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# A MODERNIZED FDA INSPECTORATE, BY MICHAEL ROGERS



Michael Rogers, the Associate Commissioner for Inspections and Investigations, shares his thoughts about the FDA inspectorates, with the Office of Inspections and Investigations (OII) - the gold standard for inspections and investigations!

Michael shares OII background, vision and mission of OII. Read more about OII *on page 4*.

## **FSDX FAQs**

Have a question?
We have the answer!

The Food Safety Data Exchange (FSDX) Frequently Asked Questions (FAQ) document is organized into sections:

- Introduction
- Point of Contact (POC)
- Top FAQs
- FSDX Portal
- FSDX System-to-System (S2S)
- FDA Systems Retirement

Learn more about Overall FSDX, including Inspection, Inventory, and Sample data sharing capabilities in addition to Training!

Learn more at FSDX FAQs!



"No winter lasts forever; no spring skips its turn." - Hal Borland

## FDA Human Foods Program (HFP)







The Human Foods Program (HFP) oversees all FDA activities related to food safety and nutrition, organized in a single group working under the Deputy Commissioner of Human Foods. Their vision is to ensure that food is a source of wellness for all U.S. consumers, and their day-to-day activities are focused at protecting and promoting the health and wellness of all people through science-based approaches to prevent foodborne illness, reduce diet related chronic disease, and ensure chemicals in food are safe. The Office of the Deputy Commissioner for Human Foods supports this work by providing leadership and strategic direction for all FDA-wide HFP activities, including food related inspections and



#### **Risk Prioritization**

The Human Foods Program centralizes their risk management activities into three main areas that run on parallel tracks, each with its own priorities.

• Microbiological Food Safety: The Office of Microbiological Food Safety works to advance strategies to prevent pathogen-related foodborne illness in close collaboration with other regulatory agencies, states, industry, and other stakeholders. Conrad Choiniere, Ph.D., is the director of OMFS.

•Food Chemical Safety: The Office of Food Chemical Safety, Dietary Supplements, and Innovation focuses on food chemical safety and dietary supplement policy and coordinates on regulatory and scientific issues for foods made through innovative technologies. Mark Hartman, MA, MPA, is the director of OFCSDSI.

Nutrition: The Nutrition Center of Excellence elevates and empowers action on nutrition science, policy, and initiatives to help reduce the burden of diet-related chronic diseases, improve health equity, and ensure the nutritional adequacy and safety of infant formula. Robin McKinnon, Ph.D., MPA, has been selected to serve as the acting director of the NCE.

Read more at Human Foods Program (HFP).

"Every spring is the only spring, a perpetual astonishment." — Ellis Peters

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### Oll Podcast: On the Frontlines – Guam Series

Office of Inspections and **Investigations (OII) Podcast Guam 5 Part Series: FDA Presence and Impact** in Pacific Islands, Hosted by Ulysses Garrett & John Zaccone

Associate Commissioner Michael Rogers provides an overview in part 1 of a 5part series explaining the FDA's presence in the Pacific Island Territories.

Listen 🗇

Transcript =

Ryan Aguillon and Cordero Kimbrell provide an on the ground perspective in part 2 of a 5-part series explaining the FDA's presence in the Pacific Island Territories.

Listen (2)

Transcript |

USPHS officers Commander Shannon Aldrich and **Lieutenant Claire Tipton** share firsthand accounts of on-theground efforts focusing on outreach, partnership building, and health fraud literacy efforts in Guam.

<u>Liste</u>n ි

Transcript |

JaCinta Batson, director of NFCC's Satellite Laboratory Branch, discusses the FDA's new screening lab established in Guam as part of a cross-program initiative.



Transcript =

Assistant Commissioner for the Office of Import Operations, Dan Solis, summarizes the agency's efforts and offers a glimpse into what to expect in the future.



Transcript





**Click here** to learn more about OII Podcasts

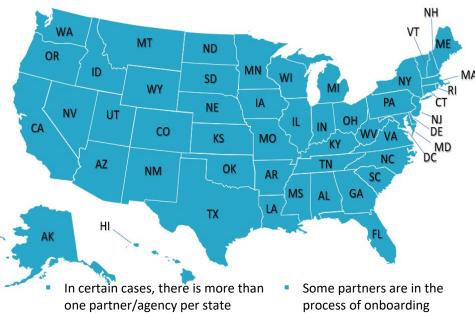
## State Participation in PFP IT WG & FSDX

All 50 States **Participating** in FSDX!

47 States participating in PFP IT WG or Sample WG

Partner agencies participating in FSDX **Portal** 

23 Partner agencies participating in FSDX S2S or FSDX Client



"An optimist is the human personification of spring." - Susan J. Bissonette



## Michael C. Rogers, MS

Associate Commissioner for Inspections and Investigations, Office of Inspections and Investigations (OII) U.S. Food and Drug Administration (FDA)

#### Continued from page 1

The FDA's inspectorates are known as the gold standard around the world and has a long history. It's part of our institutional culture, an insistence on regulatory excellence that each generation of the agency embraces and further adapts to meet current challenges. It's also rooted in our FDA legacy, born over a century ago, and built, in no small part, by FDA's workforce on the front lines, and those that support them.

