



**U.S. FOOD & DRUG  
ADMINISTRATION**

**ORA**

# **National Food Safety Data Exchange (NFSDX)**

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**June 9, 2018**







# ***Agenda***

- 1. Background: Building Upon Prior Data Exchange Success**
- 2. NFSDX and ORAPP Comparison**
- 3. NFSDX**
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  - Participating States and Integrated Systems
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# ***Background: Building Upon Prior Data Exchange Success***

- **Partnership for Food Protection Information Technology Workgroup (PFP IT WG) 2012: Bovine Spongiform Encephalopathy (BSE)**
  - Successful pilot to transfer BSE Inspection data from Pennsylvania Department of Agriculture to FDA
- **PFP IT WG 2016: NFSDX Project**
  - Established standard and vocabulary for data sharing among food regulatory partners
  - Collaborated with PFP IT WG members to document their State's system data to evaluate data fit for pilot
  - Analyzed States' system data elements and mapped to data exchange model
- **PFP IT WG 2017**
  - Delivered the business capabilities to receive Contracted Inspection data from States, States receiving requested Firm Data from FDA, and States requesting Firm Data from another State
  - Established a data exchange for sharing and moving any food safety data across disparate systems and political boundaries
  - Established plan to support future initiatives



# Comparing NFSDX and Office of Regulatory Affairs Partners Portal (ORAPP)

- ✓ System to System interface to electronically exchange info. between FDA and regulatory partners
- ✓ Stores transactional data (who sent, when it was sent, etc.)
- ✓ Currently includes the below Use Cases:
  - State-to-FDA (Contracted Inspections)
  - FDA-to-State (Firm info)
  - State-to-State (Firm info)

- × Not a website
- × Not a document repository
- × Not a data repository



**NFSDX**



**ORAPP**

Collectively, these two capabilities provide framework for eventual replacement of eSAF



- ✓ Integrated collaborative website for FDA and regulatory partners for bi-directional information exchange
- ✓ Interconnected with NFSDX and other FDA systems
- ✓ Interactive functionality and features
- ✓ User account management
- ✓ Role-based access
- ✓ Notifications and alerts
- ✓ Will incrementally expand to adopt ORA/FSMA initiatives and applications
- × Not replacing FoodSHIELD
- × Not a data repository



# ***NFSDX Drivers, Solution, and Benefits***

## **Drivers**

FDA seeks to establish a risk-driven Integrated Food/Feed Safety System.

FSMA mandates FDA to implement comprehensive new programs supporting new regulatory authorities (e.g., preventive controls and produce safety).

FDA, States, and local health departments have no automated way to share data among their disparate systems to support the new mandates.



## **Solution**

Increase sharing of accurate, timely, complete, and relevant food safety data to fulfill FDA's mandate.

Create a data exchange to automate data transfers from State to FDA, FDA to State, and State to State.



## **Benefits**

Reduce State and FDA manual and duplicate efforts for completing contracted inspections.

Improve efficiency and efficacy of FDA monitoring and regulatory activities.

Provide secure and immediate access to relevant information for operational activities.

Define a common data format for exchanging food safety data.



# ***Participating States and Integrated Systems***

<b>Scenario</b>	<b>Participating States</b>	<b>Integrated Systems</b>
1. State Submits Contracted Inspection Data to FDA	Florida, Illinois, Iowa, Minnesota, Pennsylvania, and Texas	State Systems & FDA Systems
2. State Requests Firm Data from FDA	Arkansas, Illinois, Iowa, Minnesota, and Pennsylvania	State Systems & FDA Systems
3. State (Data Requester) Requests Firm Data from Another State (Data Provider)	Arkansas, Illinois, Iowa, and Pennsylvania	State Systems and FDA System (NFSDX)



