

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

**OFFICE OF REGULATORY AFFAIRS** 

# Office of Regulatory Affairs (ORA)

Data Exchange (DX)

# **Frequently Asked Questions** (FAQs)

Document Version Number: 16.0

Document Version Date: 2/26/2024

(Updated for ORA DX Release 18.0)



### Contents

1		Introduction	4
2		Point of Contact (POC)	4
3		Top FAQs	4
	3.1	What is the ORA DX program and ORA DX Systems?	4
	3.2	Can a regulatory partner participate in both ORA DX systems (System-to-System (S2S aka NFSDX) and ORAPP)?	4
	3.3	Does a regulatory partner require agreements to participate in the ORA DX program?	5
	3.4	How does participation in the ORA DX program help a regulatory partner?	5
	3.5	How does a regulatory partner sign-up for an ORA DX capability?	5
	3.6	How can a regulatory partner engage with the FDA on the PFP and ORA DX program?	5
	3.7	Does FDA provide the data exchange specifics and file format to a regulatory partner for the System-to-System and ORAPP?	6
	3.8	What is the process for a regulatory partner to request new accounts for ORA DX systems?	6
	3.9	Is participation in ORA DX program voluntary?	6
	3.10	Are the ORA DX systems training available for all regulatory partners?	6
4		ORAPP	7
	4.1	Do ORA DX systems allow a regulatory partner to share an Excel spreadsheet of inspection data?	7
	4.2	Which browsers are supported by ORAPP?	7
	4.3	What Firm History (FH) data categories are available via ORAPP?	7
5		System-to-System (S2S aka NFSDX)	7
	5.1	Do the ORA DX systems replace regulatory partner systems?	7
	5.2	What are the steps for a regulatory partner to enable the S2S?	7
	5.3	Does the S2S support the sharing of inspection related documents?	7
	5.4	Does S2S and ORAPP offer same DX capabilities?	7
	5.5	Are ORAPP and the S2S separate systems?	8
	5.6	Is a regulatory partner required to use a specific system to participate in the S2S?	8
	5.7	How long does it take for a regulatory partner to enable the S2S?	8
	5.8	What is the difference between the S2S and FoodSHIELD?	8
	5.9	Do regulatory partners purchase the S2S?	8
	5.10	What Firm History (FH) data categories are available via S2S?	8
	5.11	How are the Firm History (FH) Application Program Interface (API) services implemented?	8
6		FDA Systems Retirement	9



	6.1	Is El	ectronic Laboratory Exchange Network (eLEXNET) retired and why?	9
	6.2	Did the ORA DX systems replace eLEXNET?		9
	6.3		the ORA DX systems replace the Electronic State Access to FACTS (eSAF), and what is the	
7		Ove	erall, ORA DX Program, Systems, and Capabilities	9
	7.1	Gen	eral	9
	7.1.1 7.1.2 7.1.3		Is FDA approval required for regulatory partner participation in the ORA DX program?	9
			How does a regulatory partner request additional information about ORA DX systems a capabilities?	
			Where can users learn more about ORA DX capabilities and training for the various domains such as Inspections, Samples, and Inventory?	10
	7.1.	4	What are the current data sharing capabilities supported by the ORA DX systems?	10
	7.1.5		How does a user access technical integration packages needed for ORA DX onboarding System-to-System?	
7.1		6	Can regulatory partners participate in any ORA DX system and capability?	10
	7.1.	7	What is FDA Product Code and how does a regulatory partner access it?	10
	7.1.8		What is the process for a regulatory partner to request termination of ORA DX accounts	
	7.1.9	9	Do ORA DX systems store data?	10
	7.1.	10	What is Domestic Mutual Reliance (DMR)?	11
	7.1.	11	What are DMR Partnership Agreements and how do they relate to the ORA DX?	11
	7.1.	12	Will the ORA DX program be expanded to include Animal Feed programs?	11
	7.1.	13	Is Manufactured Food Regulatory Program Standards (MFRPS) compliance required for regulatory partner participation in the ORA DX program?	
	7.2	Insp	pections and Inventory Data Sharing	11
	7.2.	1	Does a regulatory partner have to conduct a certain number of inspections to participate in ORA DX contracted inspection capabilities?	
7.2.		2	Do the ORA DX systems send data back to a regulatory partner?	11
	7.2.3		Are there similar ORA DX systems envisioned for drug manufacturing facilities in the future?	11
	7.2.4		Can inspection with incorrect data be returned to a regulatory partner via ORA DX systems?	12
	7.2.5		Is the inspection and sample data submitted via ORA DX available in Office of Regulator Affairs Reporting, Analysis, and Decision Support System (ORADSS), FDA system?	•
	7.2.0	6	How does FDA protect the inspection documents provided by a regulatory partner?	12



