NEW YORK STATE OF OPPORTUNITY. | Agriculture and Markets

Preventive Controls/Appendix T Training & Implementation

A State Regulatory Perspective

Heather Torino
Program Manager – Milk Control
Division of Milk Control & Dairy Services

Outline

- FSMA
- PC Rule
- Regulatory Response
- Tools
- Training
- What's Next

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

FSMA

- 7 Rules
  - Accredited Third-Party Certification
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
  - Foreign Supplier Verification Programs
  - Mitigation Strategies to Protect Food Against Intentional Adulteration
  - Sanitary Transportation of Human and Animal Food
  - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

FSMA

- 7 Rules
  - Accredited Third-Party Certification
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
  - Foreign Supplier Verification Programs (FSVP)
  - Sanitary Transportation of Human and Animal Food
  - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

PC Rule Compliance Dates

- September 19, 2016: Large businesses
- September 18, 2017: Small businesses
- September 17, 2018: Very small businesses AND facilities subject to the Pasteurized Milk Ordinance*

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

PMO Now Aligns with FDA's Preventive Controls Rule

Tweet Share

FOR IMMEDIATE RELEASE
Contact: Peggy Armstrong
(202) 220-3508
parmstrong@idfa.org

NCIMS tackles this and other issues at biennial meeting

(W – May 23, 2017) T nce on Interstate Milk Shipments (NCIMS) acted last week to align the Grade "A" Pasteurized Milk Ordinance (PMO) with the regulatory requirements in the preventive controls rule for human food under the Food Safety Modernization Act.

(L-R): John Sheehan, director of the division of dairy, egg and meat safety at the Food and Drug Administration, John Allan, IDFA vice president of regulatory affairs and international standards

The PMO is a set of standards and requirements that regulates all dairy plants producing Grade "A" products, including fluid milk, cream products, yogurt, cottage cheese, eggnog, buttermilk and many dried dairy products. NCIMS, which meets every two years, includes regulators from all 50 states and Puerto Rico and recommends changes and modifications to the PMO for final approval by the Food and Drug Administration.

"The big news from the 2017 NCIMS meeting is that we successfully harmonized the PMO with FDA's "Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food" rule, which covers most FDA-regulated foods," said John Allan, IDFA vice president of regulatory affairs and international standards. "Working together, state regulators, industry stakeholders, FDA officials and experts from academia demonstrated the strength of the NCIMS process to work through difficult issues and come out with a positive solution that advances food safety yet does not overly burden the dairy industry or cash-strapped states."

IDFA has advocated working through the NCIMS process to leverage the success of the PMO in assuring the safety of Grade "A" products while avoiding duplicative or contradictory regulations on the dairy industry. Prior to this meeting, IDFA met with representatives from the National Milk Producers Federation as well as FDA officials to build consensus on a pair of proposals developed to achieve this alignment. At the conference, NCIMS delegates approved these proposals, which will now go to FDA for final approval.

