

Micro LFFM Human & Animal Food State Surveillance Data Entry Instructions

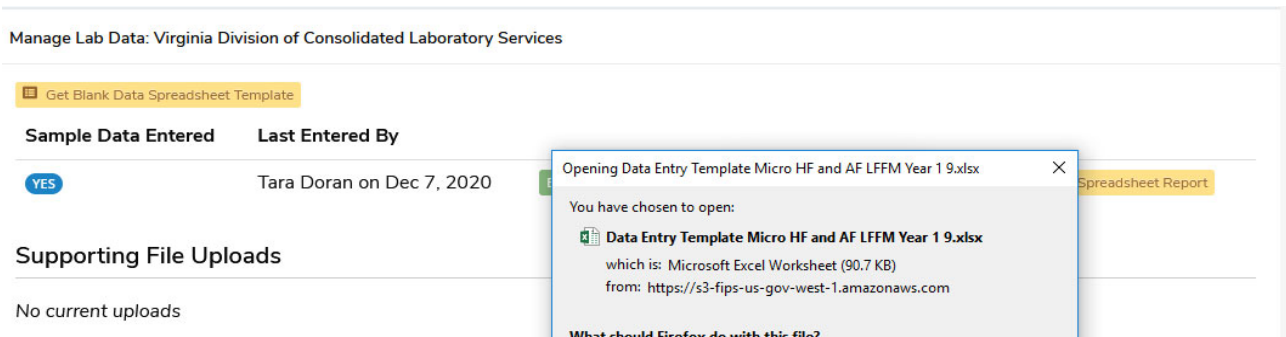
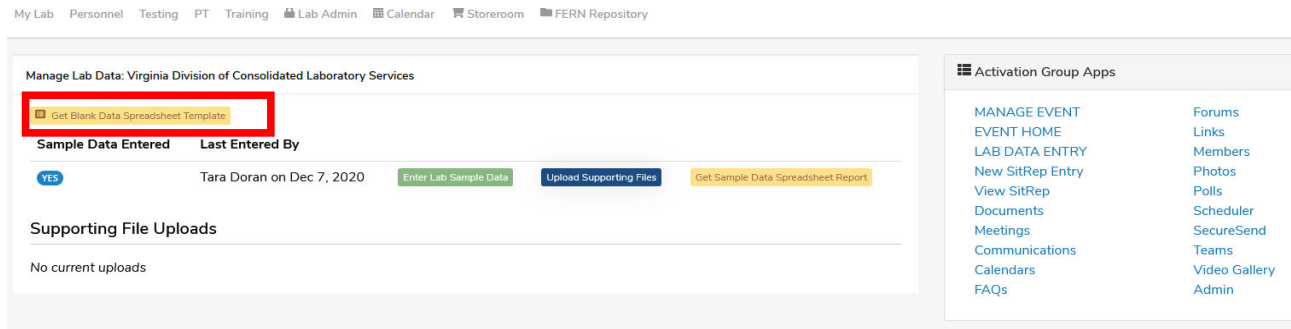
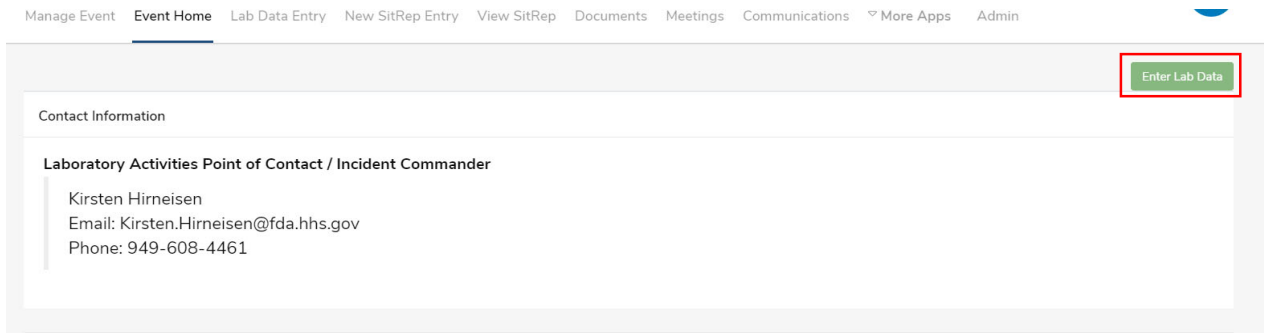
Quarterly Surveillance Data Spreadsheet

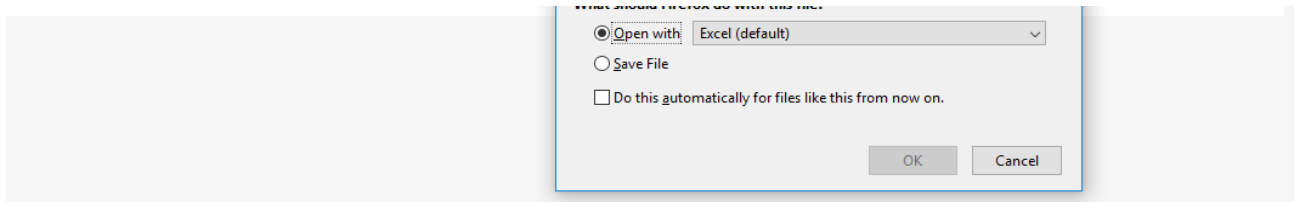
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At the Beginning of the Budget Period

1. Enter the activation workgroup “LFFM M-HAF Product Testing Track Quarterly Reporting”
2. Download the surveillance template from Lab Data Entry portion of the workgroup.
 - a. Click “Enter Lab Data”
 - b. Click “Get Blank Data Spreadsheet Template”
 - c. Open with Excel





3. Save the template in your files without changing any rows, columns or cells in the spreadsheet. You can enable editing. This will serve as the document that you will use to track your surveillance data.

