



National Program Standards Crosswalk Resource Paper

A Partnership for Food Protection Resource Document



National Program Standards Crosswalk Resource Paper

Produced by: the Partnership for Food Protection National Standards Work Group

Introduction

The Partnership for Food Protection (PFP) National Standards Work Group (NSWG) has compiled information on the standards and requirements that apply to government agencies responsible for the oversight of various sectors of the food industry in the United States. The NSWG has identified and summarized key elements that are similar across the different sets standards (see Exhibit A) that apply to food regulatory programs in four program areas:

- Grade 'A' Milk and Milk Products
- Manufactured Foods (excluding meat and poultry)
- Retail Food Protection
- Molluscan Shellfish

The documents prepared by the NSWG can be used to identify important commonalities and differences among the existing program standards and to recognize opportunities for harmonizing the program standards and their implementation by regulatory agencies. A crosswalk document allows for a side-by-side comparison of how key program elements are addressed in each of the different sets of program standards. For each of the four program areas, an Overview and Characterization Document has also been prepared that describes the basic requirements that apply, the development and implementation the standards, the nature of the regulatory community and the industry that is regulated.

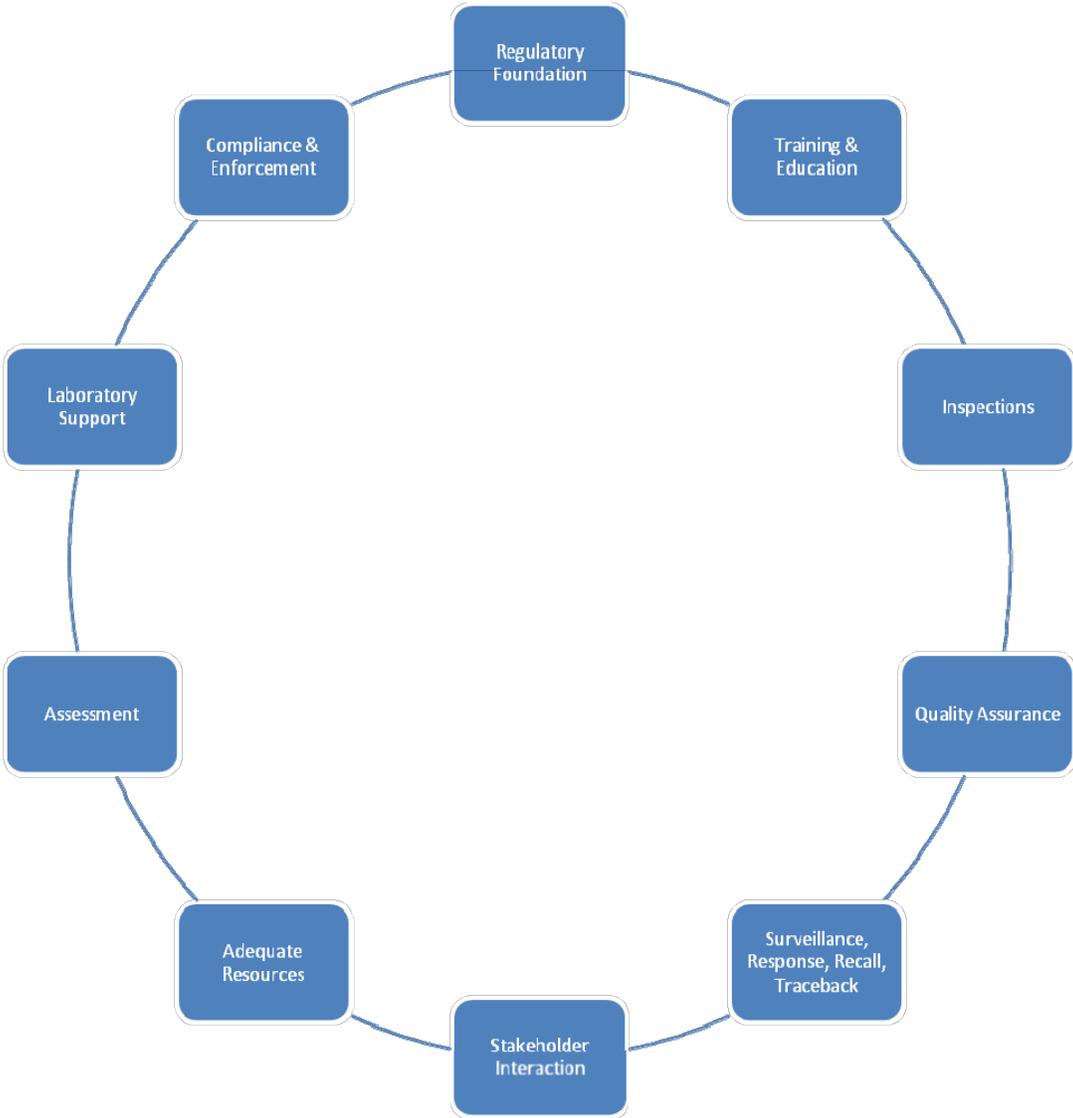
The Crosswalk Document and the Overview Documents are each organized according to basic program standard elements that exist to some degree in all program areas. Those elements are:

- Regulatory Foundation
- Trained Regulatory Staff
- Inspection Program
- Quality Assurance/ Inspection Audit Program
- Foodborne Illness and Food Defense Preparedness and Response
- Compliance and Enforcement
- Industry and Community Relations
- Program Resources
- Program Assessment
- Laboratory capability

An analysis of the similarities and differences between program requirements allows FDA and its State/local/tribal partners to determine if and where improvements can be made and how various strategies and tools can be used to promote their effective implementation. While regulatory programs may operate differently, an understanding of the respective program

standard elements across all program areas will also assist regulatory partners to identify where opportunities and challenges exist for the integration of programs between and across different levels of government and, where necessary, to strengthen the requirements that correspond to a particular program element. This will benefit any agency that manages multiple programs areas and is responsible for developing strategies for conforming to each set of “standards” and the coordination of such efforts. This crosswalk document will benefit FDA and its partners when considering appropriate changes to the criteria in one or more program area. Knowing where the similarities and differences are among standards is critical to understanding the challenges associated with developing common procedures and protocols for program management and staff that meet each of the applicable standards.

Exhibit A



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Program Element: Regulatory Foundation			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<p>The Regulatory Foundation (laws and regulations that govern the Interstate Milk Shippers Program (IMS)) is the <i>Model Grade “A” Pasteurized Milk Ordinance (PMO), Procedures Governing The Cooperative State-Public Health Service/Food And Drug Administration Program Of The National Conference On Interstate Milk Shipments (Procedures), Methods of Making Sanitation Ratings Of Milk Shippers (MMSR), and the Evaluation of Milk Laboratories (EML)</i>.</p> <p>States must adopt the PMO and NCIMS related documents or have equivalent regulations in place for not more than six (6) years prior to the most recent Conference to be determined to be in compliance with the Minimum State Program Evaluation Requirements and Criteria. Based on this statement all states must have officially adopted the 2003 PMO or equivalent regulations.</p>	<p>Manufactured Foods Regulatory Program Standards (MFRPS) Standard 1 requires that the State program have the legal authority to inspect food plants, gather evidence, collect and analyze samples, and take enforcement actions for adulteration or misbranding of foods equivalent in effect to sections of the current FD&C Act and Title 21 Code of Federal Regulations. The State program enforces provisions equivalent in effect to the Federal Regulations. In the absence of a corresponding law or regulation, a legal review by the State agency’s counsel to determine equivalency of such law.</p>	<p>Voluntary National Retail Food Regulatory Program Standard (RFRPS) Standard 1 requires that a regulatory jurisdiction’s regulations must be at least as stringent as the <i>FDA Food Code</i> on identified provisions. Not all language is required to be in the food regulation as long as it can be found in administrative rules or other legally binding language. A comparison of the jurisdiction’s rules and regulations against the <i>FDA Food Code</i> is required to demonstrate equivalency.</p>	<p>States participating in the National Shellfish Sanitation Program (NSSP) are expected to model their regulations after the Guide for the Control of Molluscan Shellfish which consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the control of molluscan shellfish. The Model Ordinance sets forth the standards and practices incumbent upon state regulatory authorities and the shellfish industry necessary for the sanitary control of molluscan shellfish.</p>

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Program Element: Trained Regulatory Staff			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<ul style="list-style-type: none"> • Training requirements apply to State, Regional and Local Governmental Units, including FDA certified State Rating Officers (SRO), Laboratory Evaluation Officers (LEO), and Sampling Surveillance Officers (SSO), regulatory personnel and dairy industry personnel. Training includes but is not limited to biennial FDA regional seminars, continuing certification of SROs, LEOs and SSOs, courses and one-on-one training. • Qualifications for initial certifications (joint inspections with a FDA CFSAN standardized Regional Milk Specialist (RMS) of a minimum of five (5) milk plants, twenty-five (25) dairy farms, one (1) single service manufacturing facility, HTST equipment testing and completion of the required paperwork for the mock exercises) and re-certification (joint inspections with a FDA CFSAN standardized Regional Milk Specialist (RMS) of a minimum of three (3) milk plants, ten (10) dairy farms, and one (1) single service manufacturing facility) of SROs, LEOs, and SSOs (initial and re-standardization: joint inspections with a FDA CFSAN standardized 	<p>MFRPS Standard 2 requires that the State program have a training plan that ensures all inspectors receive training required to adequately perform their work assignments. The plan provides for basic and advanced level food inspection training as well as continued training for professional development in the field of food processing.</p> <ul style="list-style-type: none"> • The standard requires the maintenance of a history of the training provided to all inspectors/investigators, including the individual’s start date. • Each inspector is required to complete a basic food inspection training curriculum that includes the following areas of competency: <ul style="list-style-type: none"> ○ Prevailing statutes, regulations, and ordinances ○ Public Health Principles ○ Food Defense Awareness ○ Communications Skills ○ Microbiology ○ Epidemiology ○ Basic of HACCP ○ Basic Labeling 	<p>RFRPS Standard 2 specifies that training is required by staff members to effectively understand the regulations and inspect the industry competently. Standard 2 identifies knowledge areas where staff members must document training received. The FDA’s ORA-U and other face-to-face courses are identified as the content material, but equivalent training is acceptable if the same training objectives identified in the FDA courses are met.</p> <p>For new staff members or staff members new to the retail food program, courses identified as prerequisite courses are required before conducting any independent routine inspections. These courses total 42 hours of on-line courses in the areas of:</p> <ul style="list-style-type: none"> • Prevailing statutes, Regulations, Ordinances • Public Health Principles • Food Microbiology; and • Communication Skills <p>Following required joint field work and required independent field work, an additional 26 hours of course work is required in the areas of:</p> <ul style="list-style-type: none"> • Advanced Food Microbiology 	<p>The NSSP requires each State/Tribal program must have trained regulatory staff with the knowledge, skills, and abilities, as applicable to that program.</p> <ul style="list-style-type: none"> • The shellfish program requires that at least one individual be standardized by the FDA as a Shellfish Plant Standardization Officer (SSO) which encompasses specific training through course work and field work . • The SSO conducts training of additional state/tribal inspectors for their state program. • State/Tribal personnel can take FD242 Course Sanitary Surveys of Shellfish Growing Areas. • Field training is usually provided by state staff while conducting sanitary surveys. • Patrol enforcement state/tribal personnel engaged in the patrol of classified shellfish areas must meet the NSSP specific training requirements.

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Program Element: Trained Regulatory Staff			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<p>Regional Milk Specialist (RMS) of a minimum of five (5) bulk milk hauler/samplers and 2 plant samplers) are outlined in Section V. of the <i>Procedures</i> Document. FDA certifications are valid for three (3) years.</p> <ul style="list-style-type: none"> Industry personnel responsible for fulfilling PMO program requirements in an official capacity are also subject to training, evaluation, and permitting. The training and evaluation procedures for Certified Industry Inspectors are outlined in Section 5 of the PMO and Bulk Milk Sampler/Haulers and Industry Plant Samplers are outlined in the PMO, Appendix B. Training and evaluation procedures for Industry personnel that collect and analyze official samples for regulatory compliance with the PMO in IMS listed laboratories and personnel responsible for the screening/confirmation of Beta lactam drug residues are outlined in the <i>EML</i> and Appendix N of the PMO. 	<ul style="list-style-type: none"> Control of allergens (when available) Sampling Technique and Preparation Each inspector/investigator must participate in a minimum of ten (10) joint or audit inspections with a qualified trainer and receive a minimum of two acceptable evaluations from the trainer. The inspections must be representative of the jurisdictions inventory and must be completed within 18 months of hiring. Each inspector/investigator conducting specialized food inspections must complete an advanced inspection training curriculum that includes the following coursework: <ul style="list-style-type: none"> Applications of Epidemiology & Foodborne Illness Investigations Traceback Investigations National Incident Management System (incident command system) Nutrition Labeling Acidified foods Low Acid Canned Foods Juice HACCP 	<ul style="list-style-type: none"> Basic HACCP series Epidemiology Emergency Management; and Allergen Management <p>Staff members must also pass a field competency exercise called “Standardization” every three years, and accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training.</p>	

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Program Element: Trained Regulatory Staff			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
	<ul style="list-style-type: none"> ○ Seafood HACCP • Each inspector/investigator who will conduct specialized food inspections must participate in three (3) joint inspections with a qualified trainer and receive a minimum of two (2) acceptable evaluations from the trainer. The inspections must be conducted in food plants representative of the specialty area and must be completed prior to performing independent inspections. • Each inspector/investigator must participate in continuing education that includes coursework and inspections. 36 contact hours are required every 36 months. 		