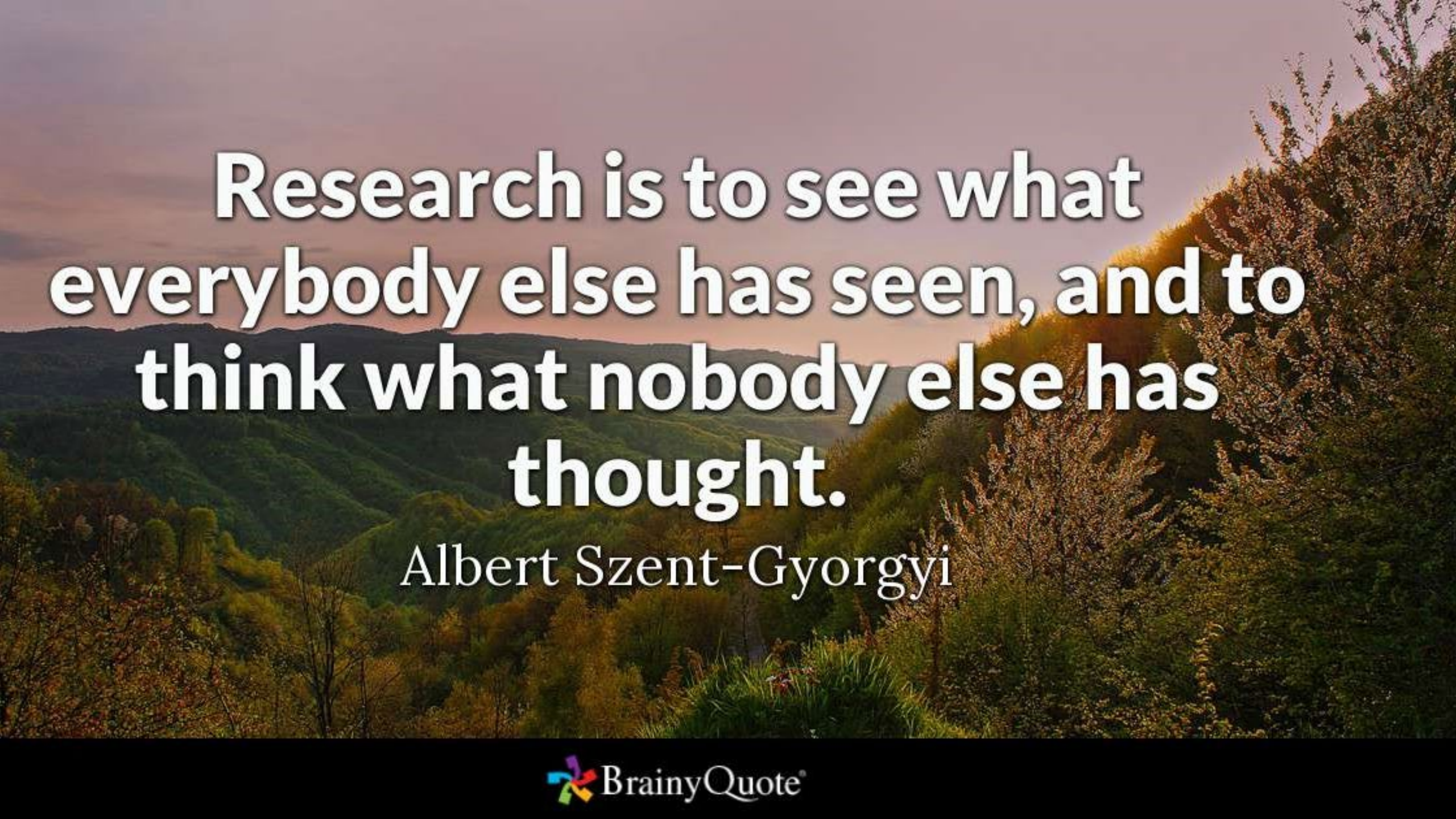
The most significant change to the PMO is the incorporation of many of the regulatory requirements of the preventive controls rule into a new Appendix T. These requirements include having a written hazard analysis plan, detailed descriptions of food safety preventive controls that protect Grade "A" dairy products from potential hazards and appropriate testing programs to demonstrate effectiveness of the controls. FDA regulators will conduct inspections every 36 months to ensure compliance with the new Appendix T requirements. The traditional quarterly inspections by state regulators to verify compliance with the main parts of the PMO will continue with some additional checks such as ensuring proper control of allergen-containing ingredients.

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

OK... so what now?

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets


regulatory
compliance


Research is to see what everybody else has seen, and to think what nobody else has thought.
Albert Szent-Gyorgyi
BrainyQuote

Navigating the PC Rule

- Break it down into subparts
  - General Provisions
  - Current Good Manufacturing Practices
  - Hazard Analysis and Risk-Based Preventive Controls
  - Modified Requirements
  - Withdrawal of a Qualified Facility Exemption
  - Requirements Applying to the Records That Must Be Established and Maintained
  - Supply-Chain Program

Tools

?


Ask
Questions

Frequently Asked Questions on FSMA

The following are questions and answers related to the Food Safety Modernization Act (FSMA).

