FDA Initiatives in Food Safety and Nutrition

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FSMA: The Goal

- Why FSMA?
  - Too many preventable food related illnesses and deaths
- Role of FDA Policy Makers
  - Establish prevention-oriented standards from farm through distribution of food to retail, based on sound science and risk
- Role FDA/State Food Safety Regulatory Staff
  - Gain industry compliance with new standards
  - Well trained, knowledgeable inspectorate to perform inspections in a uniform manner, consistent decision-making

Elements

- Compliance / Enforcement: consistency, facilitation of compliance, risk-based
- Stakeholder engagement: public health metrics, dialogue in forming standards
- Industry education and guidance, outreach, and technical assistance

Enforcement Discretion

- FDA issued several guidance documents granting enforcement discretion for some FSMA rule requirements. Examples:
  - Facilities that would be farms except for certain factors
  - Written assurance requirements in the FSVP, PC Human, PC Animal, and Produce rules
  - Animal PC requirements for certain human by-products use as animal food
  - FSVP requirements for importers of food contact substances
  - FSVP requirements for importers of grain Raw Agricultural Commodities
  - Certain supply chain requirements for co-manufacturers
  - FSVP requirements for importers of live animals that must be slaughtered and processed at establishments regulated by USDA and subject to HACCP requirements

Guiding Phase 2 FSMA Implementation: Program Alignment

- Objectives:
  - Vertically integrated, commodity-based programs
  - Specialization of inspection/compliance staff, regulatory labs
  - Clear, current, consistently applied policy
  - Roles, responsibilities, streamlined decision-making
  - Risk-based allocation of program resources
  - Agreed-upon performance/public health metrics
- Linked to Successful FSMA Implementation

PCHF Inspections

- Field assignments
  - Limited scope (modernized GMP) PC
  - Full scope PC
- FY 17 accomplishments:
  - Limited scope (modernized GMP) PC at large facilities: 720 inspections
  - Full scope PC: 165
- FY 18
  - Limited scope (modernized GMP) PC at large and small facilities
  - Full scope PC inspections: 500 (400 domestic, 100 foreign)
    - 4 States are doing full scope PC inspections
- FY 19
  - Limited scope (modernized GMP) PC at large, small and very small facilities
  - Full scope PC inspections (500 domestic, 150 foreign, 207 state)
  - GMP inspections at firms except from subparts C & G
  - Inspections at warehouses/firms subject to modified requirements in subpart D
  - Qualified Facility inspections at firms that self-attest

On-Farm Rule Readiness

- FDA is working with National Association of State Departments of Agriculture (NASDA) to implement a voluntary on-farm Produce Safety Rule Readiness Program
- Objectives
  - State of knowledge and readiness of farming community to comply with the Produce Safety rule; promote compliance
  - Promote coordination, strengthen relationships between industry, FDA, States, other produce safety partners
  - Provide on-farm learning experience for FDA and State regulators
  - Identify knowledge and guidance gaps - regional, national, commodity
- Assessment Tool made available online

Produce Safety Rule Inspections

- Collaborating with NASDA to develop a single inspectional approach that can be implemented by State regulators and FDA
  - Routine on-farm inspections will be conducted by State regulators, as funding permits
  - FDA (Produce Safety Network) may do inspections in States that choose not to conduct produce inspections
  - FDA Produce Safety Network would conduct foreign inspections

Produce Safety Rule Inspections

- Objectives
  - Facilitate compliance through standardized, education-focused regulatory inspections using farm inspection reports that include guidance and educational references
    - *Educate before and while we regulate*
  - Collect and evaluate inspection data to identify regional trends for targeted outreach, education, research, and work plan prioritization
  - Develop relationships among produce farmers, local FDA Produce Safety Network staff and regulatory partners
  - Initiate legal action as needed to protect public health

FSMA: Implications for Imports

- New system of food safety oversight for the 21st Century
- Transformational shift from response to prevention
- Parity between domestic and imported foods
- Provides additional tools to hold industry accountable for producing safe food
- Enhanced partnerships

