

# ORA Data Exchange (DX)

## Frequently Asked Questions (FAQ) Knowledge Article

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### Summary

Frequently Asked Questions (FAQs) are easy to understand support documents in a question and answer (Q&A) format that allows users to quickly find answers to questions about the Office of Regulatory Affairs (ORA) Data Exchange (DX) program and systems.

### FAQ Overview

The ORA DX program maintains two FAQ documents to support current and prospective users of ORA DX systems: **ORA DX FAQ**, and **ORA DX Sample Data Sharing FAQ**. FAQs are searchable, downloadable, and printable PDFs that contain a dynamic table of contents (TOC) for ease of navigation. Users can navigate directly to an answer by selecting a question in the **TOC** or by using the **Find** tool to search for specific information.

- **ORA DX FAQ**
  - Q&A style comprehensive document containing questions and answers regarding the overall ORA DX program and systems (ORA Partners Portal [ORAPP], System-to-System, and Enhanced DX client).
  - Organized by topics including top FAQs, ORAPP, System-to-System, FDA Systems Retirement, Overall DX Systems and Capabilities, Inspection and Inventory Data Sharing, Sample Data Sharing, and Training.
  - Accessible to the public.
  - Updated every ORA DX release.
- **ORA DX Sample Data Sharing FAQ**
  - Q&A style document that focuses on the Sample Collection, Receipt, and Analysis data sharing capabilities of the ORA DX systems.
  - Organized by topics including top FAQs, Sample Data Sharing, Sample Collections, Sample Receipt and Analysis, and the Glossary of Acronyms.
  - Accessible to authorized users who are logged into ORAPP.
  - Updated when there are significant changes to the sample data sharing capabilities.

### Access the ORA DX FAQ

The ORA DX FAQ can be accessed via the [ORAPP Homepage](#) and [Contact Us page](#) in addition to the [Partnership for Food Protection \(PFP\) Information Technology \(IT\) Workgroup \(WG\)](#) site.

#### Access via ORAPP Home Page

1. Navigate to the [ORAPP homepage](#) using a web browser.
2. In the **Contact Us** section located at the bottom of the page, select the **Frequently Asked Questions (FAQ) about the ORA Data Exchange** link.

### About the ORA Data Exchange

The Office of Regulatory Affairs Data Exchange (ORA DX) is a unified platform to securely share information between FDA, state, and local regulatory partners. Built under FDA's efforts to implement the Food Safety Modernization Act (FSMA), the Partnership for Food Protection (PFP) supporting the national Integrated Food Safety System (IFSS), and FDA's Domestic Mutual Reliance (DMR) initiatives, the ORA DX mission is to streamline submission of food safety regulatory data and support timely and accurate decision making by providing access to relevant inventory, sample, and inspection information.

[Learn more about ORA Data Exchange capabilities](#)

### PFP IT WG

The PFP Information Technology (IT) Workgroup (WG) supports the ORA DX program. The PFP IT WG objectives and activities are driven by the 5-year PFP Strategic Plan to support collaborative IT efforts across various food safety officials of local, state, and federal agencies in protecting the food supply and public health.

The PFP IT WG meets quarterly to share and discuss about the FDA's ORA Data Exchange program and elicit input from the regulatory partners. For more information on how to participate, contact us via the [Contact Us](#) page.

### News and Updates

- [What's New in the ORA Data Exchange](#)
- [ORA DX One Pager](#)
- [PFP IT WG Newsletter \(March 2024\)](#)
- [PFP IT WG Newsletter \(December 2023\)](#)
- [PFP IT WG Newsletter \(September 2023\)](#)
- [PFP IT WG Newsletter \(June 2023\)](#)

### Contact Us

- [Login Credentials Support for Existing Users](#)
- [General Information, Demo Request, or Request an Account](#)
- [Frequently Asked Questions \(FAQ\) about the ORA Data Exchange](#)

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[IFSS](#)

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[PFP](#)

[FoodSHIELD](#)  
[Sitemap](#)

[FSMA](#)  
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3. The document opens in a separate tab within the browser.