7.2.7	What are the FDA's expectations for the safeguard of contracted inspection info	
7.2.8	Are the FDA firm updates allowed via ORA DX?	
7.2.9	What is the Inventory Reconciliation (IR) capability in the ORA DX?	12
7.2.10	What happens to a regulatory partner's inventory data once submitted for IR vi	ia ORA DX?
7.2.11	Is the Food Defense Plan Quick Check (FDPQC) available for Contracted Inspecti sharing via ORA DX?	
7.2.12	What is a firm POC ID?	13
7.2.13	How does a regulatory partner lookup/retrieve a firm POC ID?	13
7.3 Sar	mple Data Sharing	13
7.3.1	What is the Lab Flexible Funding Model (LFFM)?	13
7.3.2	Is LFFM a requirement for a regulatory partner (state lab) to participate in samp exchange via ORA DX systems?	
7.3.3	How should a state lab submit an analytical work package for a positive sample LFFM?	
7.3.4	How should a state lab submit sample results that are collected under Food and contracts?	
7.4 Tra	nining	14
7.4.1	Is there on-demand training for ORA DX capabilities?	14
7.4.2	What is a Knowledge Article (KA) and how does it differ from e-Learning course	s?14
7.4.3	Where are the Knowledge Articles (KAs) located?	14
7.4.4	Are there ORA DX instructor-led courses and how can regulatory partners partic	cipate? . 14
7.4.5	Can regulatory partners share feedback or questions about training materials?.	14
7.4.6	How often are new e-Learning courses published?	14
7.4.7	Can regulatory partners request specific e-Learning courses, instructor-led cour Knowledge Articles (KAs)?	-
Glo	ossary of Acronyms	15

8



#### 1 Introduction

The Frequently Asked Questions (FAQ) for the Office of Regulatory Affairs (ORA) Data Exchange (DX) program may be updated with every ORA DX release.

This document is organized into seven sections:

- Introduction
- Point of Contact (POC)
- Top FAQs
- ORA Partners Portal (ORAPP)
- System-to-System (NFSDX)
- FDA Systems Retirement
- Overall, ORA DX including Inspection, Inventory, and Sample data sharing capabilities in addition to Training

### 2 Point of Contact (POC)

For additional information, contact the ORA Apps Desk via the <u>Contact Us page on ORAPP</u>, to share feedback and/or questions that could be included and answered in the document. Feel free to mention the ORA DX FAQ in the correspondence.

### 3 Top FAQs

This section describes the top ten FAQs identified by the ORA DX team based on ORA DX discussions with the FDA and regulatory partners.

#### 3.1 What is the ORA DX program and ORA DX Systems?

The ORA DX program enables electronic information sharing between regulatory partners and the U.S. Food and Drug Administration. The ORA DX program supports the <u>Food Safety Modernization Act</u> (FSMA), national <u>Integrated Food Safety System</u> (IFSS), <u>Partnership for Food Protection</u> (PFP), <u>Domestic Mutual Reliance</u> (DMR), and more for a safer food supply.

The ORA DX systems include two IT systems to support secure data exchange of inventory, inspection, and sample data: ORAPP and System-to-System. The ORAPP is a web portal. The System-to-System is a set of web services and uses the technical components such as XML, Java, and Soap Web Services. The ORA DX systems also include the Enhanced DX Client which supports the submission of sample data (i.e., collection, receipt, and analysis data) to FDA.

The <u>ORA DX One Pager</u> provides a quick overview of the ORA DX program and the <u>About Page on the ORAPP</u> provides additional information about the current ORA DX capabilities and the recent releases.

