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:

- **Section 1:** Includes FAQs about the **ORA Data Exchange (DX) program** and **regulatory partner participation**.
- **Section 2:** Provides FAQs about the **ORA DX Systems** (System-to-System and Partners Portal).
  Section 3: Provides FAQs about the **ORA DX Data Aspects** related to the data requirements and how the data is exchanged.

2 Point of Contact

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

3 Regulatory Partner Participation

3.1 Is the ORA Data Exchange program in pilot phase?

No. The ORA data exchange program has moved beyond its pilot phase in 2018. The System-to-System (aka NFSDX) and Partners Portal (aka ORAPP) data exchange capabilities are operational since 2018. 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 for the future participation.

3.2 Will the ORA Data Exchange program be expanded for Feed Program?

Inspections are not restricted to Food program. The 20.88 agreement covers both food and feed contracts. The current data exchange capabilities cover GMP, BSE, and seafood inspections data.

3.3 Should a regulatory partner choose System-to-System or Partners Portal, or both?

A regulatory partner could choose to participate in either of the data exchange mechanisms, or both. How a regulatory partner desires to submit and retrieve data from FDA is a driving factor in making the choice. System-to-System provides direct electronic data exchange between regulatory partner's system and FDA's system, 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.

3.4 Should a regulatory partner sign any agreements to participate in the ORA Data Exchange program?

Yes. The Food and Feed 20.88 agreement is required to participate in the data exchange program. Additionally, Memorandum of Understanding (MOU) and Interconnection Security Agreement (ISA) are required to participate in the System-to-System data exchange.

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

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

3.6 Is a regulatory partner required to use a specific system to participate in the System-to-System data exchange?

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

3.7 Does a regulatory partner have to conduct a certain number of inspections to participate in data exchange?

No. There are no minimum or maximum number of inspections that should be conducted by regulatory partners to participate in the data exchange program. However, per state contracts, a minimum of ten inspections are expected.

3.8 Can any regulatory partner participate in any data exchange capability?

Yes. Any regulatory partner can participate in any data exchange capability. There could be additional participation criteria for certain data exchange capabilities. For example, Manufactured Food Regulatory Program Standards (MFRPS) conformance is required to participate in non-contracted inspection data exchange capability.

3.9 Is there a checklist for regulatory partners to prepare for System-to-System data exchange?

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

3.10 What are the steps for regulatory partners to enable System-to-System data exchange?

The FDA team works with the regulatory partner to outline the Partner Integration Plan that identifies activities to enable the System-to-System data exchange. The integration plan is tailored for each partner and will have details on the following:

- Integration coordination and support
- Agreements between FDA and partner
- Partner development milestones
- Test data for development
- Test scripts for testing
- Enabling the System-to-System integration
- Recommendations for future upgrades

In addition to the Partner Integration Plan, an Integration Guide is provided to the partner. The guide provides the Application Program Interface (API) details, data exchange messages, error handling, security aspects, etc., for System-to-System data exchange.

3.11 How long does it take for a regulatory partner to enable System-to-System data exchange?

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.

3.12 How does participation in the ORA DX help regulatory partners?

Participation in the ORA DX provides regulatory partners improved information sharing capabilities with FDA. At a very minimum, it eliminates dual data entry in the state system and FDA system and any challenges associated with it. Partners Portal is envisioned to be the centralized and comprehensive portal for all the electronic data exchange between regulatory partners and FDA. It is planned that additional FDA data, that will benefit regulatory partners, will be made available to the partner in the future.

3.13 Is training available for regulatory partners on ORA DX Systems?

Yes, online training is provided to current users (regulatory partners), FDA state liaisons, and other FDA staff about the data exchange capabilities of the ORA DX systems. Trainees could choose from instructor-led course (lecture only or interactive) and 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.

3.14 Can the regulatory partners / state agencies not participating in the ORA DX enroll for training?

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

4 ORA Data Exchange (DX) Systems

4.1 Does FDA provide the data exchange specifics and file format to regulatory partners for System-to-System 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 and Partners Portal data exchange mechanisms. For some capabilities in Partner 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.

4.2 Will the ORA DX systems replace eSAF, and what is the timeline?

Yes, FDA plans to retire eSAF and migrate selected capabilities into ORA DX systems. The timeline for retiring eSAF is still being finalized. FDA expects to announce the timeline in 2021, and the retirement date will be scheduled for 2022 at the earliest.

4.3 Will the ORA DX replace regulatory partner system?

No. ORA DX is not intended to replace any regulatory partner's system.

4.4 Does System-to-System data exchange support uploading inspection report documents?

No. Currently, System-to-System data exchange does not support uploading the inspection report documents. Attachments or document upload capability is planned for the future. Until then, reports related to inspection data received through System-to-System must be delivered to the appropriate FDA Division via eSAF, hard copy via mail, or other FDA-approved systems as determined by the FDA Division. Please note that the method of receipt for these reports is at the discretion of the FDA Division. If the FDA Division requires reports to be uploaded in eSAF, then System-to-System data exchange cannot be used for this action until the capability is available.

4.5 How does a partner sign-up for a DX capability?

The partner could either email NFSDX_Info@fda.hhs.gov or contact their FDA state liaison or field management indicating the participation interest. 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.