Paradigm Shift for Imports

- Traditionally, the border had been our primary line of defense against unsafe imported products
- FSMA creates a multilayered safety net
  - Role of manufacturer
  - Role of importers
  - Role of third parties
  - Role of foreign regulatory bodies
  - Role of FDA

FSVP Line Entries

FSVP Implementation Stats (As of 3/24/18):

- About 9.0 M total food lines since 1st FSVP compliance date
  - 7.8 FSV lines
    - 6.7 M provided DUNS number
    - 1.1 M used UNK (i.e., no DUNS number)
      - About 14% of FSV lines)
  - 2.1 M FSX (exempt)

FSVP Inspections

- FY17: 285 FSVP inspections completed
  - No warning letters issued
  - 0 OAI
  - 179 VAI (with 174 483a forms issued)
  - 106 NAI
- FY18: Significant increase over FY17; 144 completed (as of 4/20/18)
  - 91 VAI (with 483a forms issued)
  - 53 NAI

Key Points for Foreign Suppliers

- FSVP is the cornerstone of FSMA's new preventive, risk-based approach to imports.
- Responsibility for compliance lies with U.S- based FSVP importers.
- FDA will oversee compliance through inspection of U.S- based FSVP importers.
  - NOT enforced on a shipment-by-shipment basis at ports of entry
  - Only change at entry is new data to identify FSVP importer
- Foreign suppliers can help FSVP importers comply.
  - Know your FSVP importer
  - Increase communication
  - Supply food safety information if requested by FSVP importer

Status of VQIP in 2018

- Delay in having certification bodies in FDA's Accredited Third Party Certification Program in FY2018. Therefore:
  - FDA did not receive or process any VQIP applications in FY2018
  - FDA collected no VQIP user fees in FY2018
  - FDA will not provide any VQIP benefits in FY2019
- Interested importers should have begun to prepare for the next application period.

Inspection of Food Transportation Vehicles

- SFTA places responsibility for inspection of food transportation vehicles on the U.S. Department of Transportation; FDA has no plans for conducting vehicle inspections in route
- Federal Motor Carrier Safety Administration (FMCSA)
  - oversees vehicle safety inspections
  - provides funding for state agencies and law enforcement to conduct routine vehicle inspections
  - establishes procedures for documenting observations of suspected unsanitary transport of food and reporting those to FDA and USDA
  - produced education video and brochure on role of vehicle inspectors in safe food transportation; updates being considered to reflect ST Rule

Waivers

- SFTA granted FDA authority to waive any requirement for categories of persons, vehicles or food, if the waiver will not:
  - result in conditions that would render food unsafe for human or animal health; and
  - be contrary to the public interest
- Public may petition FDA for waivers
- In April 2017, FDA published waivers for three industry sectors on the basis that existing programs provide adequate protection: Grade A Milk, Molluscan Shellfish, and Foodservice/Retail Food Establishments

IA Rule Background

- Requirements
  - Food defense plan
    - Vulnerability assessment
    - Mitigation strategies
    - Procedures for food defense monitoring
    - Food defense corrective action procedures
    - Food defense verification procedures
    - Reanalysis
  - Training
  - Records

Guidance Overview

- Issued in 3 rounds to assist with implementation
  - 10 chapters, 4 appendices published in 3 rounds (Round 1 published 06/2018)
  - Rounds 1 - 2 are intricately connected, with sections of the Vulnerability Assessment (VA) chapter published in both rounds
  - Round 2 is incorporated into one document with Round 1, issued as Revised Draft 03/2019

Stakeholder Dialogue

- Substantial dialogue with stakeholders since rule publication
- Main themes of dialogue:
  - Flexibility in implementing rule
  - Cost effective ways to comply
  - Ways to reduce paperwork