## 3.2 Can a regulatory partner participate in both ORA DX systems (System-to-System (S2S aka NFSDX) and ORAPP)?

Yes. A regulatory partner can choose to participate in either one or both ORA DX systems. The S2S provides direct electronic data exchange between a regulatory partner and FDA systems, which



requires IT resources and effort by a regulatory partner. ORAPP is a website for a regulatory partner to exchange data with the FDA. It does not require system integration effort by a regulatory partner.

## 3.3 Does a regulatory partner require agreements to participate in the ORA DX program?

Yes. the Long Term Food, Feed and Cosmetics 20.88 agreement is required to participate in the ORA DX program. Additionally, a Memorandum of Understanding (MOU) and Interconnection Security Agreement (ISA) are required to participate in the System-to-System, along with a Non-Disclosure Agreement (NDA) for uploading attachments.

#### 3.4 How does participation in the ORA DX program help a regulatory partner?

Participation in the ORA DX program provides a regulatory partner with the improved information sharing capabilities with the FDA. At a minimum, it eliminates dual data entry in the State's system and the FDA's system and challenges associated with the related data updates. ORAPP is envisioned to be the centralized and comprehensive portal for all the electronic data exchange between regulatory partners and the FDA. Additional FDA data that will benefit a regulatory partner may be made available to partners in the future.

#### 3.5 How does a regulatory partner sign-up for an ORA DX capability?

Regulatory partners should contact the ORA Apps Desk via the <u>Contact Us page on ORAPP</u>, or contact the FDA state liaison or field management to indicate participation interest. In certain instances, the FDA reaches out to the regulatory partner based on various FDA initiatives and ORA DX outreach. Every participation request is reviewed and approved by the FDA.

### 3.6 How can a regulatory partner engage with the FDA on the PFP and ORA DX program?

Regulatory partners play an important role in the ORA DX program. The FDA recommends that every regulatory partner participate in the ORA DX program. Regulatory partners are encouraged to build awareness of the ORA DX program, provide state perspective of the data sharing, and influence the priorities and scope of ORA DX data sharing capabilities. A regulatory partner could participate in the appropriate workgroups (WGs), coffee talk articles, newsletters, or recurring standing meetings.

- Coffee Talk Articles Quarterly articles focused on sharing perspectives and guidance from an ORA DX stakeholder or participant. For more information, see the PFP site.
- Inspection and Inventory WG Standing meetings with participating regulatory partners to discuss about ORA DX System-to-System Inspection and Inventory data sharing capabilities.
- PFP IT WG Newsletters Quarterly e-newsletters focused on various PFP IT WG activities related to the ORA DX program including a spotlight on ORA DX stakeholders or participants. For more information, see the PFP site.
- PFP IT WG Meetings Standing meetings with regulatory partners to share about the ORA DX program, upcoming releases, and elicit input.
- Sample WG Standing meetings with participating regulatory partners to discuss about ORA DX
   Sample data sharing capabilities. For more information, see the <a href="PFP site">PFP site</a>.

Regulatory partners can contact FDA to gather the specifics of the above collaboration opportunities or obtain additional information about the ORA DX via the <a href="Contact Us page on ORAPP">Contact Us page on ORAPP</a>.



### 3.7 Does FDA provide the data exchange specifics and file format to a regulatory partner for the System-to-System and ORAPP?

Yes. The FDA provides the data fields, formats (XML schema definitions), message constructs, etc., necessary to exchange data using the System-to-System. For ORAPP, the FDA provides predefined Excel templates with data fields, data requirements, mapping information to map state data fields to the FDA data fields, and instructions to upload the files.

## 3.8 What is the process for a regulatory partner to request new accounts for ORA DX systems?

A regulatory partner should contact the ORA Apps Desk via the <u>Contact Us page on ORAPP</u> to request new accounts for ORA DX systems. The request should include information about the users such as first and last name, agency name, email address, and DX capability information. The request goes through an FDA approval process. Once approved, the FDA authorizes and provides login credentials to the agency for the System-to-System or the user for ORAPP.

#### 3.9 Is participation in ORA DX program voluntary?

Yes. It is voluntary for a regulatory partner to participate in the ORA DX program. In the future, with the anticipated eSAF retirement, regulatory partner will need to use one of the ORA DX systems to exchange data with the FDA.