#### Access via ORAPP Contact Us Page

1. Navigate to the [ORAPP homepage](#) using a web browser.
2. Select **Contact Us** on the menu bar.

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

**1 ORA Partners Portal**

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[Learn more about ORA Data Exchange capabilities](#)

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### Contact Us

[Login Credentials Support for Existing Users](#)

3. Select the **ORA DX FAQ** link located in the FAQ section of the page.

**Contact Us**

For ORA DX Support, complete the form below or contact the ORA Applications Help Desk at 240-247-8803.

\* Category

\* Subcategory

\* First Name


\* Last Name

\* Email Address

Phone Number

Message

Click the "I'm not a robot" checkbox to complete the anti-spam verification process.

☐ I'm not a robot 

\* Indicates required field

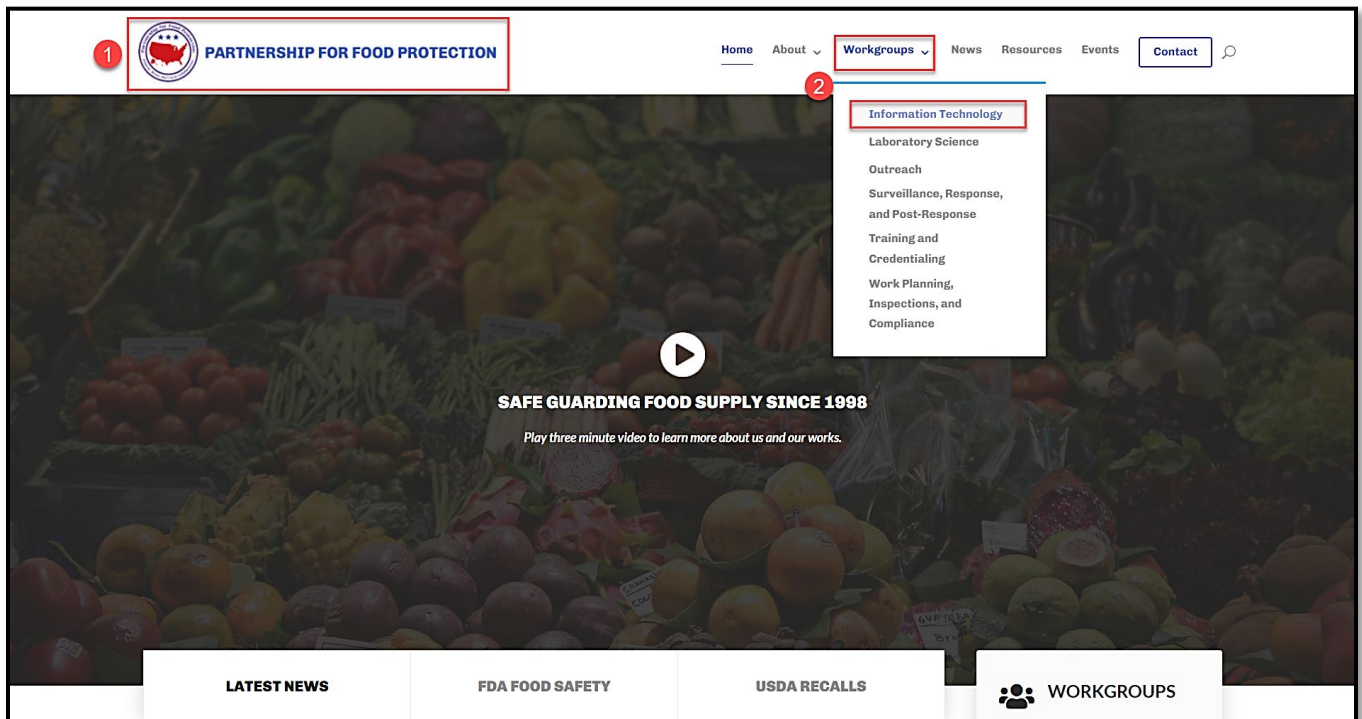
**Phone**  
Contact the ORA Applications Help Desk at 240-247-8803

**FAQ**  
[Frequently Asked Questions \(FAQ\) about the ORA Data Exchange](#)

4. The document opens in a separate tab within the browser.

#### Access via PFP IT WG Site

1. Navigate to the [PFP site](#) using a web browser.
2. Hover over **Workgroups** on the menu bar and select **Information Technology** on the dropdown menu.