Key Points of Guidance

- Guidance incorporated themes when appropriate
  - Protecting against an inside attacker remains the goal of the IA rule
  - Committed to making implementation for industry as practical and flexible as possible
  - Food safety remains our top priority

For More Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us

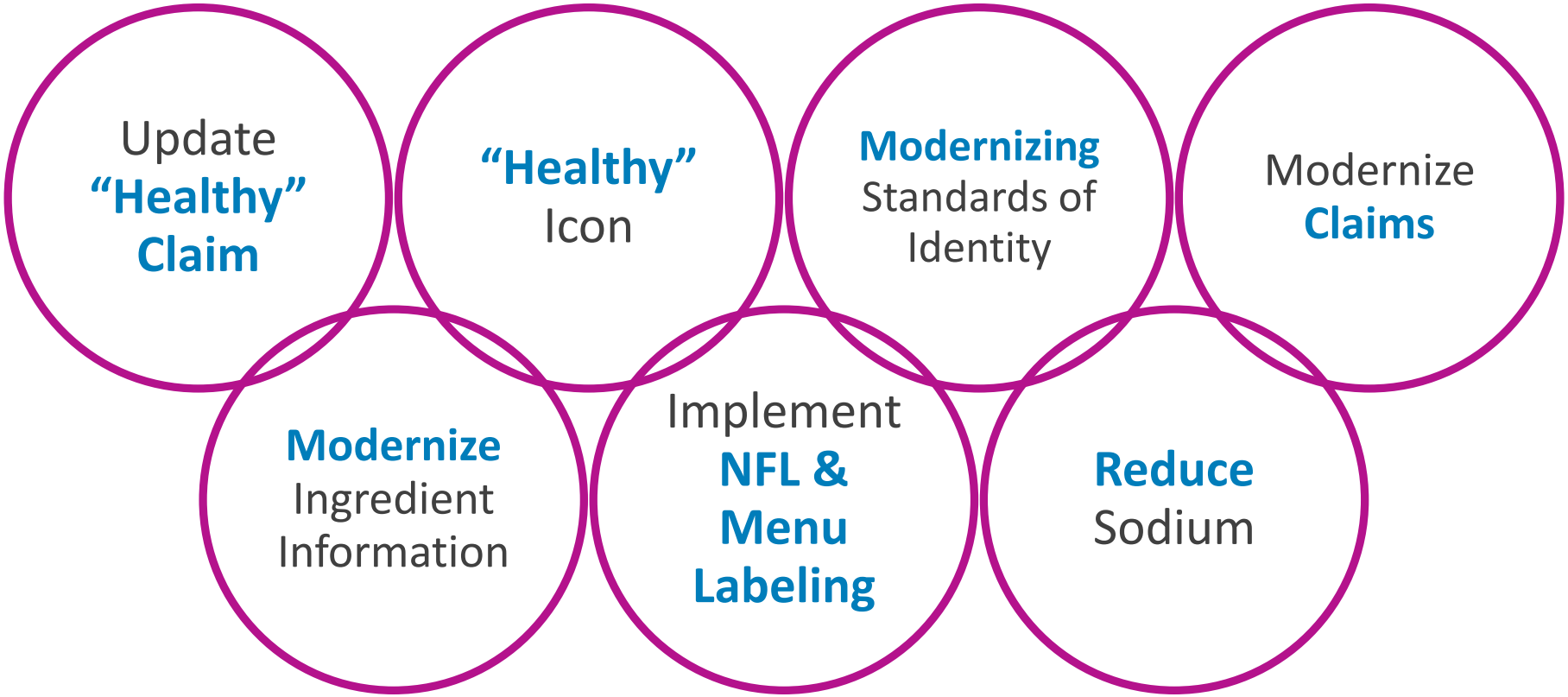
FDA Nutrition Innovation Strategy

Goals:

(1) Empower consumers with information to help them make more informed dietary choices; and

(2) Foster and support innovation already underway in the food industry that will allow industry to compete on the basis of healthful attributes.