National Program Standards Crosswalk

Program Element: Inspection Program			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<ul style="list-style-type: none"> • State inspection programs are based on the PMO or equivalent, which specifically states a permit is required and the inspection system is spelled out in the PMO. This allows for an inventory system (IMS List) to be established nationally that is recognized by each State program.. • The PMO is prescriptive in addressing compliance with the critical control point for the legal pasteurization of milk and milk products. It outlines the proper design, operation and maintenance of legal pasteurization systems that are allowed. It also addresses critical processing elements and the immediate required action to be taken by the Regulatory Agency when such violations are identified. A prescriptive number of inspections per year per type of activity (four (4)/ milk plant, two (2) per dairy farm, annual milk tank truck inspections, etc.). • The PMO requires that should any violation of the PMO be found to exist on an inspection/HACCP audit, a second inspection/HACCP audit shall be required after the time 	<p>MFRPS Standard 3 specifies that the State program have an inspection program that reduces the occurrence of foodborne illness, injury, or allergic reactions. The program provides the foundation for inspecting food plants to determine compliance with the laws administered by federal, state, and local governments. Additionally, the program must have:</p> <ul style="list-style-type: none"> • Risk-based inspection program (e.g. an inventory of food plants categorized by the degree of risk associated with the likelihood that a food safety or defense incident will occur). • Written policies and procedures for inspecting food plants • An established recall system • A system to respond appropriately to consumer complaints, • A system to resolve industry complaints about inspections • A recordkeeping system for all elements of the inspection program 	<p>RFRPS Standard 3 specifies that a jurisdiction enrolled in the program is required to have an inspection program, documented in writing, that focus on the status of risk factors, determines and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors.</p> <ul style="list-style-type: none"> • An inspection form is required that records whether key inspection items is either ‘in compliance,’ ‘out of compliance,’ ‘not observed’ during the inspection, or ‘not applicable’ to the operation being inspected. • Establishments must be categorized into at least three priority categories that determine inspectional frequency. • Policies must be established for on-site and long-term corrective actions for certain types of violations and for follow-up activities. • Policies and procedures must be in place for addressing variance requests and for verification and validation of Hazard Analysis Critical Control Point (HACCP) plans when such plans are 	<p>The NSSP requires each State/Tribal authority have an inspection program that maintains an accurate inventory of shellfish firms (e.g., harvesters, dealers, shippers) and implement a risk-based inspection program. Each State/tribal authority must have a risk-based inspection/evaluation program that documents oversight of at least the following program elements :</p> <ul style="list-style-type: none"> • Vibrio Management • Growing Area Evaluation • Control of Harvest • Plant Sanitation

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Program Element: Inspection Program			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<p>deemed necessary to remedy the violation, but not before three (3) days. If any violation of the same requirement of the PMO exists on the follow up inspection/HACCP audit, the PMO called for the permit to be suspended.</p> <ul style="list-style-type: none"> • The rating method is spelled out in the PMO, MMSR and Procedures • Recalls: All aseptically processed and packaged products from the lot that were found to contain one (1) or more non-sterile units shall be recalled and disposed of as directed by the Regulatory Agency. If regulatory tests reveal that the HTST equipment or controls are not in compliance with the provisions of the PMO, all milk and milk products that were processed during that period shall be recalled; HACCP System in total, address public health concerns such as those identified in 21 CFR Part 7, Recalls. • Consumer complaints are a part of the overall State Milk Regulatory Program and follow individual State laws and rules. The PMO also addresses consumer complaints in the HACCP section. 		<p>required by the regulations.</p>	

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Program Element: Inspection Program			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<ul style="list-style-type: none"> • The procedure to address complaints received from receiving states and municipalities is addressed in the <i>Procedures</i>. • Inspection records kept for a specific time period of 24 months. 			

National Program Standards Crosswalk

Program Element: Inspection Audit Program			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<p>Three (3) Tier Program:</p> <ul style="list-style-type: none"> • Inspections are conducted by the state regulatory agency inspector a minimum of every three (3) months for milk plants and every six (6) months for dairy farms. • State Ratings are conducted a minimum of every twenty-four (24) months by a SRO, which are accomplished by evaluating sanitation compliance and required regulatory enforcement standards in accordance to the PMO. • Check Ratings are conducted by the FDA Regional Milk Specialist and are scheduled every three (3) years for milk plants and every four (4) years for dairy farm groups, which are accomplished by assessing the evaluation of sanitation compliance and required regulatory enforcement standards in accordance to the PMO. • FDA plays a very active role in the implementation of the entire Grade “A” Milk Safety Program, providing training and technical assistance to the states. 	<p>MFRPS Standard 4 specifies that the State program conducts quality assurance reviews to assess and evaluate the effectiveness of the inspection program, recognizes trends in inspectional coverage, and identifies best practices used to achieve quality inspections and sample collections. The program should implement the following:</p> <ul style="list-style-type: none"> • Quality Assurance Program (QAP) <ul style="list-style-type: none"> ○ Field audit, which is an on-site performance evaluation of inspections, and ○ Desk audit, which is a performance review of written reports of inspections and sample collections • Performance Ratings and corrective actions plans when required • Sample reports 	<p>RFRPS Standard 4 establishes ten areas of performance that must be achieved by staff (listed in the Standard). The quality assurance program must be on-going and identify actions that will be taken when the areas of low staff performance are noted. The quality assurance program is for staff and program performance as a whole and does not address individual competency. An objective statistical measure of the overall staff performance scored on two-filed inspections during a three year period is used to determine if the standard is achieved. The staff overall must score at least a 75% rating on each of the ten measured aspects using a provided procedure.</p>	<p>The NSSP does not require that a State Regulatory Authority implement a quality assurance program however some states/tribes have established quality assurance programs for their shellfish sanitation programs, especially in the areas of plant sanitation inspection review and growing area sanitary survey documentation.</p> <p>In addition, FDA provides an audit review of NSSP member states and tribes to assess compliance to the NSSP. These reviews are based on risk and are conducted annually or biennially depending on the activity. Currently, Vibrio Management and Growing Areas are considered the highest risk and are assessed more often than Control of Harvest, Laboratory, and Plant Sanitation.</p>

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Program Element: Food Related Illness and Outbreaks/Food Preparedness and Response			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<p>Responsibility of the State program to conduct foodborne illness investigations. Assistance of the Regional Milk Specialist is often used.</p> <ul style="list-style-type: none"> • ALERT training is conducted. • PMO stipulates Foodborne Illness and Food Defense Preparedness. • Coordinates roles and responsibilities with state and industry • Laboratory support 	<p>MFRPS Standard 5 specifies that the State program have written procedures for documenting and investigating alleged food-related illnesses, injuries, and unintentional or deliberate food contamination. Additionally, the State program must have a rapid response system and team that is capable of detecting and distinguishing between outbreaks of foodborne disease and possible intentional contamination.</p> <ul style="list-style-type: none"> • Description of epidemiology support and agreement for support, such as a MOU or contract • Written planning and preparedness procedures • System for disseminating current guidance to industry • Notification and collaboration with law enforcement, FDA and other relevant agencies • Food-related complaint log or database • Customer and consumer notification • Post response system 	<p>RFRPS Standard 5 requires the program have policies and procedures for recording and investigating foodborne illness complaints, including follow-up for disposition of complaints.. Additional areas that must be addressed include: agreements with cooperating agencies/departments, reporting procedures, laboratory support documentation, trace-back procedures, recalls, media management, and data review to identify important trends or clues that could help prevent future foodborne illness outbreaks.</p>	<p>The NSSP outlines a process for managing illness outbreaks including product recall. Each shellfish processor is required to establish written recall procedures. General protocols are set to ensure that outbreak control measures are coordinated at the federal level with headquarters and regional offices, Centers of Disease Control (CDC), and FDA emergency operations and press staff. SSP include: reporting procedures; investigative procedures; product labeling to aid in traceback, communications, and data review to identify/link the associated NSSP program element; and identify trends or clues that may help prevent future outbreaks</p> <p>Communication and dissemination of information to the public can be provided by the industry, state/tribal shellfish authority, and/or FDA at anytime and is frequently provided during foodborne illness outbreaks, recalls, and shellfish growing area closures.</p> <p>Under the NSSP, State and Tribal authorities must maintain written documents describing:</p> <ul style="list-style-type: none"> • Response to illness, injury or outbreak; • Release of information to the

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Program Element: Food Related Illness and Outbreaks/Food Preparedness and Response			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
			public; <ul style="list-style-type: none"> • Access to epidemiological support available to the program; • Complaint log or database with documented timeframes for responding to complaints; and • Investigation reports and summaries.

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Program Element: Compliance and Enforcement			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<p>Compliance and enforcement actions are dictated by the appropriate sections within the PMO, Procedures and MMSR. The state conducts routine inspections.</p> <ul style="list-style-type: none"> Enforcement actions (activities) are evaluated during State Ratings and Check Ratings. Individual Check Ratings and the triennial State Program Evaluation utilizes the results from farms and plants to determine if Compliance and Enforcement actions taken by the state were appropriate and in accordance with the PMO. Minimum State Program Evaluation Requirements and Criteria address enforcement activities that are required to be in compliance with the Grade “A” Milk Safety Program. State Program Evaluations are required every three (3) years. 	<p>MFRPS Standard 6 specifies that the State program have a compliance and enforcement program that has written procedures ensuring that actions are supported by sound judgment, adequate evidence and appropriate documentation which include the following elements:</p> <ul style="list-style-type: none"> Contains written enforcement strategies Tracks critical and chronic violations and violators Uses a risk-based system to determine when a directed investigation, follow-up, or re-inspection is needed. Establishes a timeline for progressive actions. Has a system to communicate verbal and written policy and guidance to managerial and non-managerial staff. <p>This program element also includes an annual performance review of enforcement actions.</p>	<p>RFRPS Standard 6 requires that the jurisdiction have written step-by-step procedures that describe how compliance and enforcement tools are to be used to achieve compliance and the inspection tool documenting IN, OUT, NO, and NA on certain inspection items so that accurate tracking of compliance can be accomplished. The Standard does not dictate adherence to specific policies or procedures, but supplies an objective statistical means of measuring the compliance program’s effectiveness.</p> <p>Documentation on the establishment inspection report form or in the establishment file using the statistical method for file selection in the Supplement to Standard 6, Appendix F, requires at least 80 percent of the sampled establishments meet the following conditions:</p> <ul style="list-style-type: none"> The inspection and enforcement staff takes compliance and enforcement action according to the procedure (i.e. the staff follow the step-by-step compliance and enforcement procedures when violations occur), and Resolution was successfully achieved for all out-of-control risk factors or interventions that 	<p>Compliance and Enforcement actions are dictated by the appropriate sections of the NSSP. The states conduct routine inspections. Where industry deficiencies are found the state works with and coordinate with industry to obtain compliance. Where non-compliance continues the state takes administrative action to decertify and revoke harvesting licenses.</p> <p>Specifically each state/tribal program must have:</p> <ul style="list-style-type: none"> Established written enforcement strategies for food safety compliance activities that incorporate the requirements of the NSSP-MO Chapter I.@.02.C-H.; Mechanism to track critical and chronic violations and violators; Employ a risk-based system to determine when follow-up activities or re-inspection is warranted; Procedures to manage progressive enforcement actions; Procedures to communicate compliance and enforcement policy and guidance to managerial and non-managerial

National Program Standards Crosswalk

Program Element: Compliance and Enforcement			
Grade "A" Milk	Manufactured Foods	Retail Foods	Shellfish
		were recorded on the selected routine inspection.	staff; <ul style="list-style-type: none"> • Special program elements for specific food safety systems, such as Hazard Analysis and Critical Control Point (HACCP), Good Manufacturing Practices (GMP), etc.

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Program Element: Industry and Community Relations			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<p>State program personnel attend national and regional seminars addressing the PMO, Procedures, Methods and EML at least biennially. The National Conference on Interstate Milk Shipments (NCIMS) meets every two (2) years to deliberate proposed changes to the PMO and NCIMS related documents. The NCIMS provides all stakeholders, including industry, academia, regulatory and the public, an opportunity to raise questions and concerns regarding any aspect of the Grade A Milk program. These conferences, seminars and other FDA sponsored training courses are the program’s educational outreach activities.</p>	<p>MFRPS Standard 7 specifies that the State program participate in activities that foster communication and information exchange among the regulators, industry, academia, and consumer representatives.</p> <ul style="list-style-type: none"> • Interacts with industry and consumers by sponsoring or actively participating in meetings, such as task forces, advisory boards, or advisory committees. • Increase outreach for food defense, investigation strategies, and regulatory requirements. All stake holders from Federal to consumer level are invited to the meetings. 	<p>RFRPS Standard 7 specifies that programs engage in at least one activity in each of two categories annually:</p> <ul style="list-style-type: none"> • Industry and Consumer Interaction: The jurisdiction sponsors or actively participates in meetings such as food safety task forces, advisory boards or advisory committees. These forums shall present information on food safety, food safety strategies and interventions to control risk factors. Offers of participation must be extended to industry and consumer representatives. • Educational Outreach: Outreach encompasses industry and consumer groups as well as media and elected officials. Outreach efforts may include industry recognition programs, web sites, newsletters, FightBAC™ campaigns, food safety month activities, food worker training, school-based activities, customer surveys or other activities that increase awareness of the risk factors and control methods to prevent foodborne illness. Outreach activities may also include posting inspection information on 	<p>FDA, international, state/tribal, and industry representatives engage at the ISSC Meeting where attendees deliberate and adopt revisions to the NSSP and foster better control measures for ensuring molluscan shellfish safety. FDA participates with states and industry in a biennial meeting of the ISSC where revisions of the NSSP are adopted. Along with the biennial meeting of the ISSC, outreach is accomplished through:</p> <ul style="list-style-type: none"> • Annual meetings of regional regulatory and industry members are conducted to discuss shellfish safety for improved consumer safety. • Semiannual meetings of the ISSC Executive Board held in which federal, academia, state/tribal, and industry representatives act on behalf of the full ISSC body on an interim basis to address issues pertinent to the NSSP and matters of shellfish safety at the national, regional, and state/tribal level. • The ISSC maintains a webpage at http://www.issc.org/ with information to all stakeholders including the consumer on shellfish safety. • Press releases, media, meetings

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Program Element: Industry and Community Relations			
Grade "A" Milk	Manufactured Foods	Retail Foods	Shellfish
		a web site or in the press.	and publications are provided to stakeholders and consumers when needed as mandated in the ISSC by laws.