4.6 Does the System-to-System have more capabilities than Partners Portal data exchange?

Yes. Currently, System-to-System provides more capabilities than Partners Portal data exchange. Moving forward, both solutions will be enhanced incrementally to provide a comprehensive data exchange mechanism between FDA and partners.

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

No. Currently, the System-to-System has more capabilities than the Partners Portal. Both solutions will continue to be enhanced incrementally as separate tracks per FDA priorities and regulatory partner.

4.8 What capabilities are planned for the System-to-System and Partners Portal?

The new capabilities planned to be deployed in October 2020 (tentative) are:

- Submit State Collected Sample Data to FDA
- Submit State Collected Sample Data via Excel spreadsheet to FDA

Other capabilities planned for the FY21 and FY22 include:

- Expanding Firm History to provide additional information like recalls, qualified facility registration, etc.
- Bulk upload of Contracted Inspections spreadsheet
- Upload supporting documents and attachments for Contracted Inspections
- Support for additional inspection types

4.9 Do Partners Portal and System-to-System data exchange mechanisms interact?

Yes. The Partners Portal and System-to-System data exchange mechanisms are integrated within FDA framework.

4.10 What is the process for regulatory partner to request new ORA DX accounts?

To request accounts by approved regulatory partners (users) for the Partners Portal, the partner will have to email the DX Outreach Team at NFSDX_Info@fda.hhs.gov. Information about the users such as first and last name, agency name, email address, and DX capability information should be provided. FDA will authorize and provide login credentials directly to the user.

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

4.11 What is the process for regulatory partner to communicate for termination of ORA DX 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 data exchange, the partner needs to inform the 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 data exchange.

4.12 Does DX allow regulatory partners to upload an Excel spreadsheet of inspections data?

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

4.13 Will the ORA DX replace eLEXNET?

Yes. The eLEXNET capabilities are being transitioned to the ORA DX. FDA stopped collecting all surveillance, voluntary, or required data via eLEXNET on May 31, 2020. eLEXNET will be completely retired on September 30, 2020.

4.14 Why is eLEXNET being 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).

4.15 How will the states submit regulatory sample data after eLEXNET retirement?

States can submit the regulatory sample data via System-to-System, Partner Portal or Enhanced DX Client. The participating states have been provided detailed instructions, including account and process information. For additional information, contact the ORA DX Outreach team at NFSDX_Info@fda.hhs.gov.

4.16 Will existing eLEXNET users be automatically moved over to the Partners Portal?

No. Existing users will not be transitioned to Partners Portal along with eLEXNET capabilities transition. Users would need to request an account in Partners Portal.

4.17 What is the difference between FoodSHIELD and System-to-System data exchange?

FoodSHIELD is a web-based secure system and collaborative workspace for communication, coordination, education, and training among the nation's food and agriculture sectors. It is a portal dedicated to Food and Agriculture Sector professionals, serves as a critical federal-state collaboration portal enabling the planning and implementation of a collaborative Online Integrated Food Safety System.

System-to-System data mechanism enables electronic data transfer from regulatory partners' system into FDA systems of record. It also enables regulatory partners to search FDA systems of record for certain data.

4.18 What information can be shared using FoodSHIELD and System-to-System data exchange?

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 are used to share regulatory and compliance data between regulatory partners and FDA. It is built for regulatory partners 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.

5 Data Aspects

5.1 Do ORA DX systems send any data back to regulatory partners?

Currently, ORA DX systems (System-to-System and Partners Portal) send only acknowledgements of data exchange and error messages back to regulatory partners. However, both systems allow partners to download FDA firm data.

5.2 Do ORA DX systems store any data?

System-to-System data exchange 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 data exchange is integrated with FDA systems of record where the data is saved. Similar to the System-to-System, Partners Portal also integrates with the FDA systems of record. Additionally, Partners Portal stores produce safety farm inventory data files. Furthermore, Partners Portal will be a repository for reports and catalogs related to the data exchange capabilities.

5.3 Can inspections with incorrect data be returned to the regulatory partner via ORA DX?

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 data exchange.

5.4 Will contracted inspection data submitted via ORA DX be available in ORADSS, FDA system?

Yes. The ORA DX systems (System-to-System and Partners Portal) are integrated with FDA systems of record. Currently, only the System-to-System mechanism enables inspection data exchange. The inspections data is saved into eSAF. eSAF continues to integrate with 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 What is an FDA product code and how do I locate and build product codes?

An FDA product code describes a specific product and contains a combination of five to seven numbers and letters. The product code submitted with each FDA line item should match the actual product name and/or invoice description of the product.

If the product has more than one name (e.g., a fish known under several regional names), the product code may have several different synonymous definitions associated with it. The easiest way to determine the product code is to become familiar with the product itself, including the label, the processing information, intended use of product, the container type, who will use or consume the product, etc.

The Product Code Builder online tool/application will guide you through an easy and user-friendly selection process that will assist in locating and building a product code. By building upon the code portions you select, the application will provide valid choices for each of the five components of the product code (Industry, Class, Subclass, PIC, and Product). For more information and a tutorial please visit https://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm.

6 Glossary of Acronyms

Acronym	Description
AFRPS	Animal Feed Regulatory Program Standards
BSE	Bovine Spongiform Encephalopathy
CAP	Cooperative Agreement Program
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
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
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