You may also be interested in these resources:

- Common Technical Assistance Network (TAN) Questions (PDF: 497.3KB)
- Contact TAN for Assistance

Content current as of:
08/09/2019

Regulated Product(s)
Food & Beverages

Law(s) & Regulation(s)
Food Safety Modernization Act

FSMA Technical Assistance Network (TAN)

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Have a FSMA Question?

Start Here

The Technical Assistance Network staff has compiled answers to frequently asked questions on FSMA. You may also use FSMA Guidance Documents to find answers to your questions.

Submit Your Question Electronically

Didn't find your question above? Please submit your question to TAN for assistance

Content current as of:
10/30/2019

Regulated Product(s)
Food & Beverages

Guidance for Industry & Others

Search:

Export Excel

Title	Issued Date
Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Chapter 14: Recall Plan	2019/10
Guidance for Industry: Determining the Number of Employees for Purposes of the "Small Business" Definition in Parts 117 and 507 Docket Number: FDA-2018-D-0671	2019/06
Draft Guidance for Industry: Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Docket Number: FDA-2019-D-2131	2019/06
Guidance for Industry: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds Docket Number: FDA-2019-D-1266	2019/03
Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration Docket Number: FDA-2018-D-1398	2019/03
Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls Docket Number: FDA-2015-D-0138	2018/11


SO WHAT ELSE

Customers: Food Manufacturers☐ Food Service☐ Retail Stores/Direct to Consumer☐ Warehouse-Wholesale☐

1) Is this facility IMS listed? Yes☐ No☐

2) Is this facility registered with FDA under section 415 of the FD&C Act (Bioterrorism Preparedness and Response Act of 2002)? Yes☐ No☐
https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331957.htm

3) Are all individuals who are engaged in manufacturing, processing, packing, or holding food qualified as required in 117.4 (b) and (c) with training records as required in 117.4 (d)? Yes☐ No☐ Link to Part 117: https://www.ecfr.gov/cgi-bin/text-idx?SID=e9ca025764f8adff02bc93a2655d8450&mc=true&node=pt21.2.117&rgn=div5

4) Does facility have current Good Manufacturing Practices (cGMP's) in place as required in Part 117 Subpart B (see link to Part 117 from question 3)? Yes☐ No☐

5) Based upon the firm's internal review of tax forms, accounting documents, invoices, bills of lading, etc., is this facility a qualified facility? ***see FDA links below and supporting documentation.** Yes☐ No☐
Link to the FDA FSMA At-A-Glance document:
https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM461834.pdf

6) If yes, has the appropriate attestation been made? (See Below) Yes☐ No☐

Link to the FDA draft Qualified Facility Attestation site:

https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm496264.htm

7) If the firm is not a Qualified facility, does the firm address Preventive Control Requirements:

a. Does firm have a written Food Safety Plan? Yes☐ No☐

b. Does the Food Safety Plan include:
   i. Hazard Analysis - Yes☐ No☐
   ii. Preventive Controls - Yes☐ No☐
   iii. Supply Chain - Yes☐ No☐
   iv. Monitoring - Yes☐ No☐
   v. Recalls - Yes☐ No☐
   vi. Corrective Action - Yes☐ No☐
   vii. Verification - Yes☐ No☐

c. Has the firm conducted a Hazard Analysis under the PC rule? Yes☐ No☐

d. Firm has identified & implemented the necessary preventive controls:
   i. Process Controls - Yes☐ No☐
   ii. Allergen Controls - Yes☐ No☐
   iii. Sanitation Controls - Yes☐ No☐
   iv. Supply Chain Controls - Yes☐ No☐
   v. Recall Plan - Yes☐ No☐
   vi. Other Controls - Yes☐ No☐

e. Does the firm have an Environmental Monitoring Program? Yes☐ No☐
    i. Number of samples per month: _____

f. Does the firm have a Written Recall Plan? Yes☐ No☐

g. Does the firm have a Preventive Controls Qualified Individual (PCQI)? Yes☐ No☐

h. Firm has Supply-Chain management program in place? Yes☐ No☐

i. Firm has established & maintained records documenting implementation of the Food Safety Plan? Yes☐ No☐

Link to FDA Food Safety Plan Builder:
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm