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Program Element: Program Resources			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<p>Staffing, equipment, and program funding requirements are the responsibility of the State program. Limited Regional FDA/State partnership funds and funding from the FDA Division of Human Resource Development (DHRD) are used to assist the States in equipment and training funding. The Program is fully implemented in all 50 States and Puerto Rico.</p>	<p>MFRPS Standard 8 specifies that the State program assess and allocate resources needed to support a manufactured food regulatory program. The core elements for this standard include ensuring that the State has adequate:</p> <ul style="list-style-type: none"> • Staffing to administer and implement all program standards, conduct inspections, re-inspections of manufactured food plants in the state’s inventory based on risk classifications, complaint investigations, foodborne illness and outbreak support, response to emergency situations, compliance and enforcement strategies, participate in outreach activities, internal quality assurance program. • Equipment to conduct quality inspections, calibration and repair of equipment, communication systems and equipment, and hardware/software IT equipment • Program funding, such as salary, benefits, training costs, travel-related expenses, equipment/supplies, outreach expenses, laboratory expenses, legal services fees, indirect costs and overhead costs. 	<p>RFRPS Standard 8 requires a staffing level of at least one full-time-equivalent employee for every 280 to 320 inspections performed. Inspections for purposes of the calculation include all direct contact time with the establishments such as routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up, risk assessment reviews, process and variance reviews and on-site training. Minimum inspectional equipment and adequate records systems must be documented along with completion of an appendix document designed to assess support needs of the program.</p>	<p>Currently the NSSP does not have an established measure for staffing/resource adequacy or any minimum criteria. There is no NSSP specific resource assessment criterion, but some states/tribes do conduct resource assessment for their shellfish sanitation programs specifically plant sanitation inspection/license and growing area classification work. However, to date 35 states participate in the program with additional states occasionally coming onboard. Within those states that do participate adequate resources continue to be provided via state budget allocations to promote compliance with the NSSP. Within those states that do not participate, there has been some limited impact to processors wishing to participate because their product cannot be introduced for sale in interstate commerce.</p> <p>Failure to have the adequate staffing and equipment causes the program to decrease the level of conformance could cause the dealers of that state/tribe on the ICSSL to be delisted and no longer be allowed to ship molluscan shellfish interstate.</p>

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Program Element: Program Assessment			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<ul style="list-style-type: none"> • State Program Evaluations (SPE) are conducted triennially. Regional Milk Specialists evaluate the staffing, supervisory, inspection, sampling and analysis, enforcement, compliance with the PMO and related NCIMS documents, and rating work of State Regulatory and Rating Agencies to determine whether milk regulations are being interpreted and enforced in accordance with the provisions of the PMO. • Minimum State Program Evaluation Requirements and Criteria have been established. • A Strategic Action Plan is developed jointly by the FDA Region and the State to address all program areas that do not meet the minimum requirements and criteria. • A State Program Evaluation Resolution Process has been established. 	<p>MFRPS Standard 9 specifies that State program managers conduct periodic self-assessments of its manufactured food regulatory program against the criteria established in each program standard. These self-assessments are designed to identify the strengths and weaknesses of the State program by determining the level of conformance with the program standards and areas of or function of the State program that needs improvement.</p> <p>Using the forms provided or alternate equivalent forms, the jurisdiction conducts a baseline self-assessment to determine if the elements of each standard are being met.</p> <ul style="list-style-type: none"> • The jurisdiction maintains the documents required by each standard and all self-assessments, improvement plans, and program assessment validation audits. The information must be current and fit for use. • The jurisdiction uses the results of the self-assessments to complete the Self-Assessment and Improvement Plan Report. • A written strategic plan is developed to address all program elements and documentation requirements that are not 	<p>RFRPS Standard 9 specifies that retail inspection programs measure program effectiveness by assessing the occurrence of risk factors by way of a study or survey that can be used to show trends over time. Standard 9 requires that the jurisdiction complete a survey in its facilities on the frequency of occurrence of the risk factors that contribute to food borne illness. The surveys provide information on the effectiveness of the overall program and allow the effectiveness of initiatives to be measured based on a reduction in the occurrence of the risk factors. Further, Standard 9 also contained the requirements and frequencies for self-assessment, auditing, and reporting of results for listing on the FDA website as a jurisdiction participating in the RFRPS.</p>	<p>An internal mechanism for NSSP member states/tribes to conduct a program self-assessment utilizing national standards is not required but encouraged. Each program element of each state/tribal program is assessed by FDA for determination of compliance with the NSSP. Currently there is not emphasis placed on program self assessment nor sharing of that self assessment. ISSC is considering a proposal submitted to ISSC to incorporate program assessment utilizing national food safety standards. This proposal may be reviewed at the 2013 Interstate Shellfish Sanitation Conference (ISSC) Biennial meeting.</p> <p>The FDA conducts routine State Program Evaluations to evaluate overall compliance with the NSSP. Where deficiencies exist, FDA works with the state to develop corrective action plans to bring the program back into compliance. Failure to comply can result in an ISSC unresolved issue proceeding and possible delisting of the state’s shellfish processors from the Interstate Certified Shellfish Shippers List (ICSSL).</p>

National Program Standards Crosswalk

Program Element: Program Assessment			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
	<p>currently being met. The strategic plan identifies the specific element(s) of the standard(s) not being met, improvements needed to meet the requirement and the projected completion date for each element identified.</p> <ul style="list-style-type: none"> • FDA conducts a Program Assessment Validation Audits (PAVA) within 18 of enrollment, and 36 months. FDA conducts a comprehensive program audit at 60 months. 		

National Program Standards Crosswalk

Program Element: Laboratory Support			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<ul style="list-style-type: none"> Official regulatory sample analysis is required to be conducted in IMS Listed laboratories utilizing NCIMS approved methods. All States and Puerto Rico have access to State and industry laboratories that are IMS Listed. The EML provides the standards, procedures, and requirements of State and industry milk laboratories to be IMS Listed and to perform official regulatory milk sample testing and reporting under the Grade “A” Milk Safety Program. IMS Listed laboratories are evaluated and accredited by FDA certified LEOs every three (3) and if they are in compliance with the EML they are IMS Listed. IMS Listed State central milk laboratories are evaluated and accredited by FDA LPET every three (3) and if they are in compliance with the EML they are IMS Listed. All IMS Listed laboratories require the successful completion of annual proficiency sample testing (examination of split milk 	<p>MFRPS Standard 10 specifies that State programs have access to the laboratory services needed to support program functions and documents its laboratory capabilities including agreements with external laboratories. This includes:</p> <ul style="list-style-type: none"> Having access to a laboratory that is capable of analyzing a variety of samples including food, environmental, and clinical samples. Maintaining a list of services for routine and non-routine analyses such as biological hazard determinations. Having a contract or written agreement with its primary servicing laboratories. Utilizing laboratories that have a current A2LA accreditation, OR Utilizing laboratories that have quality assurance programs that incorporate management and technical requirements found in ISO/IEC 17025:2005 <i>General Requirements for the Competence of Testing and Calibration Laboratories</i>. 	<p>RFRPS Standard 5 requires the regulatory program to have an established relationship with a laboratory or laboratories that can provide analytical support including the analysis of environmental, food, and clinical samples. Programs are also required to maintain a list of laboratory contacts that can provide analytical assistance in the event of a food-related emergency that exceeds the capability of the primary laboratory.</p>	<p>Each state or tribe participating in the NSSP must have laboratory access for analysis of food, environmental, and clinical samples including marine water sampling that is used for growing area classification requirements; meat testing for pathogens, marine biotoxin testing, and clinical testing for foodborne illness outbreaks.</p> <p>All records/documentation of laboratory services for routine and non-routine analyses such as biological hazard determinations must be maintained. A state or tribe may also contract with outside laboratories as needed. Each laboratory must be accredited or certified and have a written Quality Assurance Programs (QAP). Labs that do NSSP work are required to be evaluated by a Laboratory Evaluation Officer (LEO).</p>

National Program Standards Crosswalk

Program Element: Laboratory Support			
Grade “A” Milk	Manufactured Foods	Retail Foods	Shellfish
<p>samples).</p> <ul style="list-style-type: none"> The IMS List provides a list of accredited State and industry laboratories, including the test methods they are approved to perform. 			

Appendix A:
Partnership for Food Protection, National Standards Work Group
National Shellfish Sanitation Program (NSSP) Standards that Apply
to Molluscan Shellfish State Cooperative Regulatory Program
Overview and Characterization

Characterization of the Program Requirements

FDA simply cannot monitor every growing area, shellfish processing plant, shellfish shipment, market, or restaurant without state and tribal partners. In addition, FDA could not evaluate, patrol, monitor and classify shellfish growing areas in all shellfish producing states. FDA functions as a partner in the NSSP by monitoring state/tribal activities in regards to requirements of the NSSP, standardizing and training shellfish inspectors, and evaluating NSSP compliance by states. However, FDA relies on the state/tribal shellfish and retail food programs to be vigilant in efforts to identify situations involving shellfish borne illness outbreaks.

The NSSP Model Ordinance provides current thinking on the safe and sanitary control of the growing, harvesting, processing, and shipping of molluscan shellfish for human consumption. The voluntary National Shellfish Sanitation Program's Guide for the Control of Molluscan Shellfish is written to provide a desired performance outcome within specified boundaries. The Model Ordinance provides readily adoptable standards and practices necessary for the sanitary control of molluscan shellfish. The states/tribes take the lead in accomplishing program goals via individual state's/tribes' authorities for enforcing compliance with the program. Standards are intended as a continuous improvement process and can be amended through the cooperative process of the ISSC. The process for compliance involves assessment, analysis, and development of action plans for future improvement, followed by an outside audit of Standards claimed as met. As the program improves in quality and institutes intervention strategies to improve shellfish safety within the regulated community, the frequency of occurrence of shellfish illness risk factors should decrease.

Date Established: 1925

Date Updated: Updates published every two years. Last updates 2009.

Industry Sector Regulated – Description and Size

The shellfish industry is comprised of shellfish growers, shellfish harvesters, shellfish processors, and shellfish shippers. Each of these components is regulated by the state/tribal control authority within their state/tribe. In addition, FDA is responsible for the regulatory oversight of the state/tribe control authority and evaluates those entities relative to their responsibilities for growing area classification, patrol, laboratories, and plant inspection/certification and licensing.

Thirty five states have certified shellfish shippers participating in the NSSP. Within those states are more than 2000 certified shellfish processors. Each processor who has been certified by the state control authority is listed on FDA's ICSSL which is published monthly on FDA's website for the information and use by food control officials, the seafood industry and other interested persons. In addition to a monthly listing, the FDA also has a dynamic ICSSL that is updated online as often as daily. Both listings of the ICSSL are available on FDA's website at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/InterstateShellfishShippersList/default.htm>

Of the 35 states participating in the NSSP, all coastal states where shellfish is harvested participate. In addition to US participating states/tribes there are four foreign countries participating in the voluntary program as well.

Characterization and Size of Regulatory Community

NSSP standards and practices apply to a varied regulatory community. Jurisdictions range from small to large government departments under health, environmental, natural resources, and agricultural agencies within the 35 NSSP participating states. The control of molluscan shellfish in many states has been divided between or among multiple agencies. Where this is the case the division of authority is typically to place the shellfish processing component with the health agency, patrol and harvester licensing with the natural resources or agriculture agency, and the growing area classification with the environmental or agriculture agency. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels, and scallops) moving in interstate commerce through federal/state/tribal cooperation and uniformity of State shellfish programs. Regulatory participants in the NSSP include agencies from shellfish producing and non-producing States, FDA, Environmental Protection Agency (EPA), and National Oceanic and Atmospheric Administration (NOAA). Under international agreements with FDA, foreign governments also participate in the NSSP

Participation in national and international food safety organizations for most state and tribes in the NSSP is limited to the ISSC and regional conferences and networks. Several states network with other states for joint growing areas at state borders and biotoxin testing/monitoring especially for blooms that can cover large areas. States also work together on recall and foodborne illness outbreak investigations especially during emergencies. Communication among ISSC member states/tribes include listed contacts on the ISSC webpage and the Interstate Certified Shellfish Shippers List (ICSSL) that is maintained daily. In addition, members network during ISSC conferences and committee work. Communication with FDA, other States, Tribes, industry and academia is usually via email and news spread via "list serves" and announcements.

Communication of food safety issues and concerns with trading partners on the ICSSL is limited. Some biotoxin and recall information does get exchanged via the state/tribe to other nations especially between states/tribes that border Canada. Most communication with national and international authorities during food safety incidents or emergencies occurs via FDA and the states that communicated directly with the countries on the ICSSL. These countries have a Memorandum of Understanding (MOU) with FDA to be a member of the NSSP and are listed on the ICSSL that allows them to ship directly to the U.S. Non-member countries work directly

with FDA. Under the NSSP these countries are not allowed to ship raw fresh or frozen molluscan shellfish to the US. Any non-member country that wishes to be a part of the NSSP must work directly with FDA which would evaluate their food safety program.

Process to Develop and Maintain

The ISSC has adopted formal procedures for state/tribal representatives to review shellfish sanitation issues and develop regulatory standards and guidelines under the NSSP. Following FDA concurrence, these guidelines are published in revisions of the NSSP Guide for the Control of Molluscan Shellfish. The ISSC provides the formal structure wherein state and tribal regulatory authorities, federal agencies, and the shellfish industry work cooperatively to modify the Model Ordinance and establish improved guidelines and standards for the sanitary control of the shellfish industry. The FDA administers these standards and guidelines and prepares an annual evaluation of the shellfish program of each state/tribe. Standards and guidelines are submitted in the form of Proposals to the ISSC. Anyone can submit a Proposal. The ISSC is the parliamentary-style organization made up of regulators and the regulated industry. Proposals are debated in committees and Task Forces made up of regulatory and industry representatives. Final votes on Proposals passed by the Task Forces are made by the General Assembly which is comprised of state regulators. ISSC recommendations are then sent to FDA for consideration. If FDA concurs with ISSC action, then the Proposal is incorporated into the NSSP.

Where questions or disagreement on the intent of NSSP requirements exist, FDA develops formal interpretations that are then uniformly applied by the member states and industry.

Mechanism for Assessing Implementation

NSSP standards are designed with a system for continued improvement in mind, as described in “Process to Develop and Maintain” on page 11. Under the NSSP, state shellfish programs maintain ongoing activities of industry surveillance including, inspections, certifications, licensing, classifications, sample analyses, and coordination among program elements. As a result of this process, industry compliance with NSSP requirements is maintained at a consistent level and when problems are encountered a mechanism for rapid correction is available. FDA maintains a routine program of surveillance for the ongoing evaluation of state program compliance with the NSSP. The result of these activities is a consistent and uniform level of shellfish safety throughout the nation.

Constraints to Implementation

The only constraint to program participation and implementation is a state’s lack of resources, either budgetary or staffing. Currently, 35 states participate in the program with additional states occasionally coming onboard. Tribes do have the sovereign right to participate in the program as an authority but most choose to work with a partner state. Within those states that do participate, adequate resources continue to be provided via state budget allocations to enable full compliance with the NSSP. Within those states that do not participate, there has been limited impact to processors wishing to participate and see their product recognized for sale in interstate commerce. FDA and the ISSC continue to encourage participation by all U.S. states.