#### 3.10 Are the ORA DX systems training available for all regulatory partners?

Yes. Virtual training is available for ORAPP users (regulatory partners and the FDA) at no cost. In 2022, e-Learning courses were introduced, made accessible to the public in 2023, and continue to be developed. Current course offerings can be accessed via the <a href="ORAPP Public Training Page">ORAPP Public Training Page</a>. Instructor-led courses will continue to be offered on an ad-hoc basis.

The e-Learning courses offer the following benefits:

- Varied course options to fit a modularized approach
- Clearly defined course pre-requisites
- ORA DX Capability focused and concise courses for better retention
- Courses are accessible 24/7 for self-paced learning
- Reduces environmental impact
- Ongoing access to resources for later reference

Trainees can register for instructor-led courses (lecture, demo or interactive) and receive access to training recordings. To learn more about the course catalog and training schedule, contact the ORA Apps Desk via the <u>Contact Us page on ORAPP</u>.



#### 4 ORAPP

This section describes the FAQs about ORAPP, an ORA DX system.

## 4.1 Do ORA DX systems allow a regulatory partner to share an Excel spreadsheet of inspection data?

Non-Contracted Inspection data sharing via FDA defined Excel templates is available in ORAPP. However, Contracted Inspection data is available only in the System-to-System which supports data sharing via XML only.

#### 4.2 Which browsers are supported by ORAPP?

For the browsers supported in ORAPP, click <u>here</u>.

#### 4.3 What Firm History (FH) data categories are available via ORAPP?

There are currently three available data categories in ORAPP:

- Program Risks
- Recalls
- Compliance Cases

Additional FH categories are available in S2S. (See FAQ 5.10)

### 5 System-to-System (S2S aka NFSDX)

This section describes the FAQs about the System-to-System (S2S), an ORA DX system.

#### 5.1 Do the ORA DX systems replace regulatory partner systems?

No. The ORA DX systems are not intended to replace a regulatory partner's systems.

#### 5.2 What are the steps for a regulatory partner to enable the S2S?

The FDA works with a regulatory partner to outline the systems activities to enable the S2S integration. The high-level activities can be found within the regulatory partner onboarding handbook which is part of the partner engagement package shared during the onboarding process. Additionally, integration guides are available for each S2S capability. These guides provide the Application Program Interface (API) details, data exchange messages, error handling, security aspects, etc.

#### 5.3 Does the S2S support the sharing of inspection related documents?

Yes. For inspection data sharing, S2S supports the upload and deletion of attachments/documents along with the retrieval of the list of inspection attachments.

#### 5.4 Does S2S and ORAPP offer same DX capabilities?

No. Few DX capabilities are unique to each system while few DX capabilities are available in both systems. The ORA DX systems are continuously enhanced incrementally to provide additional capabilities for a comprehensive data exchange mechanism between the FDA and regulatory partners.



#### 5.5 Are ORAPP and the S2S separate systems?

Yes. ORAPP and the S2S are separate systems yet integrated to a certain extent within the FDA's Information Technology framework.

5.6 Is a regulatory partner required to use a specific system to participate in the S2S?

No. The S2S can integrate with any system that has an ability to integrate with web services.

#### 5.7 How long does it take for a regulatory partner to enable the S2S?

Multiple factors influence the S2S integration for a regulatory partner, such as IT systems, financial and IT resources, data capture and reporting processes, and personnel availability for integration activities.

#### 5.8 What is the difference between the S2S and FoodSHIELD?

FoodSHIELD and the S2S are two separate systems. The S2S is an ORA DX system which enables electronic data sharing from a regulatory partner's system into the FDA system. The <u>FoodSHIELD</u> is a web-based system for communication, coordination, education, and training among the nation's food and agriculture sectors.

#### 5.9 Do regulatory partners purchase the S2S?

No. The S2S cannot be purchased like a commercial off-the-shelf (COTS) product. The FDA provides documentation and guidance to regulatory partners at no cost to enable the S2S integration. Regulatory partners incur their IT costs for development, testing, and other activities required for the integration.