3. Select the **ORA Data Exchange (DX) Frequently Asked Questions (FAQ)** link. The document opens in a separate window within the browser.

## Information Technology

### About

The goal of Information Technology Workgroup (IT WG) is to provide a collaborative information technology (IT) vision and approach for sustainable, uniform electronic data exchange for national Integrated Food Safety System (IFSS) partners. To achieve this goal, the workgroup has undertaken technical projects advancing abilities to harmonize a compatible IT environment between regulatory partners.

The WG identifies and addresses IT needs across various facets of an IFSS. The WG promotes data standards and develops common data schemes to facilitate secure information exchange among strategic partners to support food safety initiatives. This includes addressing the data sharing requirements, specifically by harmonizing and developing compatible IT environments among regulatory partners. Sharing of information will help to achieve the goal of mutual reliance for a safer food supply.

The PFP IT WG supports the U.S. Food and Drug Administration Office of Regulatory Affairs (ORA) Data Exchange (DX) program and systems; this includes the National Food Safety Data Exchange (System-to-System) and the ORA Partners Portal (ORAPP).

### ORA DX Resources

ORA DX program provides additional resources for the regulatory partners to learn about the ORA DX program, systems, and participation.

### One Pager

The [ORA DX One Pager](#) gives a high-level overview of the ORA DX Program; highlighting data exchange areas, benefits, solutions, and the onboarding process.

### Frequently Asked Questions (FAQs)

**3** [ORA DX FAQs](#) provide a list of frequently asked questions and answers about the ORA DX program and systems. The document is updated with every ORA DX release.

#### WORKGROUPS

- Information Technology
- Laboratory Science
- Outreach
- Surveillance, Response, and Post-Response
- Training and Credentialing
- Work Planning, Inspections, and Compliance

## Access the ORA DX Sample Data Sharing FAQ

The ORA DX Sample Data Sharing FAQ can be accessed via the **Sample Collection Guidance Materials** located on the ORAPP Sample Collections page or via the **Sample Receipt and Analysis Guidance Materials** located on the ORAPP Sample Receipt and Analysis page.

### Access via ORAPP Sample Collections Page

1. Navigate to the [ORAPP homepage](#) using a web browser.
2. **Log in** to ORAPP using the FDA provided credentials.
3. Hover over **Samples** on the menu bar and select the **Sample Collections** submenu.



4. Select the **Download Guidance Materials** link and the **Collection Guidance Materials.zip** folder appears in the **Downloads** folder. **Note:** The location of the Downloads folder varies based on the browser used.
5. Access the **Collection Guidance Materials.zip** folder from the **Downloads** folder.

**Sample Collections Data Exchange**

Submit results using the Sample Collections Excel Template that is available to download below.

[Download Sample Collections Excel Template\\_v1.6](#) [Download Guidance Materials](#)

To submit Sample Collections data for processing, **DO NOT:**

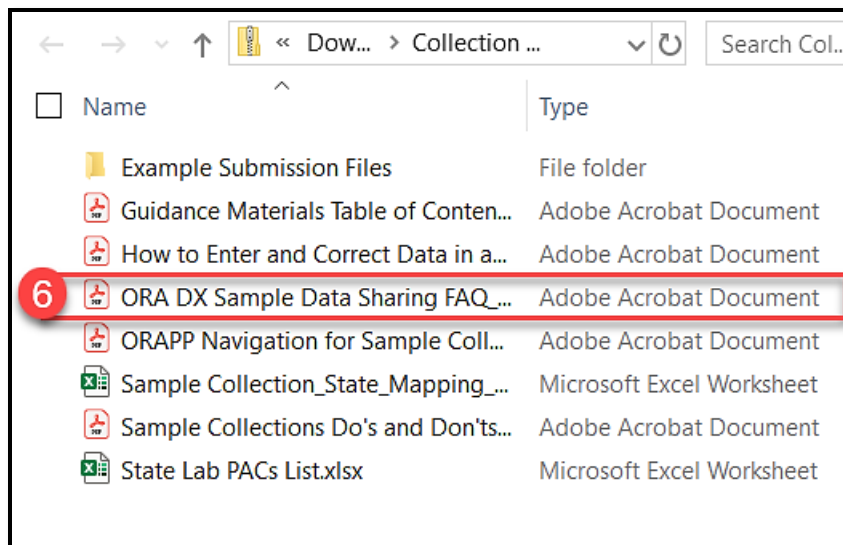
- Password-protect the file
- Reuse a previously submitted filename
- Use a filename longer than 75 characters or containing \* " : ? / \ < >
- Upload more than 10 files at one time
- Upload a file more than 2 MB in size