Current Status of Implementation

The program is fully implemented in 35 states. Personnel are available within FDA to provide guidance and limited assistance to state regulatory agencies and state regulatory agency personnel are available to assist industry in all elements of the program including the following:

- *Vibrio* Management
- Growing Area Classification
- Plant Sanitation and Shipping
- Control of Harvest
- Laboratories

Oversight

Given the unique nature of the shellfish program, standards are considered minimum criteria, and the ISSC Constitution, By-Laws and Procedures guarantee that no action or requirement on the part of any state regulatory authority will cause or require any action in excess of the requirements of the NSSP. The intent of this procedure is to ensure that state actions do not unnecessarily restrict interstate shipment of shellfish in conformance with the NSSP. The ISSC recognizes that states and tribes should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish and act accordingly within the boundaries of the NSSP. A state or tribe may face censure if it takes an action against another state's product in excess of NSSP without first notifying the other state and the ISSC. A state or tribe under censure may attend all ISSC functions and otherwise exercise rights as a member of the ISSC, but may not vote either in committees, Task Forces, or in the general assembly. The Executive Board reserves the right to take additional actions against the non-compliant State or Tribe. In addition, if a State or Tribe fails to maintain the NSSP standard, all dealers of that State or Tribe on the ICSSL may face delisting and then prevented from shipping their shellfish into interstate commerce.

Description of the Standards/Requirements

The National Shellfish Sanitation Program (NSSP) is the federal/state/tribal cooperative program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of raw molluscan shellfish produced and sold for human consumption. The purpose of the NSSP is the model ordinance to promote and improve the sanitation of raw molluscan shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state/tribal/industry cooperation and uniformity of state/tribal shellfish sanitation programs. The ISSC is a voluntary conference of NSSP member states, tribes, foreign governments, FDA, other federal government agencies, academia and molluscan shellfish dealers who work together to promulgate the model ordinance and guidance of the NSSP.

FDA facilitates NSSP implementation by providing standardization evaluation, training and technical support to states/tribes programs that has the regulatory authority for the shellfish sanitation program.

The NSSP elements are:

- Manage *Vibrio vulnificus* and *Vibrio parahaemolyticus* risk with management control plans and efforts. Specific information can be found in *NSSP-MO Chapter II. Risk Assessment and Risk Management*.
- Classify growing areas based on pollution source assessment, water quality assessment and other factors that indicate suitability for harvest. Growing area classification specific information can be found in *NSSP-MO Chapter IV. Shellstock growing Areas*.
- Patrol to deter illegal harvesting from prohibited waters. Specific information regarding patrol, licensing and penalties may be found in *NSSP-MO Chapter VIII. Control of Shellfish Harvesting*.
- Inspect facilities that handle shellfish to ensure the use of proper sanitary measures. Specific requirements to be evaluated during inspections may be found in *NSSP-MO Chapter X. General Requirements for Dealers*. *NSSP-MO Chapters XI, XII, XIII, XIV, and XV provide requirements for specific NSSP processor types*.
- Conduct laboratory testing and analysis of shellfish and water samples. Specifics regarding laboratory regulation and evaluation are found in *NSSP-MO Chapter III. Laboratory .01 and .02 Requirements for the Authority*.

For managing *Vibrio vulnificus* and *Vibrio parahaemolyticus* risk, each state/tribe must evaluate their growing areas' risk utilizing specific risk assessments, management control plans and efforts as required by the NSSP. The NSSP sets forth the basic requirements for risk analysis and control. Specific information is located *NSSP-MO Chapter II. Risk Assessment and Risk Management*.

For growing area classification the regulatory authority must conduct growing area classification including water quality monitoring, pollution source surveys and analysis, and reporting. In addition, shellfish harvesting is managed through administration of growing area management plans.

The NSSP has the following requirements for a state or tribal shellfish sanitation program:

1. **Regulatory Foundation:** The regulatory foundation used by a state/tribal regulatory authority that governs the safety of raw molluscan shellfish in interstate commerce is in the NSSP Guide for the Control of Molluscan Shellfish.

The NSSP Guide consists of a Model Ordinance (NSSP-MO), supporting guidance documents, recommended forms, and other related materials associated with the control of molluscan shellfish. The Model Ordinance sets forth the standards and practices incumbent upon state/tribal regulatory authorities and the shellfish industry necessary for the sanitary control of molluscan shellfish.

The NSSP Guide can be accessed online through the FDA's website:

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm046353.htm>

The regulatory authority is required to adopt the most recent version of the Model Ordinance in statute or have in statute. Alternatively, a state statute may contain a code that meets the most recent version of the Model Ordinance specifically laws and regulations that provide an adequate legal basis for the safety and sanitary control of all program elements applicable to that state or tribe. Failure to do so could lead to an action plan and possible removal of that state's or tribe's shellfish dealers from the Interstate Certified Shellfish Shippers List (ICSSL) therefore preventing the interstate commerce of shellfish from that state or tribe.

Each state or tribe under the National Shellfish Sanitation Program must be a competent Food Safety Authority with the following required authorities as required by the *NSSP-MO Chapter I. Shellfish Sanitation Program*:

- Jurisdiction over shellfish food supply
- Authority to take appropriate actions to prevent the spread of food borne illness
- Authority to delegate responsibility to other governmental organizations with their state or tribe such as Control of Harvest to a state, tribal or local law enforcement agency
- Authority to verify adequacy of delegated responsibility
- Statutory or legal definitions for "shellfish"
- Statutory or legal ban on food safety inspection components such as "introducing into commerce adulterated food," "adulteration of food," "receipt of adulterated food," "refusing records access," and "refusal to permit entry or inspection"
- Ability to assess penalties for violation of food safety laws
- Ability to prevent adulterated shellfish from entering into interstate commerce
- Authority to require emergency permits when necessary
- Authority to issue licenses
- Authority to promulgate regulations to enforce statutory requirements
- Authority to access records of dealers for shellfish entering into interstate commerce
- Authority to perform law enforcement for patrol including citations and penalties
- Authority to conduct inspections of any establishment (including farms) where shellfish is grown, harvested, processed, packed or held for introduction into interstate commerce
- Authority to establish reportable shellfish borne illness registry and conduct shellfish borne illness investigations
- Authority to recall or remove adulterated shellfish from interstate commerce
- Specific regulatory requirements for good manufacturing practices for shellfish handling and processing such as sanitation requirements

- Specific requirements for preventative control systems such as HACCP plan and recordkeeping requirements. The NSSP provides the HACCP critical control points and critical limits as a requirement on the dealer/processor.
- Administrative procedures for food safety regulatory activities such as inspection, re-inspection, and licensing renewal/action including the removal of a dealer from the ICSSL

Since the NSSP is a cooperative program, only dealers of NSSP member states and tribes are allowed to ship raw fresh/frozen molluscan shellfish interstate. Only dealers of member countries are allowed to ship product to the United States. Dealers of nonmember states and tribes are prohibited from shipping interstate. Member states and tribes are quick to take regulatory action such as embargo and order destruction when shellfish is found from a dealer not on the ICSSL.

2. **Trained Regulatory Staff:** The NSSP requires each State/Tribal program must have trained regulatory staff with the knowledge, skills, and abilities, as applicable to that program. Training is provided by FDA on some of the elements but only the Shellfish Plant Standardization Officer (SSO) training has specific training both course and field requirements for the SSO position. A minimum of one person per NSSP member state/tribe is required to be standardized by FDA to ensure a nationally consistent approach to application of the NSSP. State/Tribal personnel can take FD242 Course Sanitary Surveys of Shellfish Growing Areas that can be found at: <http://inside.fda.gov:9003/EmployeeResources/Training/ORAUCourses/ucm278925.htm#FD242>. Field training is usually provided by state staff while conducting sanitary surveys.

Patrol enforcement state/tribal personnel engaged in the patrol of classified shellfish areas must meet the NSSP specific training requirements such as basic law enforcement training; shellfish control regulations and in-service training on the shellfish control regulations. State/Tribal and Federal personnel that evaluation Patrol activities must take FD243 course on Patrol Evaluation that can be found at: <http://inside.fda.gov:9003/EmployeeResources/Training/ORAUCourses/ucm278925.htm#FD243>. It also sets forth the basic requirements of state/tribal patrol programs against which FDA evaluates state/tribal compliance. Specifics on patrol requirements are located *NSSP Guide Section IV. GUIDANCE DOCUMENTS Chapter II - Growing Areas .08 Growing Area Patrol and Enforcement*.

For shellfish processing plant inspection and certification the state/tribe is expected to adhere to the same NSSP training required of shellfish standardization officer (SSO) candidates and FDA Regional Shellfish Specialists (RSS). Specific standardization requirements are established in the NSSP Guidance Documents under Plant Inspection Standardization Procedures. Once standardized, the SSO conducts training of additional state/tribal inspectors for their state program. The NSSP sets forth the basic requirements that must be met by industry to ensure safe processing, including Hazard Analysis Critical Control Point (HACCP) principles and plant sanitation. The requirements for conducting inspections and the frequency of inspection by state/tribal inspectors are

specified in the NSSP. Specifics on standardization of inspections is located *NSSP Guide Section IV. GUIDANCE DOCUMENTS Chapter III - Harvesting, Handling, Processing, and Distribution .02 Shellfish Plant Inspection Standardization Procedures/NSSP Standardized Shellfish Processing Plant Inspection Form* and can be found at:

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm070629.htm#qual>.

For laboratories, either the FDA Lab Evaluation Officer (LEO) or a state/tribal LEO who has demonstrated competency to FDA conducts routine evaluations of the laboratory's competency in conducting water and shellfish meat analysis and quality analysis and quality control assurances. Specifics on standardization of inspections, conformance and nonconformance and regulation of authority is located *NSSP Guide Section IV. GUIDANCE DOCUMENTS Chapter II - Growing Areas.11 Evaluation of Laboratories by State Laboratory Evaluation Officers Including Laboratory Evaluation Checklists*.

Overall the state or tribe has the organizational responsibility for employee training and maintenance of each employee training records including:

- Job descriptions and duties for personnel
- Minimum education or other qualification requirements for personnel
- Available training for personnel at all levels of competency
- Minimum training requirements for staff

3. **Inspection Program:** The NSSP requires each State/Tribal authority have an inspection program element(s) that provides an accurate inventory of shellfish dealers and includes a risk-based inspection program. In addition, each state/tribe must have a risk-based inspection/evaluation program for *Vibrio* Management, Growing Areas, and Control of Harvest.

The risk-based inspection program and inspection/evaluation protocol and documentation for the four program elements include the following:

Vibrio Management (Highest Risk)

- *NSSP-MO Chapter II Section @.04 Vibrio vulnificus Risk Management requirements*
- *NSSP-MO P Chapter II Section @.05 Vibrio parahaemolyticus Control Plan requirements*

Growing Area Evaluation (High Risk)

- *NSSP-MO Chapter IV Growing Area Requirements for the Authority*
 - Sanitary Survey
 - Bacteriological Standards
 - Classification
 - Marine Biotoxin Control

Control of Harvest (High to Low Risk)

- *NSSP-MO Chapter VIII Control of Harvest risk factors.*
 - Shellfish Productivity
 - Ease of Harvest
 - Difficulty of Patrol

Plant Sanitation (Low Risk)

- *NSSP-MO Chapter X, XI, XII, XIII, XIV, XV, and XVI.*
 - Standardization Guide
 - Field Guide
 - 27 item inspection form

4. **Uniform Inspection Program and Inspection Audits:** The NSSP does not require that a State Regulatory Authority implement a quality assurance program however some states/tribes have established quality assurance programs for their shellfish sanitation programs, especially in the areas of plant sanitation inspection review and growing area sanitary survey documentation.

In addition, FDA provides an audit review of NSSP member states and tribes to assess compliance to the NSSP. These reviews are based on risk and are conducted annually or biennially depending on the activity. *Vibrio* Management and Growing Areas are considered the highest risk and are assessed more often than Control of Harvest, Laboratory, and Plant Sanitation.

5. **Shellfish Borne Illness and Food Defense Preparedness and Response:** The NSSP outlines a process for managing illness outbreaks including product recall. Under the *NSSP-MO Chapter X.03.B.*, each shellfish processor is required to establish written recall procedures to ensure that recalls are timely and effective and that affected program partners are informed. General protocols are set to ensure that outbreak control measures are coordinated at the federal level with headquarters and regional offices, Centers of Disease Control (CDC), and FDA emergency operations and press staff. Areas addressed under the cooperative NSSP include: reporting procedures; investigative procedures; product labeling to aid in traceback, communications, and data review to identify/link the associated NSSP program element; and identify trends or clues that may help prevent future outbreaks. *NSSP-MO Chapter II. Risk Assessment and Risk Management .01 Outbreaks of Shellfish Related Illnesses* and *.02 Presence of Human Pathogens in Shellfish Meats.*

The program must have element(s) for food recalls, consumer complaints, food industry inspection complaints and documentation under *NSSP-MO Chapter II.@.01-@.03* including:

- Outbreaks of Shellfish Related Illness

- Presence of Human Pathogens in Shellfish Meats
- Presence of Toxic Substances in Shellfish Meats

Communication and dissemination of information to the public can be provided by the industry, state/tribal shellfish authority, and/or FDA at anytime and is frequently provided during foodborne illness outbreaks, recalls, and shellfish growing area closures.

Under the NSSP, State and Tribal authorities must maintain written documents describing:

- Response to illness, injury or outbreak;
- Release of information to the public;
- Access to epidemiological support available to the program;
- Complaint log or database with documented timeframes for responding to complaints; and
- Investigation reports and summaries.

6. **Compliance and Enforcement:** Under the NSSP, each state/tribal must have procedures and policies for obtaining compliance with the NSSP. Specifically, through participation in the National Shellfish Sanitation Program and membership in the Interstate Shellfish Sanitation Conference (ISSC), states/tribes have agreed to enforce the NSSP as the requirements that are minimally necessary for the sanitary control of molluscan shellfish. The regulatory statutes of each state/tribe must set forth controls that are at least as stringent as those set forth in the Model Ordinance. However, a state/tribe cannot establish requirements for product from other state/tribes that are in excess of those outlined in the NSSP. The responsibility for enforcement of NSSP requirements falls primarily to the state/tribes with FDA providing administrative oversight and state/tribal program evaluation.