Comments:-

_____

_____

_____

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Training

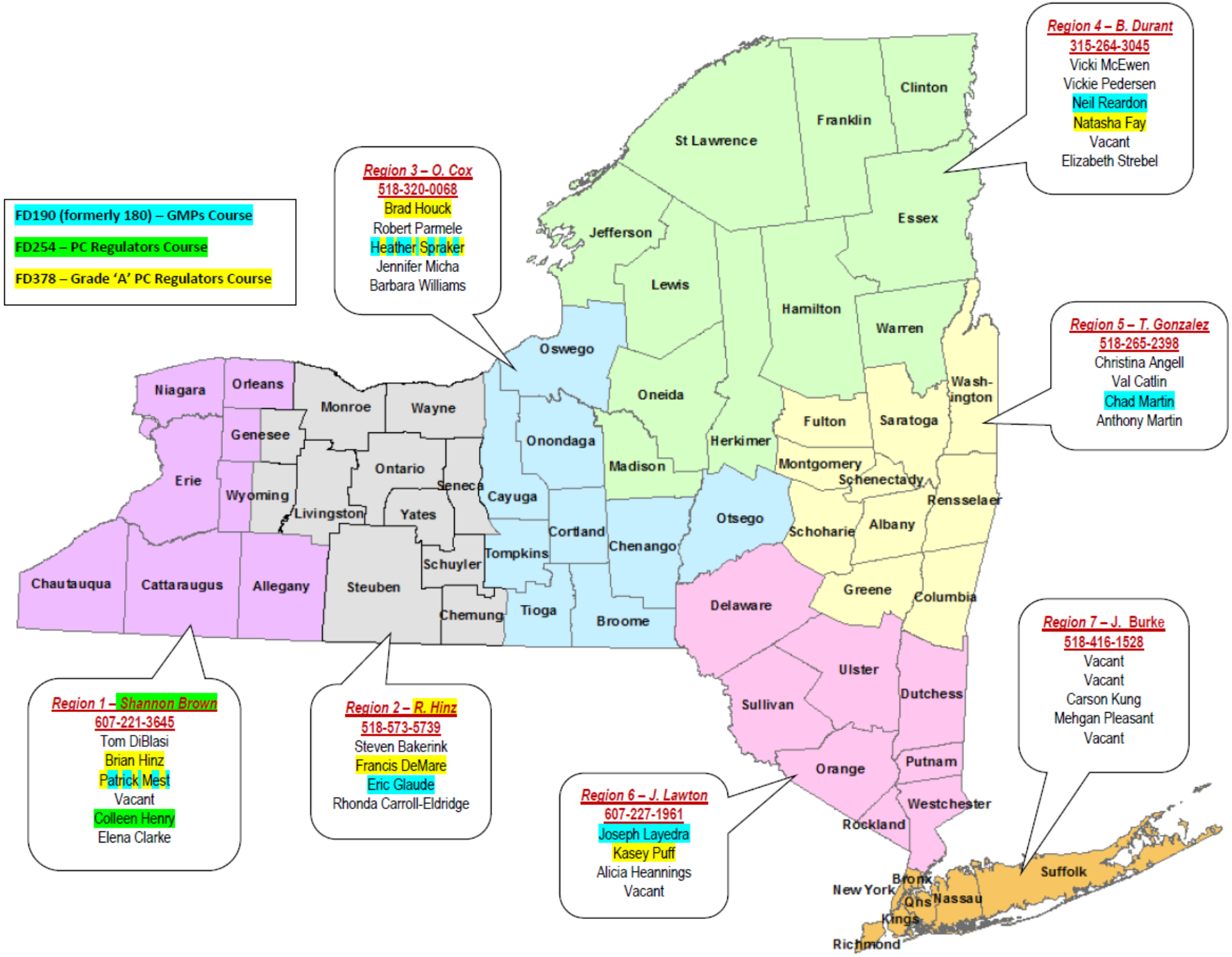
- PCQI
- GMPs
- PC for Regulators
- Grade ‘A’ PC for Regulators

Regions

FD190 (formerly 180) – GMPs Course

FD254 – PC Regulators Course

FD378 – Grade 'A' PC Regulators Course



Agriculture and Markets

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets