perimeter of the facility secured by fencing or other deterrent?
15. Is the security of doors, windows and other points of entry monitored and documented?
16. Are keys to the facility monitored or tracked?
17. Does the facility have an emergency lighting system?
18. Is the delivery and off-loading of incoming materials supervised?
19. Does the facility have a program in place to inspect product returned to the facility for tampering?
20. Are floor plans, product flow charts and/or segregation charts are in a secure location?
21. Is there a documented contractor and visitor policy? Are visitors required to show ID? Is the purpose of the visitation verified before entry into the factory? Is there evidence the policy is being followed?
22. Are visitors prohibited from sensitive areas in the plant (production, treatment etc.), unless accompanied by an authorized employee?
23. Are incoming and outgoing employee and visitor vehicles part of a regular inspection program?
24. Are parked vehicles belonging to employees and visitors identified by a marker, card or decal, provided by the plant or company?
25. Is there a policy in place stating where personal items are allowed and not allowed in the facility?

Foreign Supplier Verification Programs

Joe Levitt

Overview of FSVP Proposal

- Closely tracks supplier verification program in supplemental proposed rule for preventive controls
  - Consideration of supplier risks
  - Approach to SAHCODHA hazards
    - "serious adverse health consequences or death to humans or animals"
  - Confidentiality of Audit Reports
  - Approved supplier list
  - Deemed compliance

What's Different?

- General structure is different
  - In PC, the receiving facility has already conducted a hazard analysis as part of its food safety plan before implementing supplier controls
  - In FSVP, there is a specific requirement for the importer to conduct a hazard analysis for the imported material as part of the supplier verification program
- Scope is different
  - PC applies to registered food facilities, except for certain exemptions and modified provisions
  - FSVP applies to all importers of "food"

Hazard Analysis

- Same as in preventive controls
- If there are no significant hazards, no supplier verification required
- Importers could comply with this requirement by reviewing and assessing the hazard analysis conducted by the supplier

Supplier Risk Evaluation

- Under the "risk evaluation" provision, importers would consider (in addition to the hazards analysis), factors relating to "supplier risk"
  - Same factors as in PC
  - The risk evaluation determines the verification activities
- An importer would be required to promptly reevaluate risk factors when it learns of new information
- Forthcoming FDA guidance:
  - Specific information FDA believes importers should consider and how these factors might be weighed in evaluating overall risk
  - Circumstances under which importers should reevaluate food and supplier risks

SAHCODHA Hazards

- FDA does not believe uncertainty about SAHCODHA standard would make it difficult for importers to comply with the provision
  - Directs importers to Reportable Food Registry Questions and Answers document and weekly Enforcement Reports
  - FDA may issue further guidance to clarify what food hazards are SAHCODHA hazards
- FDA intends to provide guidance on circumstances, including both food and supplier risks, under which onsite auditing of foreign suppliers and/or other supplier verification approaches are appropriate

Very Small Importer/Supplier

- FDA proposes to increase annual sales ceiling used in proposed definition of "very small importer" and "very small foreign supplier"
  - Increase from $500,000 to $1 million
  - Revision is consistent with revised approach to the definition of "very small business" under the proposed preventive controls regulations
- FDA is still considering comments concerning whether the regulations should include any similar modified provisions for very small importers and suppliers
  - If so, what modified requirements should be
  - Whether food sales to be considered for eligibility should be limited to sales in or to the United States

Qualified Individuals Conflicts of Interest

- FDA's original proposed rule stated that a qualified individual who conducts verification activities must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity
  - Does not prohibit the importer or its employees from conducting verification
- FDA seeks comment on this provision and on additional conflict of interest issues
  - Whether such requirements should be directed at certain persons (e.g., auditors)
  - What should constitute a financial interest

The Bottom Line for Bottled Water

What It All Means

- Good Evolution in FDA Rules
  - Preventive controls generally follow HACCP
  - Food safety plans can be tailored to our industry
  - Product testing requirements already met
  - Environmental testing can likely be limited for our industry
  - No obvious SAHCODAH hazards for bottled water

What It All Means

- Key Points to Focus On
  - Validation of process controls
  - Having a written suppler oversight plan
  - Good recordkeeping practices
  - *Passing your IBWA annual audit is key to a successful FDA inspection*

New Inspection Paradigm

New Inspection Paradigm

- FDA to develop inspection cadre specially trained in and devoted to food inspections
- Systems-based approach
- Heavily dependent on records review
- Closer integration of field inspectors and HQ experts
- Rapid enforcement action if high risk to public health identified

Facility Registration

Facility Registration Reminder

- Remember that the period for renewing your facility registrations is currently open and will be until December 31, 2014
- ALL facilities must renew their registrations during this time period, even if they were recently updated

Questions?

Contact Information

Bob Hirst, Vice President
International Bottled Water Association
(703) 647-4611
bhirst@bottledwater.org

Joseph A. Levitt, Partner
Hogan Lovells US LLP
(202) 637-5759
Joseph.Levitt@hoganlovells.com