In accordance with the NSSP, states and tribes promulgate laws and regulations that enable them to carry out the requirements for *Vibrio* management, growing area classification, patrol, plant inspection/certification, licensing and laboratory evaluation as well as the authority to enforce NSSP requirements incumbent on the shellfish industry, including harvesting, processing, and shipping. States/tribes conduct routine inspection and certification of processors utilizing Hazard Analysis and Critical Control Point (HACCP) principles, license harvest vessels, enforce NSSP harvesting requirements, conduct patrols, classify growing areas, and maintain NSSP compliant laboratories. When an industry deficiency is found the state/tribe's authority works with industry to obtain compliance. The NSSP Model Ordinance Chapter I.@.02.C-H. spell out compliance requirements for renewal certification, revocation, listing on the ICSSL, inspections and enforcement. When non-compliance continues, the state/tribe takes administrative action to decertify processors and revoke harvesting licenses. FDA conducts routine evaluation of state/tribes' overall compliance with the NSSP. When deficiencies exist, FDA works one-on-one with the state/tribe to develop corrective action plans to bring the program back into compliance. When a state/tribe fails to comply, FDA works through the ISSC to obtain correction through a NSSP-defined unresolved

issue process. Continued failure by a state or tribe to make the necessary program corrections can result in the delisting of shellfish processors in that state/tribe from FDA's Interstate Certified Shellfish Shippers List (ICSSL) and the refusal of their product in interstate commerce by other states and the retail industry. Information regarding dealer certification and the ICSSL is found in *NSSP-MO Chapter I. Shellfish Sanitation Program. 02 Dealer Certification* and in *SECTION IV. GUIDANCE DOCUMENTS Chapter III - Harvesting, Handling, Processing, and Distribution .03 Dealer Certification and the Interstate Certified Shellfish Shippers List*.

Specifically each state's/tribes' program must have:

- Established written enforcement strategies for food safety compliance activities that incorporate the requirements of the NSSP-MO Chapter I.@.02.C-H.;
- Mechanism to track critical and chronic violations and violators;
- Employ a risk-based system to determine when follow-up activities or re-inspection is warranted;
- Procedures to manage progressive enforcement actions;
- Procedures to communicate compliance and enforcement policy and guidance to managerial and non-managerial staff;
- Special program elements for specific food safety systems, such as Hazard Analysis and Critical Control Point (HACCP), Good Manufacturing Practices (GMP), etc;
- Periodic review of enforcement actions to assess areas in need of improvement or corrective action, and updates policies and practices based on findings; and
- Written procedures that describe compliance and enforcement programs and records of periodic review and follow-up activity.

7. **Regulatory, Industry and Community Relations:** The NSSP requires State and Tribal authorities to work with other agencies in the event of recalls and illness investigations. In addition, the NSSP requires shellfish control authorities to address shellfish concerns with the industry and community in the prevention of shellfish borne illnesses especially in states that grow shellfish. The NSSP requires authorities to have adequate administration so that commercially harvested and recreationally harvested shellfish do not mix and enter the interstate commerce (*NSSP-MO Chapter I.@.01.E.*). State and Tribal authorities do communicate with other state/international regulatory agencies and the regulated industry. FDA participates with international, state/tribal, and industry representatives at the biennial meeting of the Interstate Shellfish Sanitation Conference (ISSC) where attendees deliberate and adopt revisions to the NSSP and foster better control measures for ensuring molluscan shellfish safety. Annual meetings of regional regulatory and industry members are conducted to discuss shellfish safety issues specific to each of the four national regions and consider strategies for improved consumer safety. Finally, semiannual meetings of the ISSC Executive Board are held in which federal, academia, state/tribal, and industry representatives act on behalf of the full ISSC body on an interim basis to address issues pertinent to the NSSP and matters of shellfish safety at the national, regional, and state/tribal level. Each of these meetings present an opportunity to discuss and act upon information regarding shellfish safety, strategies and interventions to control shellfish safety risk factor;, jurisdictional program strengths and

needs, and interactions between federal and state/tribal partners, federal and industry partners and state/tribal and industry partners. Industry members can join anytime but in order for state and tribal partners to be voting member of ISSC, membership is required and the state/tribe must meet NSSP and ISSC membership requirements. Explanation of the unique relationship between industry and regulatory bodies as it pertains to NSSP and the ISSC may be found in *NSSP-MO Chapter I. Shellfish Sanitation Program and at <http://www.issc.org/>*.

Activities and communication tools are utilized by federal, state and tribal food safety authorities to interact with industry and consumers. Records are maintained on these activities. The Interstate Shellfish Sanitation Conference (ISSC) has federal, international, state, tribal, industry and academia members who communicate and work on shellfish sanitation proposals that shape the NSSP Guide including the NSSP-MO. The ISSC maintains a network with these members that include an executive board and committees made up of the various member groups. Every biennium there is a national conference during which proposals and conference business are discussed, revised, promulgated, and then voted on for FDA review and concurrence before being added to the NSSP Guide. In addition, the ISSC maintains a webpage that is considered an important source of information for the NSSP.

FDA maintains a network with state and tribal shellfish sanitation authorities utilizing Regional Shellfish Specialists (RSS) in each region. The RSS consult, evaluate and assist state and tribal program staff, and upon request industry and academia members as well. In each region, smaller shellfish sanitation conferences occur during which states, tribes, academia and industry associated with that region meet to connect, share new ideas, and to generate and discuss new proposals for the NSSP. In addition, some regions have industry group meetings that are attended by academia, state, tribal and federal partners.

8. **Program Resources:** Currently the NSSP does not have an established measure for staffing/resource adequacy or any minimum criteria. In general, adequate staffing, equipment and funding are requirements for a successful program to be able to meet the minimum requirements of the NSSP, as verified by program evaluations. RSSs and LEOs evaluate state/tribal shellfish sanitation authorities to determine if staff and equipment are available as warranted. RSS and LEOs use the Compliance Program 7318.004 to evaluate each element of *Vibrio* Management, Growing Areas, Control of Harvest, Plant Sanitation and Shipping, and Laboratory as needed to determine if the program is meeting the NSSP requirements. Compliance Program 7318.004 can be found at:

[http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm073326.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=Compliance Program 7318.004&utm_content=1](http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm073326.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=Compliance+Program+7318.004&utm_content=1)

Program Element Evaluation Reports written by RSS for each element on an annual or biennial timetable sometimes denote programs as In Compliance but with Deficiencies, In Noncompliance, or In Major Noncompliance. Specific objective measures are provided in the NSSP Guidance Documents for Plant Sanitation and Patrol Evaluations.

Forms are available for Plant Sanitation and may be found in the NSSP Guidance Documents. This decreased program element level could be attributed to inadequate staffing and equipment that impact the program. This impact could find programs not meeting required patrol frequencies, plant and shipper inspections/renewals and/or correct laboratory procedures. When a program does not meet the NSSP standards, the program is required to provide an Action Plan on how the program is going to meet the standards. The Action Plan must state specifically what actions will be taken by the program to meet those standards with timetables. This action could mean the program will seek and acquire additional staffing, training, and equipment.

Each state and tribal shellfish sanitation authority should have an internal mechanism to determine if the adequate staffing, equipment and funding are in place to meet the requirements of the NSSP. There is not guidance provided for an internal mechanism to determine adequacy is not required under the NSSP but is encouraged. Failure to have the adequate staffing and equipment which causes the program to decrease the level of conformance could cause the dealers of that state/tribe on the ICSSL to be delisted and no longer be allowed to ship molluscan shellfish interstate. This could result in an economic burden to those dealers and the state/tribe.

At this time, there is not a NSSP specific resource assessment criterion but some states/tribes do conduct resource assessment for their shellfish sanitation programs specifically plant sanitation inspection/license and growing area classification work.

9. **Program Assessment:** An internal mechanism for member states/tribes to conduct an internal program assessment utilizing national food safety standards is not required but encouraged. Each program element of each state/tribal program is assessed by FDA for determination of compliance with the NSSP. Currently there is not emphasis placed on program self assessment nor sharing of that self assessment. ISSC is looking at a proposal that was submitted to ISSC to incorporate program assessment utilizing national food safety standards. This proposal may be reviewed at the 2013 Interstate Shellfish Sanitation Conference (ISSC) Biennial meeting.
10. **Laboratory Support:** Each state or tribe in the NSSP must have laboratory access for analysis of food, environmental, and clinical samples including marine water sampling that is used for growing area classification requirements; meat testing for pathogens, marine biotoxin testing, and clinical testing for foodborne illness outbreaks.

All records/documentation of laboratory services for routine and non-routine analyses such as biological hazard determinations must be maintained. A state or tribe may also contract with outside or contract laboratories as needed. Each laboratory must be accredited or certified and have a written Quality Assurance Programs (QAP). FDA provides a Laboratory Evaluation Officer (LEO) who evaluates labs used for the NSSP and also trains LEO for the state or tribe as requested.

All written quality assurance programs (QAP), are required to maintain:

- Calibration, verification, and maintenance of equipment

- Documentation of analytical results
- Control and maintenance of documents
- Sample accountability
- Sample integrity and chain of custody
- Qualifications and training of analysts
- Audit procedures

Under the NSSP, the ISSC has an approved methods committee that reviews and votes to approve methods for marine water sampling for classification work and meat testing for biotoxins and pathogens including *Vibrio*. These approved methods are found in the NSSP Guide Section IV. Chapter II.10 approved NSSP Laboratory tests at:

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm059224.htm>

Appendix B:
Partnership for Food Protection, National Standards Work Group
Manufactured Food Regulatory Program Standards
Overview and Characterization

Characterization of the Standards

The Manufactured Food Regulatory Program Standards establish a uniform foundation for the design and management of State programs responsible for the regulation of food plants.

FDA will use the program standards as a tool to improve contracts with States. The program standards will assist both FDA and the States in fulfilling their regulatory obligations. The implementation of the program standards will be negotiated as an option for payment under the State contract. States that are awarded this option will be expected to implement the program standards to evaluate and improve their manufactured food program. FDA recognizes that full use and implementation of the program standards by those States will take several years. Such States will, however, be expected to implement improvement plans to demonstrate that they are moving toward full implementation.

The goal is to implement a risk-based food safety program by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. The development and implementation of these program standards will help Federal and State programs better direct their regulatory activities toward reducing foodborne illness hazards in food plants. Consequently, the safety and security of the United States food supply will improve.

Date Established: The MFRPS were first published in 2007

Date Updated: Updated every three years. The second version of the MFRPS (2010) was updated and approved by OMB (OMB Control No. 0910-0601) and released in February 2011. The current document's expiration date is September 30, 2013.

Industry Sector Regulated – Description and Size

The manufactured foods industry is extremely diverse in commodities and size, representing manufacturing establishments, such as bakery and bakery products, cereal flours and related products, infant formula, bottled water, processed fruits and vegetables, sugar and confectionaries, fish and fish products, dietary supplements, juice and juice products, low acid and acidified foods, frozen desserts, and cheeses and cheese products. The food manufacturing industry sectors are categorized by the North American Industry Classification Systems (NAICS) codes. Various food trade associations within the United States represent the food manufacturers, such as the American Bakers Association, American Dairy Products Association, American Frozen Food Institute, Grocery Manufacturers Association, National Frozen and Refrigerated Foods Association, American Frozen Foods Institute, International Bottled Water Association, and International Dairy-Deli-Bakery Association.

According to the Department of Labor report, *Bureau of Labor Statistics, 2007*, the food manufacturing industries (excluding animal and dairy products) employed over 925,000 employees. The 2006 *Annual Survey of Manufacturers* highlights that the food manufacturing industry (excluding meat and dairy products) represents \$264 billion of products shipments.

Characterization and Size of Regulatory Community

The food safety regulatory system in the United States is a tiered system that involves Federal, State, and local governments. The FDA is responsible for ensuring that all foods moving in interstate commerce, except those under United States Department of Agriculture (USDA) jurisdiction, are safe, wholesome, and labeled properly. State agencies conduct inspection and regulatory activities that help ensure food produced, processed, or sold within their jurisdictions is safe. Many State agencies also conduct food plant inspections under contract with the FDA. These inspections are performed under the States' laws and authorities or the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or both.

To maximize the use of resources among the FDA and the States, particularly when their jurisdictions overlap, their inspection programs should be equivalent in effect. The Food Safety and Modernization Act (FSMA), passed in January 2010, formally recognized the importance of this effort by providing a legislative framework to support an Integrated Food Safety System (IFSS).

According to a survey of state food safety resources conducted by the Association of Food and Drug Officials (AFDO) in 2008, the state regulatory agencies conduct 91,015 manufactured food inspections each year (excluding meat and dairy products data). The FDA has contracts with 45 State food programs to conduct contract inspections for over 10,500 inspections each year in Good Manufacturing Practices (GMPs), Sanitation, Seafood, Juice, Low Acid Foods and Acidified Foods.

Process to Develop and Maintain

The Food and Drug Administration (FDA) administers these Standards. The FDA Office of Partnerships (formerly known as Division of Federal State Relations (DFSR)) has formed the Standards Implementation Staff (formerly known as the Development and Integration Branch). This branch is responsible to provide outreach, guidance and technical support to States implementing the MFRPS.

Currently, there is no formalized governance structure for development and maintenance of the MFRPS. The FDA Office of Partnerships awarded an Alliance Cooperative Agreement to the Association of Food and Drug Officials (AFDO) that will facilitate the development of a National Manufactured Food Regulatory Program Standards meeting. This meeting will serve as the organization for the MFRPS Standard Development Body. This body will be made up of key stakeholders implementing and/or impacted by the MFRPS. Proposed issues will be discussed and debated in parliamentary-style forum. Issues approved through consensus will be provided to FDA. If the FDA concurs, the recommended changes are then incorporated into the MFRPS.

The body will also serve as the vetting organization for supplemental technical guidance, model programs, and outreach development programs for MFRPS.

Mechanism for Assessing Implementation

The MFRPS are designed as a system of continuous improvement for participating agencies. State managers conduct periodic self-assessments of its manufactured food regulatory program against the criteria established in each program standard. These self-assessments are designed to identify the strengths and weaknesses of the State program by determining the level of conformance with the program standards.

Under Standard 9 – Program Assessment, if the State program fails to meet all program elements and documentation requirements of a standard, it develops a written strategic plan that includes the following information: (1) the individual element or documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

After the State has completed their baseline self-assessment and improvement plan, FDA conducts a program assessment validation audit (PAVA, hereafter known as validation audit). The validation audit should occur within 18 months of initial MFRPS implementation. A subsequent validation audit is conducted at 36 months to evaluate the State’s progress toward fully implementing the standards. Then, at 60 months, FDA will conduct a comprehensive program audit. As part of the program audit, the auditor reviews the records and supporting documents required by the criteria in each standard to determine if the self-assessment and improvement plan accurately reflect the State program’s level of conformance with each of the standards.

