ORA Data Exchange (DX)

Frequently Asked Questions (FAQ)

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1 Introduction

The Office of Regulatory Affairs (ORA) Data Exchange (DX) Program's Frequently Asked Questions (FAQ) is updated with every ORA DX release.

This document is organized into three sections of FAQs:

- **Section 3:** Includes FAQs about the **ORA Data Exchange (DX) Program** and **regulatory partner participation**.
- **Section 4:** Provides FAQs about the **ORA DX Systems** (System-to-System services and Partners Portal).
- **Section 5:** Provides FAQs about the **ORA DX Data Aspects** related to the data requirements and how the data is exchanged.

2 Point of Contact

The ORA DX Outreach Team welcomes feedback and additional questions that could be included and answered in the document. Please email your questions to NFSDX_Info@fda.hhs.gov.

3 Regulatory Partner Participation

3.1 What is the ORA Data Exchange (DX) Program?

The ORA Data Exchange (DX) Program enables information sharing between regulatory partners and Food and Drug Administration (FDA). Two IT solutions have been implemented to support secure data exchange including: Partners Portal (ORAPP) and System-to-System services (NFSDX). The DX includes the Enhanced DX Client which supports the submission of sample data (i.e., collection, receipt and analysis data) only to FDA. Participation provides regulatory partner with the following benefits: increases efficient electronic data exchange between FDA and regulatory partner, increases collaboration, and reduces dual data entry in regulatory partner and FDA systems.

3.2 Is the ORA Data Exchange (DX) Program in pilot phase?

No. The ORA Data Exchange (DX) Program systems, System-to-System services and Partners Portal have been operational since 2018. However, the systems continuously expand to accommodate various data exchange capabilities. A number of regulatory partners are participating in the ORA DX Program. Additional partners are in the process of onboarding while others have expressed interest in participating in the future.

3.3 Will the ORA Data Exchange (DX) Program be expanded for Animal Feed Programs?

The DX capabilities are currently directed toward Human Food Programs, but we are actively working with the Center for Veterinary Medicine (CVM) to integrate capabilities that would benefit the Animal Feed Programs to ensure a safe animal food (feed) supply to help ensure healthy animals and people.

3.4 Should a regulatory partner choose System-to-System services or Partners Portal, or both for data exchange systems?

The driving factor in making the choice depends on how a regulatory partner desires to submit and retrieve data from FDA. A regulatory partner could choose to participate in either of the data exchange mechanisms, or both. System-to-System services provides direct electronic data exchange between regulatory partner's systems and FDA's systems, which requires IT resources and effort. The Partners Portal is a website for exchanging data with FDA. It does not require any system integration effort by a regulatory partner.

3.5 Does ORA Data Exchange (DX) Program participation require agreements?

Yes. The Food and Feed 20.88 agreement is required to participate in the data exchange program. Additionally, a Memorandum of Understanding (MOU) and Interconnection Security Agreement (ISA) are required to participate in the System-to-System services, along with a Non-disclosure agreement required for uploading attachments.

3.6 Is Manufactured Food Regulatory Program Standards (MFRPS) compliance required for participation in the ORA Data Exchange (DX) Program?

No. The MFRPS requirement does not apply for contracted inspections data submission or other current data exchange capabilities. The regulatory partner must be MFRPS compliant only when participating in the non-contracted inspections data exchange with FDA.

3.7 Is a regulatory partner required to use a specific system to participate in the System-to-System services?

No. The System-to-System services can integrate with any system that has the ability to integrate with web services.

3.8 How does a regulatory partner sign-up for an ORA Data Exchange (DX) Program capability?

A regulatory partner could either email NFSDX_Info@fda.hhs.gov or contact their FDA state liaison or field management indicating their interest to participate in the ORA Data Exchange (DX) Program. In certain instances, FDA reaches out to the state agencies based on various FDA initiatives. Each partner participation request is reviewed and approved by FDA.