#### 5.10 What Firm History (FH) data categories are available via S2S?

There are currently four available data categories in S2S:

- Snapshot
- Consumer Complaints
- Inspections
- Investigations

Additional FH categories are available in ORAPP. (See FAQ 4.3)

## 5.11 How are the Firm History (FH) Application Program Interface (API) services implemented?

FH services are implemented using the Representational State Transfer (REST) Service. This is the first ORA DX service accessible via REST and corresponds with FDA modernization efforts. REST, with its flexible format, eliminates the necessity for backend state system modifications when adding new data elements, which is a significant benefit. However, leveraging REST services may entail some initial state development effort.



### **6 FDA Systems Retirement**

This section describes the FAQs about the FDA systems' retirement pertinent to the ORA DX systems.

#### 6.1 Is Electronic Laboratory Exchange Network (eLEXNET) retired and why?

The eLEXNET was retired on September 30, 2020. The data sharing capabilities were transitioned to ORAPP. Several factors influenced the decision to retire eLEXNET. The FDA has automated and streamlined data exchanges and has increased its analytical capacity and expertise in the event of food outbreaks or large scale-food emergencies.

Food safety testing efforts have also been streamlined and improved through targeted data collection that support compliance decisions and risk analysis. Other mechanisms are currently being used for the exchange and mining of surveillance data. The <u>Food Safety Modernization Act</u> (FSMA) built a formal system of collaboration with other government agencies. This resulted in better information sharing and coordination, increased capacity, and capability at the state, local, tribal, and territorial level. eLEXNET does not contain all the critical information for the FDA to take enforcement action, thus it no longer meets the increased regulatory requirements. The FDA is consolidating the mechanisms by which food safety agencies and partners share information so that the FDA can more easily perform risk assessments analysis and locate problem products. The FDA is transitioning to a more streamlined data exchange solution via ORAPP.

#### 6.2 Did the ORA DX systems replace eLEXNET?

Yes. Certain eLEXNET capabilities were transitioned to the ORA DX systems. The FDA stopped collecting surveillance, voluntary, or required data via eLEXNET on May 31, 2020. The eLEXNET was retired on September 30, 2020.

### 6.3 Will the ORA DX systems replace the Electronic State Access to FACTS (eSAF), and what is the timeline?

Yes. FDA is planning to retire the eSAF system and migrate select capabilities to the ORA DX systems. The FDA expects to announce the transition and retirement timeline soon.

### 7 Overall, ORA DX Program, Systems, and Capabilities

This section describes the FAQs about the overall ORA DX program, systems, and capabilities.

#### 7.1 General

### 7.1.1 Is FDA approval required for regulatory partner participation in the ORA DX program?

Yes. The FDA provides approval for regulatory partner participation based on certain agreements and factors determined by the FDA.

## **7.1.2** How does a regulatory partner request additional information about ORA DX systems and capabilities?

Regulatory partners should request information via the ORAPP Contact Us page. Links to additional resources can be found at the bottom of the ORAPP About Page.



## 7.1.3 Where can users learn more about ORA DX capabilities and training for the various domains such as Inspections, Samples, and Inventory?

Users with access to internet can learn more about the ORA DX capabilities via <u>ORAPP</u>, by selecting the respective Domain from the menu at the top right, and choosing Overview from the submenu. Additionally, the <u>ORAPP Training page</u> and the <u>ORAPP About page</u> also provide information about ORA DX training, capabilities and recent release information. For more information about training, see the <u>Training page</u> in ORAPP.

#### 7.1.4 What are the current data sharing capabilities supported by the ORA DX systems?

The ORA DX systems enable various data sharing capabilities across the inventory, inspection, and sample domains. For information on the capabilities, visit the <a href="ORAPP About page">ORAPP About page</a>.

### 7.1.5 How does a user access technical integration packages needed for ORA DX onboarding for System-to-System?

ORA DX System-to-System users can access the Technical Onboarding page by logging into ORAPP. Once on the Technical Onboarding page, integration packages can be downloaded for the necessary capabilities for the System-to-System onboarding.

#### 7.1.6 Can regulatory partners participate in any ORA DX system and capability?

Yes. A regulatory partner can choose to participate in any ORA DX system and capability. There could be additional participation criterion for certain ORA DX capabilities. For example, <a href="Manufactured Food Regulatory Program Standards">Manufactured Food Regulatory Program Standards</a> (MFRPS) conformance is required to participate in ORA DX non-contracted inspection capability.