Click the Refresh icon to view the latest processing information for the submitted files.  
Processed files can be downloaded by clicking the Download icon. The processed files will be available for download for one year from the Submission Date.

**Select Files** Refresh

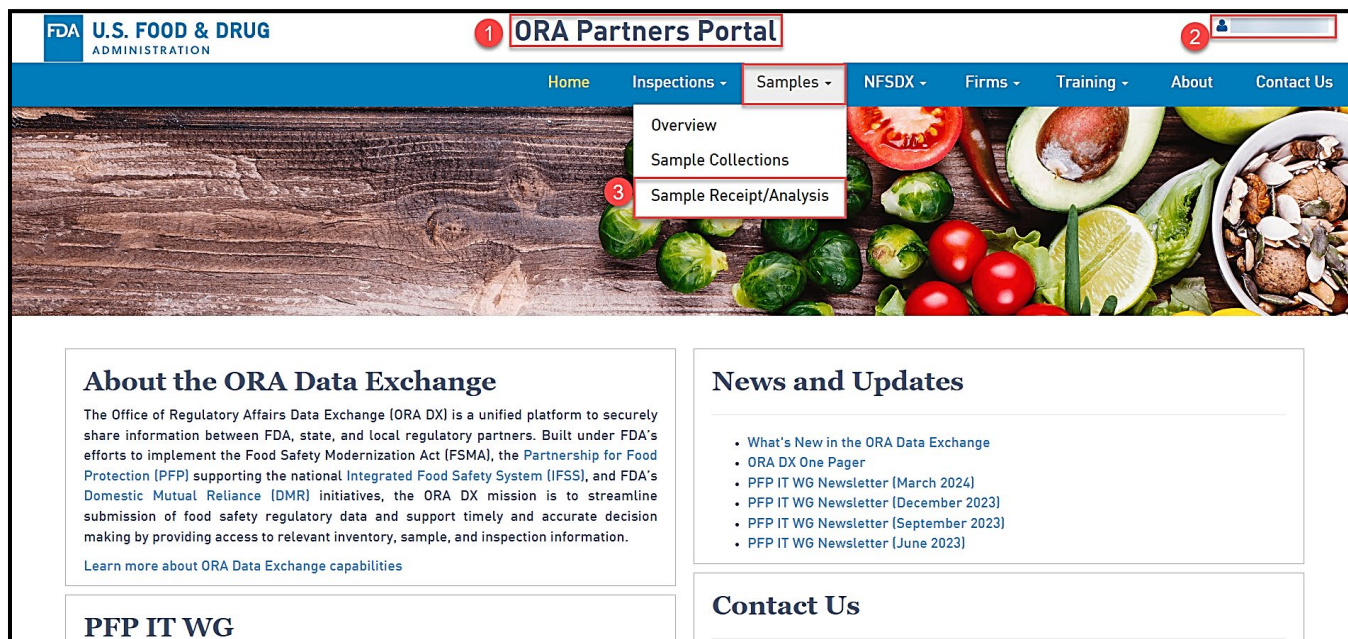
Filename	Submission Date	Submitted By	Status	Status Summary
17_0_SC_NIS_SN.xlsx	1/11/2024	Sharlitta Nipper	Success	No errors found. 1 sample collection and/or PAF/PAC additions were processed successfully. Click on the eye icon in the Status column or refer to your email to view the list of the Lab Sample Number(s) and the corresponding FDA Sample Number(s) associated with the submission file.
17_0_SC_NIF_SN.xlsx	1/11/2024	Sharlitta Nipper	Success	No errors found. 1 sample collection and/or PAF/PAC additions were processed successfully. Click on the eye icon in the Status column or refer to your email to view the list of the Lab Sample Number(s) and the corresponding FDA Sample Number(s) associated with the submission file.
Dec14_SCollection_SB10(1).xlsx	1/24/2023	Sharlitta Nipper	Success	No errors found. 1 sample collection and/or PAF/PAC additions were processed successfully. Click on the eye icon in the Status column or refer to your email to view the list of the Lab Sample Number(s) and the corresponding FDA Sample Number(s) associated with the submission file.