3.9 Does a regulatory partner have to conduct a certain number of inspections to participate in contracted inspection capabilities?

No. However, per contracted inspection contracts, a minimum of 10 inspections are expected, but there are no minimum or maximum number of inspections that must be conducted by regulatory partner to participate in the ORA Data Exchange (DX) Program.

3.10 Can any regulatory partner participate in any ORA Data Exchange (DX) Program capability?

Yes. Any regulatory partner can participate in any ORA Data Exchange (DX) Program capability; however, there could be additional criteria for participation in certain data exchange capabilities.

For example, MFRPS conformance is required to participate in non-contracted inspection data exchange capabilities.

3.11 Is there a checklist for regulatory partner to prepare for System-to-System services?

Yes, a questionnaire is available to capture partner information. A partner engagement package containing the questionnaire is shared with regulatory partner that is onboarding for System-to-System services. Regulatory partner should plan funding for the effort and IT resources with the experience in Extensible Markup Language (XML) and Simple Object Access Protocol (SOAP).

3.12 What are the steps for regulatory partner to enable System-to-System services?

FDA works with the regulatory partner to outline the activities to enable the System-to-System services. The high-level activities can be found within the regulatory partner onboarding handbook that is part of the partner engagement package shared during the onboarding process.

Also, there are integration guides for each System-to-System services capability. The guide provides the Application Program Interface (API) details, data exchange messages, error handling, security aspects, etc., for System-to-System services.

3.13 How does participation in the ORA Data Exchange (DX) Program help regulatory partner?

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

3.14 Is training available for regulatory partner on ORA Data Exchange (DX) Program systems?

Yes, virtual training is available for current users (regulatory partners), FDA state liaisons, and other FDA staff about the data exchange capabilities of the ORA Partners Portal (ORAPP) system of ORA Data Exchange (DX) Program.

The following trainings are currently being offered:

- FDA Collected Samples
  - Samples Receipts and Analysis
- Firm Search History and Firm History
- Help Desk Support Training
- Non-Contracted Inspection
- State Collected Samples
  - Samples Collection
  - Samples Receipts and Analysis

Trainees can choose from instructor-led courses (lecture only or demo or interactive) and potentially have access to the pre-recorded videos. To learn more about the course catalog and training schedule, please contact the Training Team at NFSDX_Info@fda.hhs.gov.

3.15 Can a regulatory partner / state agency not participating in the ORA Data Exchange (DX) Program enroll for training?

No. Currently, training is provided for participating state agencies only. However, in the future the ORA Data Exchange (DX) Program training may be offered to non-participating state agencies.

3.16 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 Integrated Food Safety System (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 their state.

3.17 Is LFFM a requirement for labs to participate in sample data sharing?

No. LFFM is not a requirement to participate in sample data sharing. However, sample data is currently submitted to FDA via the ORA Data Exchange (DX) Program for FDA assignments and not for surveillance purposes.

3.18 Does ORA Data Exchange (DX) Program participation require FDA approval?

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

3.19 Is ORA Data Exchange (DX) Program participation voluntary?

Yes. It is voluntary to use the ORA DX. In the future, with eSAF planned to be retired, regulatory partner will need to use one of the ORA Data Exchange (DX) Program systems to submit their data as it will eventually take the place of eSAF.

4 ORA Data Exchange (DX) Program Systems

4.1 What technical components are used for the System-to-System services capabilities?

System-to-System services use the following technical components: XML schema definitions, Java, and Soap Web Services.

4.2 Does FDA provide the data exchange specifics and file format to regulatory partner for System-to-System services and Partners Portal data exchange?

Yes. FDA provides the data fields, formats (XML schema definitions), message constructs, etc., necessary to exchange data using System-to-System services and Partners Portal data exchange mechanisms. For some capabilities in Partners Portal, FDA provides predefined Excel templates with data fields, data requirements, mapping file to map state data fields to FDA data fields, and instructions to upload the spreadsheets for data entry.

