Office of Regulatory Affairs (ORA)

Data Exchange (DX)

Frequently Asked Questions (FAQs)

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FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

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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.

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2 Point of Contact (POC)

For additional information, contact the ORA Apps Desk at appsdesk@fda.hhs.gov 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?

The ORA DX program enables information sharing between regulatory partners and Food and Drug Administration (FDA). Two IT systems have been implemented to support secure data exchange: Partners Portal (ORAPP) and System-to-System (NFSDX). The ORA DX program also includes the Enhanced DX Client which supports the submission of sample data (i.e., collection, receipt, and analysis data) to FDA. Participation provides regulatory partner with the benefits such as increase in efficient electronic data exchange between FDA and regulatory partner, increase in collaboration, and reduction of dual manual data entry in regulatory partner and FDA systems.

3.2 Should a regulatory partner participate in both of the ORA DX systems (System-to-System and Partners Portal)?

No. A regulatory partner could choose to participate in either of the ORA DX systems, or both. The System-to-System (NFSDX) provides direct electronic data exchange between regulatory partner and FDA systems, which requires IT resources and effort by regulatory partner. The Partners Portal (ORAPP) is a website for regulatory partner to exchange data with FDA. It does not require any system integration effort by a regulatory partner.

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

Yes. The Food and Feed 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 regulatory partner with the improved information sharing capabilities with FDA. At a minimum, it eliminates dual data entry in the State's system and FDA's system and any challenges associated with the related 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 may be made available to partners in the future.

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

Regulatory partner should contact the ORA Apps Desk at appsdesk@fda.hhs.gov or contact FDA state liaison or field management to indicate participation interest. In certain instances, FDA reaches out to the regulatory partner based on various FDA initiatives and ORA DX outreach. Every participation request is reviewed and approved by FDA.

3.6 Which technical components are used in the System-to-System?

The System-to-System uses the technical components such as XML schema definition, Java, and Soap Web Services.

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

Yes. FDA provides the data fields, formats (XML schema definitions), message constructs, etc., necessary to exchange data using the System-to-System. For the Partners Portal, FDA provides predefined Excel templates with data fields, data requirements, mapping information to map state data fields to 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 at appsdesk@fda.hhs.gov 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, FDA authorizes and provides login credentials to the agency for the System-to-System or the user for the Partners Portal.

3.9 Is a regulatory partner's participation in ORA DX program on a voluntary basis?

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 FDA.

3.10 Is ORA DX systems training available for any regulatory partner?

Yes. Virtual training is available for current users (regulatory partners) of the Partners Portal at no cost. There are additional trainings internal to FDA.

The following trainings are currently offered:

- FDA Collected Samples
  - Samples Receipts and Analysis
- Firm Search History and Firm History
- Non-Contracted Inspection
- State Collected Samples
  - Samples Collection
  - Samples Receipts and Analysis

Trainees can register for instructor-led courses (lecture or demo or interactive) and potentially have access to the recordings. To learn more about the course catalog and training schedule, contact the ORA Apps Desk at appsdesk@fda.hhs.gov.

4 Partners Portal (ORAPP)

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

4.1 Do ORA DX systems allow a regulatory partner to upload an Excel spreadsheet of inspections data?

Yes. The Partners Portal supports Non-Contracted Inspection data sharing via FDA defined Excel templates. However, the System-to-System does not support any Excel spreadsheet.

4.2 Which browsers are supported by the Partners Portal?

For the browsers support in the Partners Portal, click here.

5 System-to-System (NFSDX)

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

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

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

5.2 What are the steps for a regulatory partner to enable the System-to-System?

FDA works with a regulatory partner to outline the systems activities to enable the System-to-System 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 System-to-System capability. These guides provide the Application Program Interface (API) details, data exchange messages, error handling, security aspects, etc.

5.3 Does the System-to-System support the sharing of inspection report documents?

Yes. For inspection data sharing, the System-to-System supports the upload and deletion of attachments along with the retrieval of the list of inspection attachments - not to be confused with the actual attachments.

5.4 Do the System-to-System and Partners Portal 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 FDA and regulatory partner.

5.5 Are the ORA DX systems (Partners Portal and System-to-System) separate systems?

Yes. The Partners Portal and System-to-System are separate systems yet integrated to a certain extent within FDA's Information Technology framework.

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

No. The System-to-System 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 System-to-System?