#### 7.1.7 What is FDA Product Code and how does a regulatory partner access it?

The FDA Product Code describes a specific product and is broken into the five fields: Industry, Class, Subclass, Process Indicator Code, and Product. The <u>Product Code Builder</u> is an online tool/application that assists in locating and building product codes. The application provides valid combinations for each of the five fields of the product code.

### **7.1.8** What is the process for a regulatory partner to request termination of ORA DX accounts?

A regulatory partner should contact the ORA Apps Desk via the <u>Contact Us page on ORAPP</u>, to request to terminate ORA DX systems' accounts for ORA DX System-to-System capabilities. However, a regulatory partner need not notify the FDA about any of their state system user account changes.

Additionally, regulatory partners should inform the FDA of the intent to discontinue use of ORAPP user accounts. A request to deactivate the user account should be sent to the ORA Apps Desk via the <u>Contact Us page on ORAPP</u>. The FDA would then proceed with deactivating the account and notifying the requestor.

#### 7.1.9 Do ORA DX systems store data?

No. The ORA DX systems store only transactional data (i.e., who sent what information, when it was sent, etc.) pertinent to the data exchange. The ORA DX systems integrate with the FDA systems of record.



#### 7.1.10 What is Domestic Mutual Reliance (DMR)?

DMR is a seamless partnership that enables the FDA and states with comparable regulatory public health systems to rely on, coordinate with, and leverage one another's work, data, and actions for a safer food supply. To learn more, visit the FDA's <u>Domestic Mutual Reliance webpage</u>.

#### 7.1.11 What are DMR Partnership Agreements and how do they relate to the ORA DX?

The DMR Partnership Agreements help the FDA to work in cooperation with the states to support the goal of a safer national food supply. As envisioned in the FSMA, the PFP, and the New Era of Smarter Food Safety (NESFS) blueprint, these agreements enhance the existing relationships with states and government counterparts, moving the nation toward an IFSS.

For each DMR Partnership agreement, there is a strategic plan document. The strategic plan outlines how the FDA, and the state partner will collaborate to achieve domestic mutual reliance by leveraging each other's commitment, knowledge, expertise, and regulatory resources. Joint collaborative efforts include manufactured human food firm inventory reconciliation and maintenance, data sharing, work planning, training, etc. Some of these efforts are achieved by utilizing the ORA DX capabilities. Also, within the strategic plan, ORA DX onboarding objectives are established. To learn more, visit the FDA's <u>Domestic Mutual Reliance webpage</u>.

#### 7.1.12 Will the ORA DX program be expanded to include Animal Feed programs?

Yes. The DX capabilities are currently directed toward Human Food programs. The FDA is working with the <u>Center for Veterinary Medicine</u> (CVM) to identify capabilities that would benefit the Animal Feed programs to ensure a safe animal food (feed) supply.

## 7.1.13 Is Manufactured Food Regulatory Program Standards (MFRPS) compliance required for regulatory partner participation in the ORA DX program?

No. The MFRPS conformance is not required to participate in the ORA DX program. However, a regulatory partner must be MFRPS compliant when participating in the non-contracted inspection data exchange with the FDA via ORA DX systems.

#### 7.2 Inspections and Inventory Data Sharing

## 7.2.1 Does a regulatory partner have to conduct a certain number of inspections to participate in ORA DX contracted inspection capabilities?

No. Per state contract for contracted inspections, a minimum of 10 inspections are expected. However, there are no minimum or maximum number of inspections that must be conducted by a regulatory partner to participate in the ORA DX program.

#### **7.2.2** Do the ORA DX systems send data back to a regulatory partner?

Yes. The ORA DX systems send FDA inventory data, acknowledgements, notifications, error messages, and invalid data back to a regulator partner.

### 7.2.3 Are there similar ORA DX systems envisioned for drug manufacturing facilities in the future?

Yes. Although the ORA DX program started out with food and feed programs, it could potentially be expanded to exchange different commodities and other types of data. There are also other



avenues currently in place where foreign regulators can contact the FDA for information about inspectional activities.

## **7.2.4** Can inspection with incorrect data be returned to a regulatory partner via ORA DX systems?

Yes. The ORA DX systems send error messages along with incorrect data back to a regulatory partner.