# NFSDX State Integration Status

State	Current Status	Details
Arkansas	Testing Complete	<ul style="list-style-type: none"><li>• Internal testing and User Acceptance Testing (UAT) has been completed</li><li>• State waiting to finalize agreements</li></ul>
Florida	Testing Complete	<ul style="list-style-type: none"><li>• Interconnection Security Agreement (ISA) in review by State</li><li>• Prepping system for Production deployment</li></ul>
Illinois	Testing	<ul style="list-style-type: none"><li>• ISA sent to State for signatures</li><li>• UAT testing for State-to-State search with Pennsylvania. Updates will be available 6/20/2018 for testing</li></ul>
Iowa	Testing	<ul style="list-style-type: none"><li>• ISA sent to State for signatures</li><li>• UAT testing for State-to-State search with Pennsylvania. Updates will be available 6/20/2018 for testing</li></ul>
Minnesota	Testing	<ul style="list-style-type: none"><li>• Memorandum of Understanding (MOU), ISA and 20.88 in review by State</li><li>• UAT testing for State-to-State search with Pennsylvania. Updates will be available 6/20/2018 for testing</li></ul>
Pennsylvania	Testing	<ul style="list-style-type: none"><li>• State system going through internal testing</li><li>• UAT is scheduled to begin on 6/20/2018</li><li>• ISA and MOU in review by State</li></ul>
Texas	Development	<ul style="list-style-type: none"><li>• Continuing development efforts</li><li>• ISA and MOU in review by State</li></ul>

Note: Florida likely to be first State to integrate with NFSDX



# ***NFSDX and ORAPP Milestones***

<b>NFSDX / ORAPP Milestones</b>	<b>Functionality</b>
<b>NFSDX Release 1.0 May 2017</b>	<ul style="list-style-type: none"><li>• State Submits Contracted Inspection Data to FDA</li></ul>
<b>NFSDX Release 2.0 September 2017</b>	<ul style="list-style-type: none"><li>• State Requests Firm Data from FDA</li><li>• State (Data Requester) Requests Firm Data from Another State (Data Provider)</li></ul>
<b>Office of Regulatory Affairs Partners Portal (ORAPP) Release 1.0 March 2018</b>	<ul style="list-style-type: none"><li>• Facilitate communication and collaboration between FDA, States, and other potential regulatory partners. Features include: Catalogs, Resources, Notifications, and News</li><li>• Integrate several NFSDX functionalities such as Firm search</li></ul>

Note: The NFSDX release schedule is independent of each State's NFSDX integration schedule



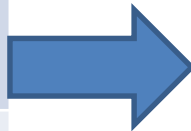


# ***ORAPP Drivers, Solution, and Benefits***

## **Drivers**

FDA seeks to streamline and centrally manage food safety information across FDA, States, and local health departments.

FDA and regulatory partners need a user-friendly interface to facilitate communication and collaboration.



## **Solution**

Build an interactive portal that provides role-based access to exchange food safety related information, with the following capabilities:

- Maintain system-related documents catalog
- Support Firm data searches
- Publish system status, notifications, and alerts
- Generate reports
- Manage user accounts



## **Benefits**

Offer comprehensive user interface to provide users from FDA and regulatory partners with a single location to perform all NFSDX-related activities.


Deliver the framework for NFSDX and for other systems to integrate with ORAPP.

Provide centralized inclusive site for wide-range IT related activities for selected business functions.

Ensure optimal user experience (UX).




# ORAPP Home Page

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ORA PARTNERS PORTAL

[Home](#) [Resources](#) [Catalogs](#) [Search](#) [Reports](#) [Contact Us](#) [Contribute](#)

**ORA NEWS**

**Upcoming Events**


- 7th Manufactured Food Regulatory Program Alliance
- 122nd AFDO Annual Educational Conference

**HELPDISK**

Production Environment Questions and Issues

Send an email to the ORA Applications Helpdesk:  
[AppsDesk@fda.hhs.gov](mailto:AppsDesk@fda.hhs.gov)

**Note:** when emailing the ORA Applications Helpdesk to report the issue, please ask the Helpdesk specialist to assign your helpdesk ticket to the [NFSOX SUPPORT queue](#).