Constraints to Implementation

The following potential constraints to implementation of the MFRPS have been identified;

1. **Funding and Contractual Process.** Continuation of federal funding to support State contract agreements for manufactured foods inspections, audit and sampling programs, training reimbursement, and MFRPS implementation. Substantial changes within the current contract or acquisition process, or the process for approval of the new changes could delay funding and/or jeopardize funding for programs.
2. **Access and Utilization of Funding:** One obstacle that may prevent full access and utilization of the funds by the intended entities involves accessibility of funds by jurisdictions. Financial systems in some potential jurisdictions may require the funds to go into general revenue rather than into the program budget, which acts as a disincentive to apply for available funding. As a result, a portion of the funding received may go back to the Treasury and FDA will continue to have states with unmet training needs.
3. **Commissioning and/or Confidentiality Agreements** for key staff at the state and local level.
4. **Information Technology:** There is a need for the various electronic systems across the nation to be able to communicate. State programs need to be given access to

eSAF/eSAM (electronic State access to FACTS and/or MARCS) in order to be able to share their inspection information. FDA procedures for accepting and using state/local inspectional and laboratory data for regulatory or enforcement actions. Progress has been made in this area, but more needs to be done before a National Work plan can be implemented.

5. Availability of training programs provided to State, local, territorial, or tribal departments or agencies. State representatives have communicated concerns that FDA does not always allocate training slots/seats to meet the needs of states conducting contractual inspections/sampling for FDA, especially those that have mandatory training prior to conducting advanced food level inspections (seafood, juice, low acid foods and acidified foods).
6. Availability of resources and competing priorities. Availability of State staff, funding and equipment. Competing agency priorities may distract or inhibit participation in contract manufactured food programs.

Current Status of Implementation

The MFRPS started with five pilot states in 2007; OR, NC, WI, MO and NY. As of November 2012, there are currently 41 state agencies (within 40 states) enrolled in the Manufactured Food Regulatory Program Standards (MFRPS).

The Office of Partnerships Standards Implementation Staff conducts monthly conference calls/web cast with States and FDA District representatives to discuss implementation of the MFRPS. The monthly broadcast outreach are used for communicating tips on how to implement individual standards and provide a forum that allow states to share best practices, programs and worksheets. The Office of Partnerships leads the expansion and update features to FoodSHIELD, which allow FDA to record all conference calls/web cast for future viewing and downloading. Membership in the MFRPS Work Group through FoodSHIELD has grown from 45 state and FDA representatives in August 2010, to more than 196 members in October, 2012.

Oversight

Currently, oversight for the State support of MFRPS resides within the FDA Office of Partnerships. FDA audit responsibilities reside with the FDA Office of Regulatory Affairs (ORA), Office of Operations.

Description of the Standards

The Manufactured Food Regulatory Program Standards establish a uniform foundation for the design and management of State programs responsible for the regulation of food plants. The elements of the program standards describe best practices of a high-quality regulatory program. Achieving conformance with them will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation.

The program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from foodborne illness and

injury. These elements include the program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each standard has corresponding self-assessment worksheets and certain standards have supplemental worksheets and forms for determining a level of conformance with such standards. The State program is not required to use the forms and worksheets contained herein; however, alternate forms should be comparable to the forms and worksheets for program standards. These program standards do not address the performance appraisal processes that a State agency may use to evaluate individual employee performance

1. **Regulatory Foundation:** Standard 1 describes the elements of the regulatory foundation used by a State program to regulate food plants. The outcome of this standard is a State program that has the legal authority and regulatory provisions to protect public health by ensuring the safety and security of the food supply.

The State program has the legal authority to inspect food plants, gather evidence, collect and analyze samples, and take enforcement actions for adulteration or misbranding of foods equivalent in effect to sections of the current FD&C Act.

The State program uses its laws and regulations to broaden its scope of regulatory authority.

2. **Trained Regulatory Staff:** Standard 2 defines the essential elements of a training program for inspectors. The outcome of this standard is a State program that has trained inspectors with the knowledge, skills, and abilities to competently inspect food plants.

The State program has a training plan that ensures all inspectors receive training required to adequately and effectively perform their work assignments. The plan provides for basic and advanced food inspection training, field training, as well as continued training for professional development in the field of food processing. The State program maintains a history of the training provide to all inspectors.

The State program requires that each inspector complete a basic food inspection training curriculum that consists of coursework and field training described here:

- Prevailing statutes, regulations, and ordinances
- Public Health Principles
- Food Defense Awareness
- Communications Skills
- Microbiology
- Epidemiology
- Basic of HACCP
- Basic Labeling
- Control of Allergens (when available)
- Sampling Technique and Preparation

Each inspector/investigator must participate in a minimum of ten (10) joint or audit inspections with a qualified trainer and receive a minimum of two (2) acceptable evaluations from the trainer. Joint or audit inspections are conducted in firms that are representative of the food plants in the State program's establishment inventory and must be completed within 18 months of hiring.

The State program requires each inspector who will perform specialized food inspections to complete coursework listed here:

- Applications of epidemiology & food borne illness investigations
- Traceback investigations
- National Incident Management System (incident command system)
- Nutrition labeling
- Acidified foods
- Low acid canned foods
- Principles of Juice HACCP
- Principles of Seafood HACCP

Each inspector/investigator who will conduct specialized food inspections must participate in three (3) joint inspections with a qualified trainer and receive a minimum of two (2) acceptable evaluations from the trainer

Each inspector/investigator must participate in continuing education that includes receiving 36 contact hours of classroom training and participate in at least two (2) joint or audit inspections with a qualified trainer.

3. **Inspection Program:** Standard 3 describes the elements of an effective inspection program for food plants. The outcome of this standard is a State program has an inspection program that reduces the occurrence of foodborne illness, injury, or allergic reaction by: focusing inspection resources on high risk plants, products, and processes; obtaining immediate correction and long-term improvements by manufactured food processors; and responding efficiently to prevent unsafe products from reaching consumers or to remove unsafe food from the human food systems.

The State program inspection system provides the foundation for inspecting food plants to determine compliance with the laws administered by Federal, State, and local governments.

- Risk-based Inspection Program: State program maintains an accurate inventory of its food plants. The inventory is categorized by the degree of risk, with inspections prioritized based on ranking.
- Inspection Protocol: State program has written policies and procedures for inspecting food plants.
- Established Recall System State program has written recall procedures for sharing information, removing recalled food products from the market, performing recall audit checks, and maintaining essential recall information records.

- Consumer Complaints: State program has a system for handling consumer complaints.
 - Food Industry Inspection Complaints: State program has a system to resolve complaints from industry on inspections.
 - Record Keeping System: State program has a record keeping system for all elements of the inspection program.
4. **Regulatory and Industry Relations:** Standard 4 describes the basic quality assurance reviews necessary to evaluate the effectiveness of the inspection program, recognize trends in inspectional coverage, and identify best practices used to achieve quality inspections and sample collections. The outcome of this standard is a State program systematically evaluates and improves its inspection and sample collection systems to ensure that activities and information are accurate, complete, and comply with the jurisdiction's procedures and policies.

The State program implements a quality assurance program (QAP) that identifies elements of its inspection and sample collection processes that need improvement. The QAP has the following components:

- Field Inspection Audit: An on-site performance evaluation of inspections.
 - Desk Audit: A performance review of inspection and sample collection reports.
 - Corrective Action: State develops, implements and documents corrective action plans when performance ratings fall below 80 percent. State program calculates performance factor and overall audit ratings.
 - Annual review of the QAP component results.
5. **Foodborne Illness and Food Defense Preparedness and Response:** Standard 5 describes the functions and related activities necessary to investigate food-related illnesses, outbreaks, and hazards as well as coordinating roles and responsibilities with other jurisdictions and notifying the public. The outcome of this standard is a State program that has written procedures for documenting and investigating alleged food-related illnesses, injuries, and unintentional or deliberate food contamination. The State program has procedures for:
- Contract support for foodborne illness and injury investigation: The State program develops and coordinates the operation of written support agreement between coordinating jurisdictions having authorities or responsibilities during a foodborne illness, recall or other food related emergency or event. This agreement should outline roles, duties and responsibilities of each jurisdiction.
 - Rapid response system and team capable of detecting and distinguishing between intentional and deliberate contamination.
 - Documented timeframes for response and an emergency contact list.
 - Consumer Complaint Log or Database: Tracks, correlates and analyzes foodborne illness or injury complaint data received by the program.
 - Conducting illness or injury investigations, and collects information using established epidemiology procedures similar to those found in *“International Association for*

- Food Protection Procedures to Investigate a Foodborne Illnesses, Fifth Edition*” and “*Guidelines for Foodborne Disease Outbreak Response*”. The State program uses these guidelines to direct response and outbreak activities including traceback and trace forward investigations, notification of relevant food regulatory and law enforcement agencies, mitigation and enforcement strategies, establishment of criteria for releasing information to the public, identification of contributing factors, maintenance of investigational findings and distribution of reports and summaries.
- **Laboratory Support:** Provides regulatory laboratory support for investigations of illness, injury and outbreaks associated per Standard 10.

6. **Compliance and Enforcement:** Standard 6 describes the State agency’s strategies, procedures, and actions to enforce the laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program. The outcome is a State program that has a compliance and enforcement program with written procedures ensuring actions are supported by sound judgment, adequate evidence and appropriate documentation that are all submitted in program prescribed formats and timeframes.

The following elements are part of this standard:

- The program has a compliance and enforcement programs that:
 - Contains written enforcement strategies
 - Tracks critical and chronic violations and violators
 - Uses a risk-based system to determine when a directed investigation, follow-up, or re-inspection is needed
 - Establishes a timeline for progressive actions, and
 - Has a system to communicate verbal and written policy and guidance to managerial and non-managerial staff.
 - In addition, the State program conducts an annual performance review of enforcement actions. This assessment is used to determine if internal procedures for enforcement and compliance actions are followed, which is gauged by calculating a performance rating. If the rating falls below 80%, then corrective action is required.
7. **Industry and Community Relations:** Standard 7 describes the elements of industry and community outreach activities developed, accomplished by the State program. The outcome is a State program uses outreach activities to inform varied populations about food related issues.

The State program participates in activities that foster communication and information exchange among the regulators, industry, academia, and consumer representatives. It also coordinates or participates in outreach activities that provide educational information on food safety and defense issues. Outreach efforts are tailored to a target population and may include dissemination of information using electronic sources and traditional methods such as mailings.

8. **Program Resources:** Standard Number 8 describes the elements for assessing the resources (staff, equipment, and funding) needed to support a manufactured food regulatory program. The outcome is a State program assesses and allocates resources needed to support a manufactured food regulatory program.

The State program has adequate staff to:

- Provide the direction, support, and oversight needed to implement the program standards
- Coordinate a training curriculum and ensure it is properly delivered and tracked
- Inspect food plants in its establishment inventory at an adequate frequency that is based on the plant's risk classification and the necessary inspection and travel time
- Administer and monitor its inspection quality assurance program
- Prepare for and respond to emergency situations
- Implement compliance and enforcement strategies
- Participate in outreach and education activities
- Conduct self-assessments of the manufactured food regulatory program

The State program has adequate equipment:

- Equipment is calibrated
- The State program has computers, software, and equipment necessary to maintain and secure records
- The State program has equipment needed for routine and emergency communications
- The State program provides inspectors with equipment needed to conduct quality inspections

The State program is adequately funded to cover the following expenses:

- Salary and benefits
- Training costs
- Travel-related expenses
- Equipment and supplies
- Industry and community outreach expenses
- Laboratory expenses
- Legal services fees
- Indirect costs
- Overhead costs

9. **Program Assessment:** Standard 9 describes the process a State program uses to assess and demonstrate its conformance with the MFRPS. The outcome is a State program conforms to the program standards through well-defined and written evaluation activities and a process for continuous improvement.

Managers conduct periodic self-assessments of its manufactured food regulatory program against the criteria established in each program standard. These self-assessments are designed to identify the strengths and weaknesses of the State program by determining the level of conformance with the program standards.

The results of the self-assessments are used to determine areas or functions of the State program that need improvement. The results of the baseline self-assessment are used to develop an improvement plan and establish timeframes for making improvements. Subsequent self-assessments are used to track progress toward meeting and maintaining conformance with the program standards.

After the State has completed their baseline self-assessment and improvement plan, FDA conducts a program assessment validation audit. The validation audit should occur within 18 months. A subsequent validation audit will be conducted at 36 months to evaluate the State's progress toward fully implementing the standards. Then, at 60 months, FDA will conduct a comprehensive program audit. As part of the program audit, the auditor reviews the records and supporting documents required by the criteria in each standard to determine if the self-assessment and improvement plan accurately reflect the State program's level of conformance with each of the standards.

10. **Laboratory Support:** Standard 10 describes the elements of laboratory support for a manufactured food regulatory program. The outcome is a State program has access to laboratory services described in Standard 10.

The State program has access to the laboratory services needed to support program functions and documents its laboratory capabilities including agreements with external laboratories. The State program:

- Has access to a laboratory that is capable of analyzing a variety of samples including food, environmental, and clinical samples
- Maintains a list of services for routine and non-routine analyses such as biological hazard determinations
- Has a contract or written agreement with its primary servicing laboratories
- Utilizes laboratories that have a current A2LA accreditation, OR
- Utilizes laboratories that have quality assurance programs that incorporate management and technical requirements found in ISO/IEC 17025:2005 "General Requirements for the Competence of Testing and Calibration Laboratories"

Appendix C:
Partnership for Food Protection, National Standards Work Group
National Voluntary Retail Food Regulatory Program Standards
Overview and Characterization

Characterization of the Standards

The National Voluntary Retail Food Regulatory Program Standards are written to provide a desired performance outcome for the program within broad boundaries. Recognizing that jurisdictions are of varying size and organizational structure, the creators hoped to provide maximum flexibility in the methods used to achieve each Standard while still achieving a measurable, quality outcome. Standards 4 and 6 are particularly successful in providing an objective outcome measure for that program element.

These Standards are intended as a continuous improvement process. The process involves a self-assessment, which should result in a gap analysis and action plan for future improvement, followed by an outside audit of Standards claimed as met. The idea is that priorities can be established for future program improvements to be accomplished at the jurisdiction's own pace and depending upon the available resources. Another feature is a self-survey of the occurrence of foodborne illness risk factors in regulated establishments. As the program improves in quality and institutes intervention strategies to improve food safety within the community, the frequency of occurrence in foodborne illness risk factors should decrease, providing a performance measure for the entire program.