6. Open the **ORA DX Samples Data Sharing FAQ** document to reference the contents.



#### Access via ORAPP Sample Receipt and Analysis Page

1. Navigate to the [ORAPP homepage](#) using a web browser.
2. **Log in** to ORAPP using the FDA provided credentials.
3. Hover over **Samples** on the menu bar, then select **Sample Receipt and Analysis** submenu.



4. Select the **Download Guidance Materials** link and the **Sample Analysis Guidance Materials.zip** folder appears in the **Downloads** folder. **Note:** The location of the Downloads folder varies based on the browser used.
5. Access the **Sample Analysis Guidance Materials.zip** folder from the **Downloads** folder.

**ORA Partners Portal**

Home Inspections Samples NFSDX Firms

**Sample Receipt and Analysis Data Exchange**

Submit results using the Sample Receipt and Analysis Excel Template that is available to download below.

[Download Sample Receipt and Analysis Excel Template\\_v2.8](#) [Download Guidance Materials](#)

To submit Sample Receipt and Analysis data for processing, **DO NOT**:

- Password-protect the file
- Reuse a previously submitted filename
- Use a filename longer than 75 characters or containing \* " : ? | \ / < >
- Upload more than 10 files at one time
- Upload a file more than 2 MB in size

Click the Refresh icon to view the latest processing information for the submitted files.  
Processed files can be downloaded by clicking the Download icon. The processed files will be available for download for one year from the Submission Date.

Select Files Refresh

Colorado Department of Public Health				
Filename	Submission Date	Submitted By	Status	Status Summary
17_0_SR_SA_NIS_ERROR_SN.xlsx	1/12/2024	Sharlitta Nipper	Errors	The submission was not successfully processed due to validation error(s). 0 sample receipts and/or analyses were processed successfully and 2 returned errors that need to be corrected. Click on the eye icon in the Status column or refer to your email to review the error(s) associated with the submission. Make any necessary corrections and resubmit the file using a new filename.
17_0_SR_SA_NIS_SN.xlsx	1/12/2024	Sharlitta Nipper	Success	No errors found. 2 sample receipts and/or analyses were processed successfully. Click on the eye icon in the Status column or refer to your email to view the list of the FDA Sample Number(s) associated with the submission file.

6. Open the **ORA DX Sample Data Sharing FAQ** document to reference the contents.

Navigation: < > << Dow... > Sample An... Search Sa...

Name	Type
Analysis Type Specific Guidance	File folder
Example Submissions	File folder
Guidance Materials Table of Conte...	Adobe Acrobat Document
How to Enter, Update, and Correct ...	Adobe Acrobat Document
<b>ORA DX Sample Data Sharing FAQ...</b>	<b>Adobe Acrobat Document</b>
ORAPP Navigation for Sample Rec...	Adobe Acrobat Document
Sample Receipt and Analysis Do's ...	Adobe Acrobat Document
State_Mapping_File_V17.0.0.xlsx	Microsoft Excel Worksheet

## Contact Us

The ORA DX Training Team would love to hear from you to continuously improve ORA DX training. Contact us via the [ORAPP Contact Us](#) page for ORA DX training inquiries and support, course and KA requests, or to provide feedback on ORA DX training.