Multiple factors influence the System-to-System 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 FoodSHIELD and System-to-System?

The 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.

The System-to-System is an ORA DX system which enables electronic data sharing from regulatory partner's system into FDA system.

5.9 What information can be shared using the FoodSHIELD and System-to-System?

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.

The System-to-System 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.

5.10 Can a regulatory partner purchase the System-to-System?

No. The System-to-System cannot be purchased like a commercial off-the-shelf (COTS) product. FDA provides documentation and guidance to regulatory partner at no cost to enable the System-

to-System integration . Regulatory partners incur their IT costs for development, testing, and other activities required for the integration.

6 FDA Systems Retirement

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

6.1 Why was Electronic Laboratory Exchange Network (eLEXNET) retired?

Several factors influenced 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) 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 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 the Partners Portal.

6.2 Did the ORA DX systems replace eLEXNET?

Yes. Certain eLEXNET capabilities migrated to the ORA DX systems. FDA stopped collecting any 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 Electronic State Access to FACTS (eSAF), and what is the timeline?

Yes. FDA is planning to retire eSAF and migrate selected capabilities into the ORA DX systems. FDA expects to announce the transition and retirement timeline in 2021.

7 Overall ORA DX Program, Systems, and Capabilities

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

7.1 Does a regulatory partner participation in ORA DX program require FDA approval?

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

7.2 How does a regulatory partner request additional information about ORA DX systems and capabilities?

Regulatory partner should contact the ORA Apps Desk at appsdesk@fda.hhs.gov or use the links on the Contact Us page of the Partners Portal.

7.3 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 the state.

7.4 Is LFFM a requirement for a state lab to participate in sample data exchange via ORA DX systems?

No. LFFM is not a requirement for a 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.

7.5 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 FDA State Liaison and the Emergency Response Coordinator. In the near future, work packages may be submitted via the ORA DX systems.

7.6 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 FDA Program Division Director or assigned FDA designee. In the future, the sample results may be submitted via the ORA DX systems.

7.7 How does a regulatory partner access FDA Establishment Identifier (FEI) without firm search and history access in the Partners Portal?

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.

7.8 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 Product Code Builder 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.

7.9 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 FDA for information about inspectional activities.

7.10 What is the process for a regulatory partner to request termination of ORA DX systems' accounts?

A regulatory partner should contact the ORA Apps Desk at appsdesk@fda.hhs.gov to request to terminate ORA DX systems' account. However, a regulatory partner need not notify FDA about any of their system's user account changes.

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

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

7.12 Is Manufactured Food Regulatory Program Standards (MFRPS) compliance required for a 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 inspections data exchange with FDA via ORA DX systems.

7.13 Can a regulatory partner enroll for ORA DX systems training without participating in the ORA DX program?

No. Currently, training is available for ORA DX systems users only. However, in the future the ORA DX systems training/preview may be offered to prospective ORA DX program participants.

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

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

7.15 Can any regulatory partner participate in any ORA DX system and capability?

Yes. Any regulatory partner can choose to participate in any ORA DX system and capability. There could be additional participation criteria for certain ORA DX capabilities. For example, MFRPS conformance is required to participate in ORA DX non-contracted inspection capability.

7.16 Do the ORA DX systems send any data back to a regulatory partner?

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

7.17 Do ORA DX systems store any 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.

7.18 Can inspections 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 regulatory partner.

7.19 Is the contracted inspection data submitted via ORA DX available in ORADSS, FDA system?

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

7.20 Are FDA firm updates allowed via ORA DX?

Yes. Currently, the System-to-System allows updates for FDA firm inventory along with the inspection data. The recommended inventory updates are inspection specific and are manually reviewed by 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 FDA and regulatory partner. FDA firm inventory will be updated using insights from the regulatory partner during planning and inspections phases. Similarly, updates from FDA inventory will be sent to regulatory partner during their planning and pre-inspections preparation activities.

7.21 How is FDA protecting the documents that a regulatory partner provides to FDA as a result of an inspection?

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

7.22 How does FDA expect a regulatory partner to safeguard information collected as a result of contracted inspections?

Every regulatory partner working with FDA is required to sign a single signature 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) at ORAinfoshare@fda.hhs.gov for additional information.

8 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
POC	Point of Contact
RRT	Rapid Response Teams
SOAP	Simple Object Access Protocol
XML	Extensible Markup Language