**ORA Partners Portal Mission Statement**


The Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. It authorized the Food and Drug Administration (FDA) to enhance and expand regulations on how foods are grown, harvested, and processed, and directed FDA to develop a national integrated food safety system (IFSS) in partnership with State and local regulatory partners.

To improve the efficiency and efficacy of FDA inspections, as well as meet federally-mandated FSMA requirements, in 2010 FDA sought to develop an IFSS solution with which food safety data can be exchanged, analyzed, and acted upon, across all levels of the regulatory spectrum. Establishing the National Food Safety Data Exchange (NFSOX) in 2017 was the first step in achieving the goal of an IFSS. The NFSOX provides regulatory partners with an investigative tool that will allow sharing and exchange of food safety information, such as inspection findings and facility information, on a national basis.


Mandated by FDA, the Office of Regulatory Affairs (ORA) Partners Portal has become the next logical step in IFSS development. The ORA Partners Portal is designed to facilitate communication and collaboration between FDA, the States, and other potential regulatory partners on the development, implementation, and usage of the NFSOX and, in the long term, other ORA applications.

The ORA Partners Portal is expected to grow into a platform that consolidates and integrates FDA food safety, lab operation, and other business functions, providing users a single sign-on and one-stop shop for all information related to these business functions. It is envisioned to aggregate a vast array of data and resources to equip regulatory partners with the tools and information needed to successfully plan and implement FSMA compliance activities, to maintain and exchange FSMA-related documentation, such as instructions, policies, and procedures, notifications, and inspection data, and, in the long term, to expand Firm searches to include farms, foreign manufacturers, and various FSMA-compliant suppliers.


The core mission of the ORA Partners Portal is commitment to empower and support FDA/ORA regulatory partners through collaboration while continually seeking ways to improve operations and increase support of food safety regulations.

**Resources**


Browse and download various documents, such as guides for integrating State systems with NFSOX, the NFSOX State Questionnaire, and State Agreement templates (e.g., Technical Memorandum of Understanding and 20.88 Agreement).

**Catalogs**

Find the latest logical data XML schema version used for NFSOX Contracted Inspection data submissions and Firm searches in FDA and State systems, Inspection and Firm data mappings, Reference data type codes and descriptions, and Error Messages and Business Rules lists used in NFSOX business scenarios.

**Search**

Perform an FDA Firms search based on multiple search criteria, with an option to export the Firms list to Excel and drill down to Firm details based on Firm Establishment Identifier (FEI).

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\* State :

Export To Excel

FEI	Firm Legal Name	Doing Business As	Operational Status	Operational Status Date	Address	Establishment Type	Last Inspection Date	Last Violative Inspection Date
No data to display								



# *Regulatory Partners Outreach & Agreements*

- **The PFP IT WG Meeting (monthly):**
  - Discuss NFSDX and ORAPP initiatives that advance food safety data exchange and integration
  - Provide continuous updates and conduct demonstrations regarding NFSDX and ORAPP
  - Update project strategies and goals based on PFP IT Workgroup feedback
- **Each State and FDA agrees to execute the following three legal agreements to integrate with NFSDX:**
  - Memorandum of Understanding (MOU)
  - Interconnection Security Agreement (ISA)
  - 20.88 Agreement





## ***Project Phase II High Level Scope***

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- **Phase II Project Kick-off held on 4/5/2018**
- **Planning to add more functionality to NFSDX and ORAPP**
  - Include Laboratory data submissions and other use cases to NFSDX
  - Integrate Observation Corrective Action Report (OCAR) Resource Library and Produce Safety and Preventive Control with ORAPP
- **Reach out to more States and increase current States' participation in NFSDX**
- **Provide ORAPP training and associated training materials**



## *Who to Contact?*

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- **For Partnership for Food Protection (PFP) IT Workgroup membership and/or NFSDX/ORAPP information, please contact:**
  - Barbara Thiel, NFSDX Business Program Manager  
[Barbara.Thiel@fda.hhs.gov](mailto:Barbara.Thiel@fda.hhs.gov)



# Questions