Date Established: 1997

Date Updated: Updates published every two years. Last updates 2011.

Industry Sector Regulated - Description and Size

The restaurant and retail food store industry is comprised of single, independent proprietors, as well as large chain establishments. In recent years, the retail food store industry, which was a traditional grocery store concept, now more closely resembles the restaurant industry with the advent of soup and salad bars and delis selling hot-held and cold-held, ready-to-eat foods.

According to the National Restaurant Association, the restaurant industry has around 945,000 locations, employing 12.7 million people, and generating \$580 billion dollars annually. The Food Marketing Institute's (FMI) numbers apply only to supermarkets, which are defined as stores with over 30,000 square feet and generating between \$2 and \$8 million dollars in sales annually. While FMI primarily represents large multi-store operations, the National Grocers Association (NGA) represents independent retail and wholesale grocers. The NGA does not have published numbers regarding the size of the independent grocery industry, so the entire retail food store industry would be considerably larger than the numbers presented here.

Characterization and Size of the Regulatory Community

The restaurant and retail food store industries are regulated by the state, local, and tribal jurisdictions with regulatory authority. The Retail Standards set quality criteria for the various elements of jurisdictional programs. The National Voluntary Retail Food Regulatory Program Standards apply to a regulatory community as varied as the industry. Jurisdictions range from one-person, rural departments to large metropolitan health or agriculture departments comprised of 35 to 50 or more staff members.

Jurisdictions also vary not only in size, but also in structure. Some states have centralized programs that regulate all the industry within the state. Other states have “home rule” constitutional structures, in which the state regulates unincorporated areas only, while any community can organize its own health department and adopt its own regulations. Some of these “home rule” states may have as many as 300 jurisdictions which regulate the industry within its boundaries. Still other states have only two or three organized jurisdictions within their boundaries, in addition to the state controlled program. A very rough estimate of the total number of jurisdictions in the country is 3000, however it is unclear how many of these jurisdictions have food programs or are of sufficient size to make participation practical (see Constraints to Implementation).

Process to Develop and Maintain

The Food and Drug Administration administers these Standards. Proposed changes to the Standards are submitted in the form of issues to the Conference for Food Protection (CFP). Anyone can submit an issue. The CFP is a parliamentary-style organization made up of the regulated industry and regulators. Issues are discussed and debated in Councils, made up of an equal number of industry and regulatory representatives along with a consumer and academic representative. Final votes on proposed issues passed by the Councils are made by the General Assembly, which is made up only of regulators. CFP recommendations are then sent to FDA that considers these recommendations in light of agency policy and good public health. If the FDA concurs, the recommended changes are then incorporated into the Standards

Mechanism for Assessing Implementation

These National Voluntary Retail Food Regulatory Program Standards are designed as a system of continuous improvement for participating agencies. A resource disk is provided to participants, which enables them to perform a self-assessment of their program against the criteria in each of the Program Standards. The resource disk contains guidance documents, worksheets, and summary conclusion documents for each standard. Each Standard lists source documents such as actual policies and procedures as well as the worksheets and summary documents and that must be retained by the jurisdiction as proof that the self-assessment is an accurate assessment of the program. Another manual is available with instructions for conducting an occurrence of foodborne illness risk factors survey. An ACCESS run program is also provided to compile and generate analytical reports based on the data collected.

Jurisdictions then send to FDA in a conclusion report called the FDA National Registry Report and Permission to Publish. This document shows the results of the self-assessments and audits of Standard claimed as met. The jurisdictions self-assessed results are then posted on the FDA website titled, "Listing of Jurisdictions Enrolled in the Draft Voluntary National Retail Food Regulatory Program Standards." An "X" marks each standard claimed as met by a jurisdiction.

The system encourages jurisdictions to identify gaps in their programs and to set action plans and milestones for program improvements and to enable more Standards criteria and elements to be met as time as resources allow. The self-assessment cycle is to be repeated every 5 years.

Participants are to have audits performed with one year of each self-assessment, done by any individual not under the same supervisory authority as the program. The resource disk also contains guidance for conducting an audit and worksheets to record the audit conclusions. Another FDA National Registry Report and Permission to Publish is submitted by the participating jurisdiction signed by the auditor. Audited Standards are then indicated by a date audited shown under the original X on the FDA website listing.

Constraints to Implementation

Four areas of consideration represent constrains to jurisdictions in implementing the National Voluntary Retail Food Regulatory Program Standards.

1. The manner in which regulations are adopted in a jurisdiction can represent a hurdle in some instances. Jurisdictions which adopt regulations as rules or ordinances generally have an easier time updating their regulatory foundation. Jurisdictions where the regulations are part of an act or law are generally slower to adopt changes to food safety regulations. Laws or acts must go to the legislative branch for alteration, rather than through a board of health or board of commissioners.
2. In one-person jurisdictions, Standards 2 and 4 represent a challenge from a practical point of view. Standard 4 requires a quality assurance program, with field work to demonstrate inspection competency and quality. Standard 2 – training -requires not only course work, but also field work and work with a "standardized" person to demonstrate uniformity and understanding of the regulations. Both of these Standards work better in jurisdictions with several staff members. In some instances these handicaps can be overcome if the state program is willing to work with these small jurisdictions or if several small jurisdictions can work cooperatively to achieve the requirements.
3. Many jurisdictions are understaffed in relation to their inspectional workload. Many times, managers in these jurisdictions are overwhelmed and do not believe they have time to devote to program improvement, particularly if the improvement involves policy or procedural development.
4. Jurisdictions must find an auditor outside their chain of command to conduct the audit. They are encouraged to exchange audit services with a neighboring jurisdiction, but many jurisdictions report difficulty in finding someone willing, confident enough or informed enough in food safety programs to conduct an audit. Large parts of the audit can be conducted by exchanging documents by mail, but some of the Standards such as Standard 6 involve a process of selecting files at random, and must be conducted on-site.

On-site auditing can pose a problem if the auditor incurs expenses for travel. Jurisdictions have no budget or cannot get approval for expenditures related to auditing their program.

Current Status of Implementation

Currently there are 357 jurisdictions enrolled in the National Voluntary Retail Food Program Standards. Some jurisdictions have not had the audits performed and/or have not repeated the self-assessment at the required intervals. Small amounts of funding in the last two years in support of the Standards has improved adherence to the process of self-assessment and audit.

Oversight

There is no qualification for auditors and no mechanism to remove participants who do not have audits performed within the specified time frames or who do not repeat the self-assessment at the required interval. Participants are asked to request removal of their information if they do not meet the self-assessment and audit time frames, but currently several of the jurisdictional listings are out of date.

Description of Standards

This is a collection of nine program standards that address the critical functions that make up a retail food regulatory program. The nine areas are:

1. **The Regulatory Foundations** (laws and regulations that govern restaurants and food stores): The regulatory foundation used as the measurement for achievement of Standard 1 is the *FDA Model Food Code*. The regulatory jurisdiction's regulations must be at least as stringent as the *Model Food Code* on identified provisions.

Not all regulatory language is required to be in the food regulation as long as it can be found in administrative rules or other legally binding documents. A comparison of the jurisdiction's rules and regulations against the *FDA Model Food Code* is required to demonstrate equivalency.

2. **Trained Regulatory Staff:** Training is required by staff members to effectively understand the regulations and inspect the industry competently. The Standard 2 identifies knowledge areas where staff members must document training received. FDA's Division of Human Resource Development provides face-to-face and online course training which identify critical elements for regulatory inspections. Similar training outside of FDA is acceptable if the training is deemed equivalent and objectives identified in the FDA courses are met.

New staff members to the retail food program must complete courses identified as prerequisites before conducting any independent routine inspections. These courses total 42 hours of on-line courses in the areas of:

- Prevailing statutes, Regulations, Ordinances
- Public Health Principles
- Food Microbiology; and
- Communication Skills

Following the required joint and independent field work, an additional 26 hours of course work is required in the areas of:

- Advanced Food Microbiology
- Basic HACCP series
- Epidemiology
- Emergency Management; and
- Allergen Management

Staff members must also pass a field competency exercise called “Standardization” every three years and accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training.

3. **Inspection Program Based on Hazard Analysis Critical Control Point Principles** (functional aspects of an inspection program such as inspection policies, inspection frequency, inspection procedures, etc.): A jurisdiction participating in the Retail Standards is required to have an inspection program, documented in writing that focuses on the status of risk factors, determines and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors.

An inspection form is required that records whether key inspection items are either ‘in compliance,’ ‘out of compliance,’ ‘not observed’ during the inspection, or ‘not applicable’ to the operation being inspected. Establishments must be categorized into at least three risk categories that determine inspectional frequency. Policies must be established for on-site and long-term corrective actions for certain types of violations and for follow-up activities. Policies and procedures must be in place for addressing variance requests and for verification and validation of Hazard Analysis Critical Control Point plans when such plans are required by the regulations.

4. **Uniform Inspection Program** (quality assurance for staff performance): Standard 4 identifies ten areas of performance that the staff as a whole must achieve. These ten areas are listed in the Standard. The quality assurance program must be on-going and identify actions that will be taken when areas of low staff performance are noted. The quality program is for staff and program performance as a whole and does not address individual competency, which is addressed in Standard 2 as a part of the training and field competency requirements.

This Standard does not describe how the program is to be achieved. An objective statistical measure of the overall staff performance using individual performance scores on two field inspections with a supervisor or designated QA person during a three-year period is used to determine whether the Standard is achieved and the program is effective.

The staff, overall, must score at least a 75% rating on each of the ten measured aspects using a provided procedure.

5. **Foodborne Illness and Food Defense Preparedness and Response** (investigative, reporting, and support procedures for investigating foodborne outbreaks and incidents): Standard 5 requires policy and procedures for recording and investigating foodborne illness complaints, including follow-up for disposition of complaints within 24 hours. Additional areas that must be addressed include: agreements with cooperating agencies/departments, reporting procedures, laboratory support documentation, trace-back procedures, recalls, media management, and data review to identify important trends or clues that could help prevent future foodborne illness outbreaks.
6. **Compliance and Enforcement** (procedures and policies for obtaining compliance with the regulations): Standard 6 requires that the jurisdiction have written step-by-step procedures that describe how compliance and enforcement tools are to be used to achieve compliance and the inspection tool documenting IN, OUT, N/O, and N/A on certain inspection items so that accurate tracking of compliance can be accomplished. The Standard does not dictate adherence to specific policies or procedures, but supplies an objective statistical means of measuring the compliance program's effectiveness.

Documentation on the establishment inspection report form or in the establishment file using the statistical method for file selection in the Supplement to Standard 6 requires at least 80 percent of the sampled establishments meet the following conditions:

- The inspection and enforcement staff takes compliance and enforcement action according to the established procedure (i.e. the staff follow the step-by-step compliance and enforcement procedures when violations occur), and
 - Resolution was successfully achieved for all out-of-control risk factors or interventions that were recorded on the selected routine inspection.
7. **Industry and Community Relations** (efforts to communicate with consumers and the regulated industry): Standard 7 requires agency participation with consumer and industry representatives annually in meetings that provide information on food safety, strategies and interventions to control risk factors, jurisdictional programs, etc. and must have educational outreach to the community.

The jurisdiction must document through minutes, agenda and/or other records participation in at least one activity in each of the below categories annually to meet this standard.

- **Industry and Consumer Interaction** – The jurisdiction sponsors or actively participates in meetings such as food safety task forces, advisory boards or advisory committees. These forums shall present information on food safety, food safety strategies and interventions to control risk factors. Offers of participation must be extended to industry and consumer representatives.

- **Educational Outreach** – Outreach encompasses industry and consumer groups as well as media and elected officials. Outreach efforts may include industry recognition programs, web sites, newsletters, FightBAC™ campaigns, food safety month activities, food worker training, school-based activities, customer surveys or other activities that increase awareness of the risk factors and control methods to prevent foodborne illness. Outreach activities may also include posting inspection information on a web site or in the press.
8. **Program Support and Resources** (a self survey of available resources and criteria for personnel to workload ratios): Standard 8 requires a staffing level of at least one full-time-equivalent employee for every 280 to 320 inspections performed. Inspections for purposes of the calculation include all direct contact time with the establishments such as routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up, risk assessment reviews, process and variance reviews and on-site training. Minimum inspectional equipment and adequate records systems must be documented along with completion of an appendix document designed to assess support needs of the program.
 9. **Program Assessment:** This Standard contains a metric for measuring program effectiveness and provides administrative details regarding how to participate in the Standards. Standard 9 requires that the jurisdiction complete a survey in its facilities on the frequency of occurrence of the risk factors that contribute to foodborne illness. The risk factors are identified and a database program and instructions are provided for conducting the survey, which must be repeated every 5 years. The surveys provide information on the effectiveness of the overall program and allow the effectiveness of initiatives to be measured based on a reduction in the occurrence of the risk factors. Further, this Standard contains the requirements and frequency for self-assessment, auditing, and reporting of results for listing on the FDA website as a jurisdiction participating in the Program Standards.

Appendix D

Partnership for Food Protection, National Standards Work Group

Standards that Apply to the National Grade A Milk Program

Characterization and Overview

Characterization of the Standards

The Pasteurized Milk Ordinance (PMO) is the basic standard used in the voluntary Cooperative State-USPHS/FDA Program for the Certification of Interstate Milk Shippers. The PMO is the ordinance used to regulate the production, transportation, processing, handling, sampling, examination, labeling, and sale of Grade “A” milk and milk products; the inspection of dairy farms, milk plants, receiving stations, transfer stations, milk plant truck cleaning facilities, milk tank trucks and bulk milk hauler/samplers; the issuing and revocation of permits to milk producers, bulk milk hauler samplers, milk tank trucks, milk tank transportation companies, milk plants receiving stations, transfer stations, milk plant truck cleaning facilities, haulers, and distributors; and the fixing of penalties.

Date Established: The First Ordinance: 1924

Date Updated: Updates published every two years. Last updates 2011.

Industry Sector Regulated-Description and Size

The Grade “A” Milk Industry includes milk producers and milk processors, milk distributors, bulk milk hauler/sampler, milk transportation companies, receiving stations, transfer stations, milk tank truck cleaning facilities, and Single Service Container Manufacturers servicing the Grade “A” milk industry.

Characterization and Size of Regulatory Community

The NCIMS delegate body is composed of representatives from each state and U. S. territory that chooses to send such a representative. In some cases, a state has a split vote, i.e., they might have two representatives, one who is responsible for milk sanitation rating, and one who is responsible for enforcement of Grade “A” milk sanitation laws.