4.3 Will the ORA Data Exchange (DX) Program systems replace Electronic State Access to FACTS (eSAF), and what is the timeline?

Yes. FDA plans to retire eSAF and migrate selected capabilities into the ORA Data Exchange (DX) Program systems. The timeline for retiring eSAF is still being finalized. FDA expects to announce the timeline in 2021.

4.4 Will the ORA Data Exchange (DX) Program replace regulatory partner systems?

No. The ORA Data Exchange (DX) Program is not intended to replace any regulatory partner's systems.

4.5 Does System-to-System services support uploading inspection report documents?

Yes. Currently, System-to-System services supports the uploading and deletion of attachments along with the retrieval of the list of inspection attachments - not to be confused with the actual attachments themselves.

4.6 Are the data exchange capabilities the same in the System-to-System services and Partners Portal data exchange?

No. There are capabilities that are unique to each and available in both. Moving forward, both solutions will be enhanced incrementally to provide a comprehensive data exchange mechanism between FDA and partner.

4.7 Do Partners Portal and System-to-System services mechanisms interact?

Yes. The Partners Portal and System-to-System services mechanisms are integrated within FDA's Information Technology framework.

4.8 How long does it take for a regulatory partner to enable System-to-System services?

It will vary depending on multiple factors, such as regulatory partner's systems, financial and IT resources, data capture and reporting processes, and availability for integration activities.

4.9 What is the process for regulatory partners to request new ORA Data Exchange (DX) Program accounts?

Regulatory partners should email the ORA DX Outreach Team at NFSDX_Info@fda.hhs.gov to request new ORA Data Exchange (DX) Program accounts. Information about the users such as first and last name, agency name, email address, and DX capability information should be provided. The request goes through an approval process. Once approved, the FDA will authorize and provide login credentials directly to the user.

System-to-System services are between state and FDA systems. The FDA provides agency-specific system credentials (not individual user) and connection information for approved regulatory partners.

4.10 What is the process for regulatory partner to communicate for termination of ORA Data Exchange (DX) Program accounts?

The partner will have to email the ORA DX Outreach Team at NFSDX_Info@fda.hhs.gov requesting to terminate Partners Portal user account.

For System-to-System services, the partner needs to inform the ORA DX Outreach Team at NFSDX_Info@fda.hhs.gov about the intent to discontinue the data exchange usage. The agency specific system credentials will be disabled by FDA. However, the state does not have to notify FDA about any individual state user access changes to the state system that is integrated with the System-to-System services.

4.11 Does ORA Data Exchange (DX) Program allow regulatory partner to upload an Excel spreadsheet of inspections data?

Yes and No. Certain capabilities in Partners Portal (ORAPP) allow predefined Excel templates provided by FDA to be used for data exchange. System-to-System services does not have Excel spreadsheet upload capabilities.

4.12 Did the ORA Data Exchange (DX) Program replace Electronic Laboratory Exchange Network (eLEXNET)?

Yes. Certain eLEXNET capabilities have been transitioned to the ORA Data Exchange (DX) Program. FDA stopped collecting all surveillance, voluntary, or required data via eLEXNET on May 31, 2020. eLEXNET was completely retired on September 30, 2020.

4.13 Why was eLEXNET retired?

There are several reasons that factored into the decision to retire eLEXNET. 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 Food Safety Modernization Act (FSMA) builds a formal system of collaboration with other government agencies. This results in better information sharing and coordination, increased capacity and capability at the state, local, tribal and territorial level. eLEXNET doesn't contain all the critical information for FDA to take

enforcement action, thus it no longer meets the increased regulatory requirements. FDA is consolidating the mechanisms by which food safety agencies and partners share information so that FDA can more easily perform risk assessments analysis and locate problem products. FDA is transitioning to a more streamlined data exchange solution via Partners Portal (ORAPP).