# 7.2.5 Is the inspection and sample data submitted via ORA DX available in Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS), FDA system?

Yes. The inspection data is saved in eSAF, and sample data is saved in the Field Accomplishments and Compliance Tracking System (FACTS). The eSAF system continues to integrate with FACTS and on a scheduled basis, inspection data is exported from eSAF to FACTS. ORADSS accumulates inspection and sample data from FACTS.

#### 7.2.6 How does FDA protect the inspection documents provided by a regulatory partner?

The FDA protects all non-public information, regardless of the source. Contact the FDA/ORA Division of Information Disclosure Policy (DIDP) (<a href="mailto:ORAinfoshare@fda.hhs.gov">ORAinfoshare@fda.hhs.gov</a>) for additional information.

### **7.2.7** What are the FDA's expectations for the safeguard of contracted inspection information?

Every regulatory partner working with the FDA is required to sign a single signature Non-Disclosure Agreement (NDA). The NDA requires the state to protect information collected during contract work and prevent disclosure to any party not covered by the contract. Contact the FDA/ORA Division of Information Disclosure Policy (DIDP) at <a href="mailto:ORAinfoshare@fda.hhs.gov">ORAinfoshare@fda.hhs.gov</a> for additional information.

#### 7.2.8 Are the FDA firm updates allowed via ORA DX?

Yes. Currently, the System-to-System allows updates for the FDA firm inventory along with the inspection data. The recommended inventory updates are inspection specific and are manually reviewed by the FDA State Liaisons or State Contract Monitors in eSAF. Post approval, the changes are propagated to internal FDA systems. Future ORA DX releases shall provide two-way inventory reconciliation between the FDA and regulatory partner. The FDA firm inventory will be updated using insights from the regulatory partner during planning and inspection phases. Similarly, updates to the FDA inventory will be sent to the regulatory partner during their planning and pre-inspection preparatory activities.

#### 7.2.9 What is the Inventory Reconciliation (IR) capability in the ORA DX?

The IR capability in ORAPP allows a regulatory partner to submit their firm inventory via an Excel template for automated matching and reconciliation with the FDA firm inventory. The IR capability enables a regulatory partner to reconcile and correct inconsistencies in their firm inventory.



### 7.2.10 What happens to a regulatory partner's inventory data once submitted for IR via ORA DX?

The regulatory partner's inventory is compared against the FDA inventory and the matching results are returned to the regulatory partner. Additionally, matching results enable the state liaisons to discuss inconsistencies with the appropriate regulatory partner. The reconciliation of the inventory data is completed manually outside of the IR system process. The submitted data and matching results are retained in ORAPP for two years.

## 7.2.11 Is the Food Defense Plan Quick Check (FDPQC) available for Contracted Inspections data sharing via ORA DX?

Yes. The FDPQC data sharing is available via the System-to-System. This data sharing is similar to the eSAF functionality. However, the FDPQC data sharing will be available for regulatory partners in the near future.

#### 7.2.12 What is a firm POC ID?

The firm POC ID is an FDA unique identifier for a firm's point of contact.

#### **7.2.13** How does a regulatory partner lookup/retrieve a firm POC ID?

The FDA firm POC ID is exchanged with states as part of the inspection results data sharing capability via the System-to-System.

#### 7.3 Sample Data Sharing

#### 7.3.1 What is the Lab Flexible Funding Model (LFFM)?

LFFM is a cooperative agreement that is intended to enhance the capacity and capabilities of state human and animal food testing laboratories in support of an IFSS. Specifically, through sample testing in the areas of microbiology, chemistry, and radiochemistry, and the development of special projects that would support and expand that testing. This project will strengthen and improve FDA's efforts to prevent foodborne illnesses and minimize foodborne exposures through building a nationally integrated laboratory science system. It also equips partner laboratories with additional resources that can be employed to build and increase sample throughput capacity within the state.

## 7.3.2 Is LFFM a requirement for a regulatory partner (state lab) to participate in sample data exchange via ORA DX systems?

No. LFFM is not a requirement for a regulatory partner (state lab) to participate in sample data sharing via ORA DX systems. The sample data exchange is currently enabled for FDA assignments and not for surveillance purposes.