As FDA's field inspectorate, Office of Inspections and Investigations (OII) is especially attuned to this standard. When our investigators travel around the globe to inspect foreign facilities, they know the work will require extensive technical knowledge, language and cultural adaptations, and other logistical challenges. But the FDA gold standard, recognized worldwide, carries them in their work. It is also true that the work products that OII generates, helps to inform the Agency's decisions.

At OII, we have no shortage of histories to draw on to inspire our great regulatory responsibility. The sulfanilamide elixir crisis, of the 1930s, in which over 100 Americans died, including children, after consuming an elixir prepared with a poisonous solvent (diethylene glycol), readily comes to mind.

## Tell us what you think!

Please share your thoughts about the PFP IT WG newsletter and Coffee Talk articles. If there are any areas of interest you'd like to see featured or if you would like to participate, send your thoughts via an email to PFP-IT-WG-Info@fda.hhs.gov.

**Oll Vision:** Our global inspections and investigations ensure FDA regulated products are safe, trusted, and accessible.

**Oll Mission:** We conduct rigorous, transparent, and science-based inspections and investigations, providing real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health.

I sometimes wonder what investigators of that era, including those who collected remaining supplies of the elixir to stop further harm and death, would think of our inspectorate today. I think our forebears would be proud.

The people of this agency, working on the front lines and engaging face-to-face, provide the undeniably unique human element—educating and motivating industry to always do better. We are all customers of the work we are charged with doing, since we and our families depend on the safety of FDA-regulated products every day.

As we face a new era, the FDA reorganization will help us deliver more effectively on our gold standard. But it will always be about the people, including our current OII teams, mentors, and our FDA family and alumni, who will continue to inspire us and carry forward a prestigious legacy.

To learn more, see FDA Modernization Efforts for Establishing a Unified Human Foods Program, New Model for Field Operations and More.

"Spring is nature's way of saying, 'Let's party!'" – Robin Williams



## **FSDX Frequently Asked Questions (FAQs)**

#### What does FDA regulate?

The scope of FDA's regulatory authority is very broad. FDA's responsibilities are closely related to those of several other government agencies. Often frustrating and confusing for consumers is determining the appropriate regulatory agency to contact. For a full list of traditionally-recognized product categories that fall under FDA's regulatory jurisdiction, learn more at What Does FDA Regulate?

#### Foods, including:

- dietary supplements
- bottled water
- food additives
- infant formulas

 other food products (although the U.S. Department of Agriculture plays a lead role in regulating aspects of some meat, poultry, and egg products)



## Resources and **Useful Information**

PFP-IT-WG-Info@fda.hhs.gov

**PFP Strategic Plan** 

**PFP IT WG Page** 

**PFP Website** 

**Food Safety Data** Exchange (FSDX) Portal

For additional FSDX FAQs read more . . .



Be sure to check out the FSDX Training page to learn more about

e-Learning courses and the Knowledge Articles.

The FSDX Training Team has developed e-Learning courses to add to the list of growing training resources!

#### **Checkout these Knowledge Articles:**

- Sample Collections Errors & Corrections
- Sample Receipt & Analysis **Errors & Corrections**
- Multi-File Submission for Sample Collections
- Multi-File Submission for Sample Receipt and Analysis

#### Freshen Your Skills with e-Learning Courses:

- Non-Contracted Inspections (NCI) Overview
- Non-Contracted Inspections (NCI) Submission
- Non-Contracted Inspections (NCI) Submission Errors, Corrections & Resubmission

"If Winter comes, can Spring be far behind?" - Percy Bysshe Shelley







## Food Safe Shopping & Storage

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Following these tips when buying and storing food can help prevent foodborne illness

DO



DON'T

Keep produce separate from meat, poultry, seafood, and eggs in shopping carts and bags

Choose meat, poultry, or seafood in damaged or leaking packaging

DO



DON'T

Place meat, poultry, seafood, and eggs in plastic bags at checkout

Buy eggs with cracked shells or damaged cartons

DO



DON'T

Keep produce and other ready-to-eat foods in a separate area of the refrigerator from meat, poultry, seafood, and eggs

Remove eggs from carton or keep them in the refrigerator door

DO



DON'T

Refrigerate food within 2 hours of grocery shopping, or 1 hour if kept in air temperatures above 90 °F

Place raw meat, poultry, or seafood on upper shelves of the refrigerator where they can drip onto other foods

DO



DON'T

Set refrigerator temperature to 40 °F or below and freezer at 0 °F or below (as indicated by an appliance thermometer)

Overfill the refrigerator or freezer

DO



DON'T

Defrost food in the refrigerator, in cold water, or in the microwave – and cook immediately

Thaw meat, poultry, or seafood on the counter

Source: FDA - Food Safe Shopping, Storage and Meal Prep

"Can words describe the fragrance of the very breath of spring?" – Neltje Blanchan