4.14 Which browsers are supported by ORAPP?

ORAPP supports Google Chrome, Microsoft Edge, Mozilla Firefox (12+), and Internet Explorer (11+). There are some pages that can only be viewed using Google Chrome and Microsoft Edge; accessing certain pages via Internet Explorer and Mozilla Firefox results in a timeout error.

4.15 How can I request additional information about DX capabilities?

Requests for additional information can be sent to the ORA DX Outreach team at NFSDX_Info@fda.hhs.gov. Requests can also be sent from the Contact Us page on the ORA Partners Portal (ORAPP).

4.16 How does regulatory partner submit regulatory sample data now that eLEXNET is retired?

Regulatory partner can submit the regulatory sample data via System-to-System (NFSDX), Partners Portal (ORAPP) or Enhanced DX Client. The participating states have been provided detailed instructions, including account and data submission process information. Any state is welcome to participate at any time in the ORA DX sample data submission. For additional information, contact the ORA DX Outreach team at NFSDX_Info@fda.hhs.gov.

4.17 Were eLEXNET users automatically migrated over to the ORA Partners Portal(ORAPP)?

No. Existing eLEXNET users were not migrated to ORAPP along with eLEXNET capabilities transition. User accounts were created for the ORA DX participating states. eLEXNET users could request an account in ORAPP by contacting the ORA DX Outreach team at NFSDX_Info@fda.hhs.gov.

4.18 What is the difference between FoodSHIELD and System-to-System services?

FoodSHIELD is a web-based system for communication, coordination, education, and training among the nation's food and agriculture sectors. This secure system allows public health and food regulatory officials at the local, state, and federal levels across the nation to work together. It also helps communicate food safety information among other government agencies.

System-to-System is an ORA DX system which enables electronic data transfer from regulatory partner's system into FDA systems of record. It also enables regulatory partner to search FDA systems of record for certain data.

4.19 What information can be shared using FoodSHIELD and System-to-System services?

FoodSHIELD is used to form workgroups to share information specific to a particular subject area or project among states and FDA. FoodSHIELD is purposely used to share best practices for, but

not limited to, various cooperative agreements, such as Animal Feed Regulatory Program Standards (AFRPS), Manufactured Food Regulatory Program Standards (MFRPS), and Rapid Response Teams (RRT). It is used to share situational food outbreak information. It enables members across different regulatory jurisdictions and agencies to analyze, synthesize, coordinate, and integrate their ideas and efforts by collaborating and sharing food safety information.

System-to-System services is used to share regulatory and compliance data between regulatory partner and FDA. It is built for regulatory partner to electronically exchange data with FDA. Currently, it enables the contracted inspection, BSE, Seafood, and Samples data exchange with FDA in addition to FDA firm search and state-to-state firm search capabilities.

4.20 Are there similar ORA Data Exchange (DX) Systems being envisioned for drug manufacturing facilities in the future?

Although the ORA Data Exchange (DX) program started out with food and feed programs, moving forward, it could potentially be expanded to exchange different commodities and other types of data.

There are also other avenues in place where foreign regulators can reach out to the FDA for information about inspectional activities.

4.21 What are the new additions in the ORA Data Exchange (DX) and the systems being retired?

For usability, we are making the ORA Data Exchange (DX) easier to use than the previous systems. ORA DX uses standard schema definitions to clearly define the required and optional data elements that can be exchanged between systems and all ORA DX participants. As an example, for sample data sharing it uses standardized data elements. The system that was retired is eLEXNET, and it was replaced by ORA DX.

4.22 Can a regulatory partner purchase the System-to-System (NFSDX) services?

No. System-to-System services cannot be purchased like a commercial off-the-shelf (COTS) product. All files and documentation that are required for System-to-System integration are provided by FDA at no cost. Regulatory partners incur their IT costs for development, testing, and other activities required for integration.