### 7.3.3 How should a state lab submit an analytical work package for a positive sample under LFFM?

A state lab should provide the analytical work package to the FDA State Liaison and the Emergency Response Coordinator.



### **7.3.4** How should a state lab submit sample results that are collected under Food and Feed contracts?

A state lab should submit sample reports and information to the FDA Program Division Director or assigned FDA designee. In the future, the sample results may be submitted via the ORA DX systems.

#### 7.4 Training

#### 7.4.1 Is there on-demand training for ORA DX capabilities?

Yes. The ORAPP <u>e-Learning page</u> contains many e-Learning courses designed for on-demand training and reference. These courses are organized by categories on ORAPP.

ORA DX e-Learning courses are short duration videos (<10 minutes) that provide guidance and instruction on specific data sharing capabilities of the ORA DX systems, particularly ORAPP. ORA DX e-Learning courses are on-demand, virtual, non-interactive, and available to the public. For more information go to the ORAPP e-Learning Page.

#### 7.4.2 What is a Knowledge Article (KA) and how does it differ from e-Learning courses?

A KA is a periodical (<5 pages) that delivers guidance and instructions on specific topics of the ORA DX systems. KAs are distributed periodically via email to ORA DX participants and will be available on ORAPP soon.

KAs focus on a specific feature within a data sharing capability while a set of e-Learning courses focus on an entire ORA DX data sharing capability. The e-Learning courses are maintained to be current with the ORA DX systems. KAs are time-based snapshot articles designed to describe a specific feature.

#### 7.4.3 Where are the Knowledge Articles (KAs) located?

Anyone can access KAs on the new Knowledge Articles page via the Training menu on ORAPP.

#### 7.4.4 Are there ORA DX instructor-led courses and how can regulatory partners participate?

Yes. ORA DX instructor-led courses are conducted to increase the understanding of the ORA DX systems via instructor and student interactions. Instructor-led courses are structured and focused training materials that are accompanied by a live system demo and practice exercises. Instructor-led courses are available for ORA DX systems users only.

#### 7.4.5 Can regulatory partners share feedback or questions about training materials?

Yes. The ORA DX training team values regulatory partner feedback to continuously improve ORA DX training. Contact the ORA DX training team via the <u>ORAPP Contact Us page</u>.

#### 7.4.6 How often are new e-Learning courses published?

Courses are added to the <u>e-Learning page</u> when enhancements (new features and capabilities) are made to the ORA DX systems. e-Learning courses are also updated as needed for maintenance.



## 7.4.7 Can regulatory partners request specific e-Learning courses, instructor-led courses, or Knowledge Articles (KAs)?

Yes, requests for specific training or KA's can be submitted to the ORA DX Training team via the ORAPP Contact Us page for consideration.

### **8** Glossary of Acronyms

Acronym	Description
AFRPS	Animal Feed Regulatory Program Standards
BSE	Bovine Spongiform Encephalopathy
CAP	Cooperative Agreement Program
CI	Contracted Inspection
CVM	Center for Veterinary Medicine
DIDP	Division of Information Disclosure Policy
DMR	Domestic Mutual Reliance
DX	Data Exchange
eLEXNET	Electronic Laboratory Exchange Network
eSAF	Electronic State Access to FACTS
FACTS	Field Accomplishments and Compliance Tracking System
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FDPQC	Food Defense Plan Quick Check
FEI	FDA Establishment Identifier
FSMA	Food Safety Modernization Act
FY	Fiscal Year
GMP	Good Manufacturing Practice
IFSS	Integrated Food Safety System
IR	Inventory Reconciliation
ISA	Interconnection Security Agreement
IT	Information Technology
KA	Knowledge Article
LBS	Lab Business Services
LFFM	Lab Flexible Funding Model
MFRPS	Manufactured Food Regulatory Program Standards
NCI	Non-Contracted Inspection
NFSDX	National Food Safety Data Exchange
ORA	Office of Regulatory Affairs
ORADSS	Office of Regulatory Affairs Reporting, Analysis, and Decision Support System
ORAPP	ORA Partners Portal
PFP IT WG	Partnership for Food Protection Information Technology Workgroup
POC	Point of Contact
SOAP	Simple Object Access Protocol
XML	Extensible Markup Language