Nutrition Innovation Strategy Initiatives



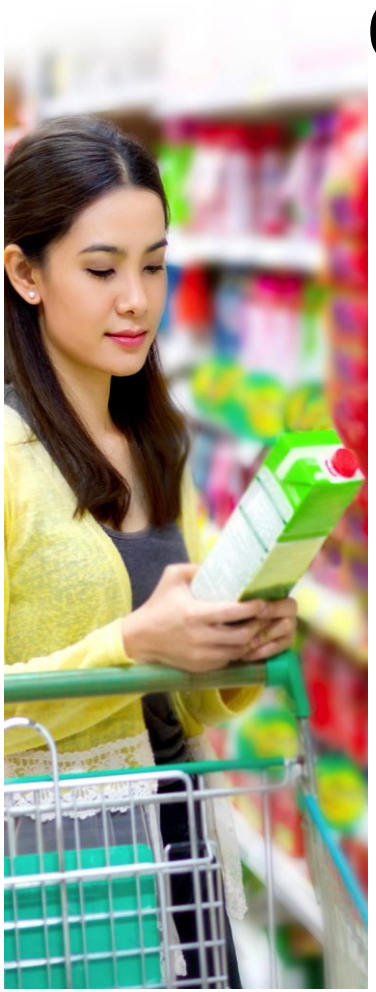
Modernizing Claims and Ingredient Information

- Claims -- quick signals for nutritional benefits
- “Healthy” claim – what is it and how to do it
- Interest in claims where diets fall short of guidelines
- Availability of nutrients
  - Those we need to limit (e.g., added sugars)
  - Those where we need more (e.g., potassium)
- Making ingredient–information more consumer-friendly
  - Readable and understandable
  - Common Usage

Modernizing Standards of Identity

- Standards of identity establish requirements related to the content and production of certain food products.
- Taking a fresh look in light of marketing trends and the latest nutritional science.
- Goals
  - Maintaining basic nature and nutritional integrity
  - Allowing flexibility for innovation to produce more healthful foods

Reducing Sodium - Overview of FDA Approach



- Draft, voluntary guidance on sodium reduction targets
  - Gradual approach
  - Targets for 150 categories of food
  - Applies to food manufacturers, restaurants and food service operations
- Draft targets serve as a basis for continued dialogue

NIS - Next Steps

- Review comments (comment period closed 10/11/18)
- All the initiatives have their own timelines
- The initiatives have different goals and will produce different deliverables such as requests for information, guidance documents, and/or rules based on their goals
- More stakeholder engagement to help inform how best to promote public health in the evolving food and beverage marketplace

Toxic Elements Strategy

- FDA created a workgroup to implement a toxic element strategy in late 2017
  - To identify, target and prioritize efforts
  - To ensures consistency and collaboration across policy decisions
- Overall goal: Reduce exposure to toxic elements to the extent feasible

Initial Steps

- Identifying preliminary priorities:
  - Reducing exposures to arsenic, cadmium, lead, and mercury
  - Focus on children and other susceptible populations
- Finalizing guidance on arsenic in infant rice cereals and apple juice
- Modernizing the Total Diet Study program
- Research on exposures, co-exposures, mitigation

Outbreak Investigations and Recalls

- Enhance and improve outbreak investigation capacity and response
  - CORE and field capacity and turnaround
  - Increase traceability and use of WGS
- Recall guidances
  - Streamlined process
  - Expedited release of recall information
  - Enhanced disclosure of retail distribution

Enhance Oversight of Dietary Supplements

- Respond to Novel Ingredients
- Ensure Product Integrity
- Collaborate with Stakeholders

Focusing on Smarter Food Safety

- Tech-Enabled Response and Traceability
  - Improves diagnosis and prevention
  - Mitigates costs
- Enhancing Risk-Based Analysis
- Emerging Issues
  - Novel Food Technologies
  - Evolving Food Business Models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