5 Data Aspects

5.1 Do the ORA Data Exchange (DX) Program systems send any data back to regulatory partner?

The ORA Data Exchange (DX) Program systems (System-to-System and Partners Portal) does send data back to regulator partner. System-to-System services send firm search results, list of contracted inspection attachments and other information such as, transmission acknowledgements and error messages. Also, the Partners Portal provides an interactive user interface to share information with regulatory partner such as, firm search results, firm history, etc.

5.2 Do ORA Data Exchange (DX) Program systems store any data?

System-to-System services does not store any data beyond transactional data (i.e., who sent what information, when it was sent, etc.) pertinent to the data exchange. The System-to-System services is integrated with FDA systems of record where the data is saved. Similar to the System-to-System services, Partners Portal also integrates with the FDA systems of record. Additionally, Partners Portal enables the submission of produce safety farm inventory data files, sample analysis, and NCI data files along with reports and catalogs related to the data exchange capabilities.

5.3 Can inspections with incorrect data be returned to the regulatory partner via ORA Data Exchange (DX) Program?

Error messages are sent back for any submissions with incorrect data. Also, corrections or updates to inspection data can be submitted via the System-to-System services.

5.4 Will contracted inspection data submitted via ORA Data Exchange (DX) Program be available in ORADSS, FDA system?

Yes. The inspections data is saved into eSAF. eSAF continues to integrate with Field Accomplishments and Compliance Tracking System (FACTS) and on a scheduled basis, contracted inspection data is exported from eSAF to FACTS. ORADSS accumulates inspection data from FACTS (inspections performed by FDA and state inspections from eSAF).

5.5 How do I retrieve FDA Establishment Identifier (FEI) numbers without Partners Portal firm search and history access?

The FEI Portal allows a user to look up an FDA Establishment Identifier (FEI) based on a firm name and address or validate an address of an FEI.

5.6 What is an FDA product code and how do I find them?

An FDA product code describes a specific product and contains a combination of five to seven numbers and letters. The Product Code Builder online tool/application assists in locating and building product codes. The application provides valid choices for each of the five components of the product code (Industry, Class, Subclass, PIC, and Product).

5.7 How should a state lab submit an analytical work package for a positive sample under lab flexible funding model (LFFM)?

The state lab should provide the analytical work package to the FDA State Liaison and the Emergency Response Coordinator. At this time, work packages cannot be submitted via the ORA DX; however, this capability is in scope for the future.

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

The 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.

5.9 How is FDA protecting the documents that the state provides to FDA as a result of an inspection?

FDA protects all non-public information, regardless of source. Please contact FDA/ORA Division of Information Disclosure Policy (DIDP) (ORAinfoshare@fda.hhs.gov) for additional information.

5.10 How does FDA expect state to safeguard information collected as a result of contracted inspections?

Every state working with the FDA is required to sign a single signature non-disclosure agreement (NDA). The NDA requires state to protect information collected during contract work and prevent disclosure to any party not covered by the contract. Please contact FDA/ORA Division of Information Disclosure Policy (DIDP) (ORAinfoshare@fda.hhs.gov) for additional information.

6 Glossary of Acronyms

Acronym	Description
AFRPS	Animal Feed Regulatory Program Standards
BSE	Bovine Spongiform Encephalopathy
CAP	Cooperative Agreement Program
DIDP	Division of Information Disclosure Policy
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
FEI	FDA Establishment Identifier
FSMA	Food Safety Modernization Act
FY	Fiscal Year
GMP	Good Manufacturing Practice
IFSS	Integrated Food Safety System
ISA	Interconnection Security Agreement
IT	Information Technology
LBS	Lab Business Services
LFFM	Lab Flexible Funding Model
MFRPS	Manufactured Food Regulatory Program Standards
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
RRT	Rapid Response Teams
SOAP	Simple Object Access Protocol
XML	Extensible Markup Language