Presently, all 50 states and Puerto Rico participate in the conference.

Process to Develop and Maintain

The PMO is developed with the assistance of Milk Regulatory and Rating Agencies at every level of Federal, State, and Local Government, including State Health and Agriculture Departments; all segments of the dairy industry, including producers, milk plant operators, equipment manufacturers, and associations; academia and individual sanitarians.

Changes to the PMO are made by deliberating proposals submitted by state regulatory agencies, FDA, USDA, producers, processors, consumers, etc., who have an interest in ensuring that the

dairy products we consume are safe. The proposals are assigned to one of three councils, who then discuss the merits of each proposal assigned to that council, with a resulting recommendation to the delegate body. Final votes on Proposals are made by the General Assembly, which is comprised of state regulators. If FDA concurs with NCIMS action then the proposals are incorporated into the PMO.

Mechanism for Assessing Implementation

IMS standards are designed with a system for continued improvement in mind, as described in “Process to Develop and Maintain” above. Under the IMS Program, state milk programs maintain ongoing activities of industry surveillance including, inspections, certifications, licensing, sample analyses, and coordination among program elements. As a result of this process, industry compliance with IMS requirements is maintained at a consistent level. Where problems are encountered a mechanism for rapid correction is available. FDA maintains a routine program of surveillance for the ongoing evaluation of state program compliance with the NCIMS. The result of these activities is a consistent and uniform level of Grade “A” Milk safety throughout the nation.

Current Status of Implementation

The program is fully implemented in all 50 states and Puerto Rico.

Oversight

Oversight resides with the NCIMS Conference, FDA, and the State Rating Agency that oversees the Grade “A” Milk Program.

Responsibilities are outlined in *Procedures Governing The Cooperative State-Public Health Service/Food And Drug Administration Program Of The National Conference On Interstate Milk Shipments*, Section IV. Oversight and Responsibilities

Section VII. Procedures Governing A State’s Participation In The Cooperative Program For Certification Of IMS Listed Shippers.

STATE PROGRAM EVALUATIONS

- PHS/FDA shall evaluate the inspection, supervisory, and rating work of Regulatory and Rating Agencies triennially to determine whether milk regulations are being interpreted and enforced in accordance with the provisions of the *Grade “A” PMO*.
- Any State in substantial non-compliance as determined by PHS/FDA will be referred to the NCIMS Executive Board for determination of listing on a separate page in the *IMS List*. The State upon notification of PHS/FDA and the NCIMS Executive Board will have an opportunity to address the NCIMS Executive Board to explain why they believe they should not be so listed. If such listing is required, annual evaluations shall be conducted until substantial compliance as determined by PHS/FDA is achieved. Any

State not in substantial compliance a second consecutive year will be notified by PHS/FDA and provided an opportunity for a hearing by the NCIMS Executive Board. The NCIMS Executive Board, as a result of the hearing, may determine that the State should not be an active participant in future NCIMS Conferences until substantial compliance is achieved.

Description of Standards

The Interstate Milk Shippers Program utilizes the Grade “A” Pasteurized Milk Ordinance (PMO), *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures)*, *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*, and the *Evaluation of Milk Laboratories (EML)* for the sanitary standards, requirements and procedures it follows to ensure the safety of Grade “A” Milk and Milk Products.

The oversight and responsibilities of the Milk Regulatory and Rating Agencies at every level of Federal, State, and Local Government: all segments of the dairy industry, including producers, milk plant operators, equipment manufactures, and laboratories can be found in the Grade “A” PMO and accompanying documents.

1. **Regulatory Foundation:** The Regulatory Foundation (laws and regulations that govern the National Conference on Interstate Milk Shippers Program (NCIMS)) are the Model Grade “A” Pasteurized Milk Ordinance (PMO), *Procedures Governing The Cooperative State-Public Health Service/Food And Drug Administration Program Of The National Conference On Interstate Milk Shipments (Procedures)*, *Methods of Making Sanitation Ratings of Milk Shippers (MMSR)*, and *Evaluation of Milk Laboratories (EML)*.

States must adopt the PMO and the NCIMS related documents or have equivalent regulations in place for not more than six (6) years prior to the most recent Conference to be determined to be in compliance with the Minimum State Program Evaluation Requirements Criteria.

2. **Training and Education:** The training and certification requirements for Federal, State, and industry personnel having responsibility for the regulation of the Grade “A” Milk Industry are in incorporated into the PMO and accompanying documents. The training and certification requirements assure that the milk regulations are being interpreted and enforced in accordance with the provisions of the Grade “A” PMO and have resulted in greater uniformity.
 - PHS/FDA provides assistance in the training of representatives of State, Regional and Local Governmental Units, including FDA certified State Rating Officers (SRO), Laboratory Evaluation Officers (LEO), Sampling Surveillance Officers (SSO), regulatory personnel and dairy industry personnel. Training includes but is not limited to FDA regional seminars, continuing certification of SROs, LEOs and SSOs, courses and one-on-one training.

- Qualifications for initial certifications (joint inspections with a FDA CFSAN standardized Regional Milk Specialist (RMS) of a minimum of five (5) milk plants, twenty-five (25) dairy farms, one (1) single service manufacturing facility, HTST equipment testing and completion of the required paperwork for the mock exercises, and recertification (joint inspections with a FDA CFSAN standardized Regional Milk Specialist (RMS) of a minimum three (3) milk plants, ten (10) dairy farms, and one (1) single service manufacturing facility) for SRO's, (initial standardization and approval by PHS/FDA as a LEO and recertification per the requirements and criteria listed in the most recent edition of the *EML*) for LEO's, and (joint inspections with a FDA CFSAN standardized Regional Milk Specialist (RMS) of a minimum of five (5) milk haulers, one (1) plant sampler, one (1) industry plant sampler) for SSO's as outlined in Section V. of the *Procedures* Document. FDA certifications are valid for three (3) years.
 - Industry personnel responsible for fulfilling PMO program requirements in an official capacity are also subject to training, evaluation, and permitting. The training and evaluation procedures for Certified Industry Inspectors are outlined in Section 5 of the PMO and Bulk Milk Sampler/Haulers and Industry Plant Samplers are outlined in the PMO, Appendix B. Training and Evaluation procedures for Industry personnel that collect and analyze official samples for regulatory compliance with the PMO in IMS listed laboratories and personnel responsible for the screening/confirmation of Beta lactam drug residues are outlined in the EML and Appendix N of the PMO.
 - FDA sponsors regional milk seminars biennially for the state milk regulatory, milk rating and milk laboratory personnel. Dairy Industry is permitted to attend appropriate sessions.
3. **Inspection Program:** The State Program is based on the PMO or Equivalent, which specifically states a permit is required. The functional aspects of the inspection program such as inspection policies, inspection frequency, and inspection procedures, can be found in the PMO.

The PMO is very prescriptive in addressing compliance with the critical control point for the legal pasteurization of milk and milk products. It outlines the proper design, operation and maintenance of legal pasteurization systems that are allowed. The PMO also addresses critical processing elements and the immediate required action to be taken by the Regulatory Agency when such violations are found.

The PMO requires that should any violation of the PMO be found to exist on an inspection/HACCP audit, a second inspection/HACCP audit shall be required after the time deemed necessary to remedy the violation, but not before three (3) days. If any violation of the same requirement of the PMO exists on the follow-up inspection/HACCP audit, the PMO calls for the permit to be suspended.

The rating method is spelled out in the PMO, MMSR and Procedures documents.

Recalls: All aseptically processed and packaged products from the lot that were found to contain one (1) or more non-sterile units shall be recalled and disposed of as directed by

the Regulatory Agency. If Regulatory tests reveal that the HTST equipment or controls are not in compliance with the provisions of the PMO, all the milk and milk products that were processed during that period of time shall be recalled; HACCP System in total, address public health concerns such as those identified in 21 CFR Part 7, Recalls.

Consumer complaints are a part of the overall State Milk Regulatory Program and follow individual State laws and rules. The PMO also addresses consumer complaints in the HACCP section. A procedure to address complaints received from receiving states is addressed in the *Procedures*.

4. **Inspection Uniformity:** The objective of State Ratings and Check Ratings are to provide an assessment of State and Local sanitation activities regarding public health protection and milk quality control. Rating results are used for the purpose of evaluating the sanitation compliance and enforcement requirements of shippers to determine the degree of compliance with public health standards as expressed in the Grade “A” PMO. Rating results are further utilized as a means of uniform education and interpretation, in addition to providing a basis for the acceptance/rejection of shippers by Regulatory Officials beyond the limits of routine inspection. The rating method for evaluating the sanitary quality of milk measures the extent to which a shipper complies with the standards contained in the Grade “A” PMO. These nationally recognized standards are used as a yardstick in order that ratings of individual Bulk Tank Units (BTU’s) or attached shippers and milk plants may be comparable to each other, both interstate and intrastate. Ratings are expressed in terms of percentage compliance. Procedures for collection of data, computation of Sanitation Compliance Ratings for raw milk for pasteurization and pasteurized milk, and computation of the Enforcement Rating of the Regulatory Agency, responsible for administering milk sanitation regulations, are described in the *Methods of Making Sanitation Ratings of Milk Shippers*.

The NCIMS Program is a three (3) tier program.

- First Tier: Inspections conducted by a State Regulatory Agency Inspector, a minimum of every three (3) months for milk plants and every six (6) months for dairy farms. Responsible for the day to day oversight (inspections, sampling, etc.) of the dairy industry.
- Second Tier: State Ratings conducted a minimum of every twenty-four (24) months by a Certified State Rating Officer (SRO), an employee of the State Regulatory Agency responsible for the oversight of the Grade “A” Milk Program. State Ratings provide an assessment of State and Local sanitation activities regarding public health protection and milk quality control. This is accomplished by evaluating sanitation compliance and enforcement standards of the current edition of the Grade “A” PMO and Related Documents as listed in the *Procedures* Document.
- Third Tier: Check Ratings conducted by a Regional Milk Specialist, an employee of the Food and Drug Administration and are scheduled every three (3) years for milk plants and every four (4) years for dairy farm groups. Check Ratings provide an assessment of State and Local sanitation activities regarding public health protection and milk quality control. This is accomplished by evaluating sanitation compliance

and enforcement standards of the current edition of the Grade “A” PMO and Related Documents as listed in the Procedures.

5. **Foodborne Illness and Food Defense Preparedness and Response:** This is primarily the responsibility of the state. Investigations of complaints and foodborne illness are often conducted with the assistance of the Regional Milk Specialist.
- ALERT training is conducted at seminars, state meetings, and as part of check ratings.
 - RMS coordinates Roles and Responsibilities with the State and Industry
 - Provide Laboratory Assistance
 - Additionally, the PMO addresses Foodborne Illness and Food Defense Preparedness in the following areas:
 - Section 8. Animal Health
 - Section 13. Personnel Health
 - Section 14. Procedure When Infection or High Risk of Infection Is Discovered
 - Appendix A. Animal Disease Control

6. **Compliance and Enforcement Program:** Compliance and Enforcement actions are dictated by the appropriate sections within the PMO, Procedures and MMSR.

Enforcement actions (activities) are evaluated during State Ratings and Check Ratings. The Enforcement evaluation calculated by a FDA Regional Milk Specialist during a Federal Check Rating provides a means of measuring the degree to which the enforcement provisions of the Grade “A” PMO are being applied by the Regulatory Agency.

Individual Check Ratings and the triennial State Program Evaluation (SPE) utilizes the results of Check Ratings from farms and plants to determine if Compliance and Enforcement Actions were appropriate and in accordance with the PMO.

Minimum State Program Evaluation Requirements and Criteria address enforcement activities that are required to be met to be determined to be in compliance with the Grade “A” Milk Safety Program. State Program Evaluations are required every three (3) years.

7. **Industry and Community Relations:** This standard describes the outreach activities developed and accomplished by the state programs.
- Participation in the NCIMS by Milk Regulatory and Rating Agencies at every level of Federal, State, and Local Government, including both Health and Agriculture Departments; all segments of the dairy industry, including producers, milk plant operators, equipment manufacturers, and associations; many educational and research institutions; and individual sanitarians.
 - Training at the State, Regional and Local Level with National and Regional seminars addressing the PMO, Procedures, Methods, and EML. Required biennially.

- Industry and Academia are an integral part of the NCIMS. Industry and Academia along with FDA and State regulators sit on NCIMS committees and hold council positions at the Conference.
 - State and Local Dairy Associations/Meetings
 - Food Defense Task Forces
 - Rapid Response Teams
8. **Program Resources:** Determining staffing, equipment and funding requirements for the program is the responsibility of the state. Limited Regional FDA/State partnership funds and funding from DHRD are used to assist the states in equipment and training funding. The Program is fully implemented in all 50 states and Puerto Rico.
- The Grade “A” programs are beginning to feel the impact of budgetary constraints. This is evident by the inability to fill vacancies, elimination of positions, and restrictions on travel.
9. **Program Assessment:** State Program Evaluations (SPE) are conducted triennially. Regional Milk Specialists evaluate the staffing, supervisory, inspection, sampling and analysis, enforcement, compliance with the PMO and related NCIMS documents, and rating work of Regulatory and Rating Agencies to determine whether milk regulations are being interpreted and enforced in accordance with the provisions of the PMO. Minimum State Program Evaluation Requirements and Criteria have been established. A Strategic Action Plan is developed jointly by the FDA Region and the State to address all program areas that do not meet the minimum identified levels. A State Program Resolution Process has been established.
10. **Laboratory Support:** The certification and evaluation of all milk laboratories and milk laboratory analysts are conducted in accordance with the *Evaluation of Milk Laboratories* document (EML).
- The EML provides the standards, procedures, and requirements of State and industry milk laboratories to be IMS Listed and to perform official regulatory milk sample testing and reporting under the Grade “A” Program.
 - Official regulatory sample analysis is required to be conducted in IMS Listed Laboratories utilizing NCIMS approved methods.
 - All States and Puerto Rico have access to State and industry laboratories that are IMS listed.
 - IMS laboratories are evaluated and accredited by FDA certified LEO’s every three (3) years and if they are in compliance with the EML they are IMS Listed.
 - IMS Listed State central milk laboratories are evaluated and accredited by FDA LPET every three (3) years and if they are in compliance with the EML they are IMS Listed.
 - All IMS Listed laboratories require the successful completion of annual proficiency sample testing (examination of split samples).
 - The IMS List provides a list of accredited State and industry laboratories, including the test methods they are approved to perform.