Throughout the Budget Period

4. Record surveillance data throughout the budget period in the spreadsheet without changing anything about the template including column headers, sizes, blank areas, row heights, etc.

a. Columns A-P are required to be filled out for each sample (see exception for column G, below). If you do not have the information for those columns you can write “unknown”.

i. Recording ‘unknown’ is **not appropriate** for all fields.

1. For example – If an expiration date is not listed on the label, it is okay to record ‘unknown’ in this field. It is not appropriate to record ‘unknown’ for manufacturer/brand, or collection date, or other key identifying information about the sample.

ii. For human food samples, record “N/A – Human Food” in column F, and then column G can be left blank

b. **SPECIAL NOTES – IMPORTANT:**

i. If your lab chose to use LFFM funds to do Cronobacter testing for the recent event in Infant Formula, please report all LFFM funded Cronobacter samples. As there is no column for Cronobacter in the reporting template, please use the "Other Analyte" Column and write in "Cronobacter sakazakii" (NOTE: This is not an option in the drop down menu and must be typed in).

ii. Commodity Category (Assigned) – Column E – this MUST be the commodity category selected for your sample-product must match the assigned commodity/hazard pair category that was on your approved Sampling Plan

1. Special note – if your laboratory participated in the FDA 3rd party (IEH) cereal assignment, record your samples against the category “RTE packaged/boxed cereals & granolas (not bulk)”, even if it was not on your current budget period's approved sampling plan. In Comments (very last field), record “FDA 3rd Party Cereal Assignment”. Record samples that were analyzed during the LFFM budget period/reporting period.

iii. Country of Origin – this it is the country of the manufacturer/processor (responsible firm).

Examples:

1. Enoki mushrooms, says ‘distributed by’ a US company, product of China – record China as country of origin

2. Cashews, says ‘packed/processed by’ a US company, and on label lists ‘contains cashews from vietnam, brazil, ivory coast’ – record US as country of origin

3. Identity of firm that produced the product unclear – record ‘unknown’ for country of origin

iv. Collecting Entity – Column M

1. If collected by laboratory analysts, write “Laboratory”

2. If collected by a regulatory program, write the Agency name and the program name – E.g., State Department of Agriculture, Food Safety Division

3. Special note – if your laboratory participated in the FDA 3rd party (IEH) cereal assignment, enter “IEH – FDA 3rd Party Cereal Assignment”

v. Analyte fields: Screen, Confirmatory, Final

1. Screen Result values:

- a. CRO – Cannot Rule Out – please select if a screen was performed and the result was detected
- b. ND – Not Detected – please select if a screen was performed and the result was not detected
- c. N/A – Not Performed – please select if you were testing for the analyte, but did not perform a screening test

2. Confirmatory Result values:

- a. Salmonella spp. (or other analyte) Found – please select if a confirmatory test was performed and the result was detected
- b. No Salmonella spp. (or other analyte) Found – please select if a confirmatory test was performed and the result was not detected
- c. N/A – Not Performed – please select if you were testing for the analyte, but did not perform a confirmatory test (e.g., because the screen was not detected)

3. Final Result values

- a. Salmonella spp. (or other analyte) Found – please select if the confirmatory test showed that the target analyte was detected
- b. Negative – please select if a screen test showed the target analyte was not detected (no confirmatory test performed), or a confirmatory test showed the target analyte was not detected.

vi. Salmonella Serotype – Column U – for poultry feed samples positive for *Salmonella* only, please enter the Salmonella serotype

vii. Comments – Column BG – for positive samples, please include any details re: state action taken on the sample results – embargo, recall, consumer advisory, etc.

c. Leave testing columns **blank** if you did not perform that testing.

i. Do not put N/A in columns/fields for analytes you didn't test for. For example – Tomatoes analyzed for Salmonella: N/A in Confirmatory test has meaning (confirmatory test was not performed, screen was Not Detected); do not put N/A in the Listeria, Campy, Cyclo analysis fields – leave them blank.

d. Leave Turn-Around-Time columns **blank** – we will fill them out later using a formula (NETWORKDAYS - number of work days between the time you finished analysis and the time you started the analysis, will also remove federal holidays from the calculation).

e. Please check all dates for typos (correct budget periods) before submitting

5. FDA ORS will coordinate when your surveillance data should be uploaded to the data entry section. This will happen on a quarterly basis and should not be done until prompted. **NOTE: Any sample testing resulting in a CRO or confirmed positive must be communicated immediately to the LFFM Inbox and HAF Division Inbox and cannot wait until the quarterly upload.**

Submitting your Data

How the FERN Activation Data Entry Module Works

When you upload a new spreadsheet (dataset), the system looks at the Sample ID field and compares it to the data already in the system that your lab submitted.

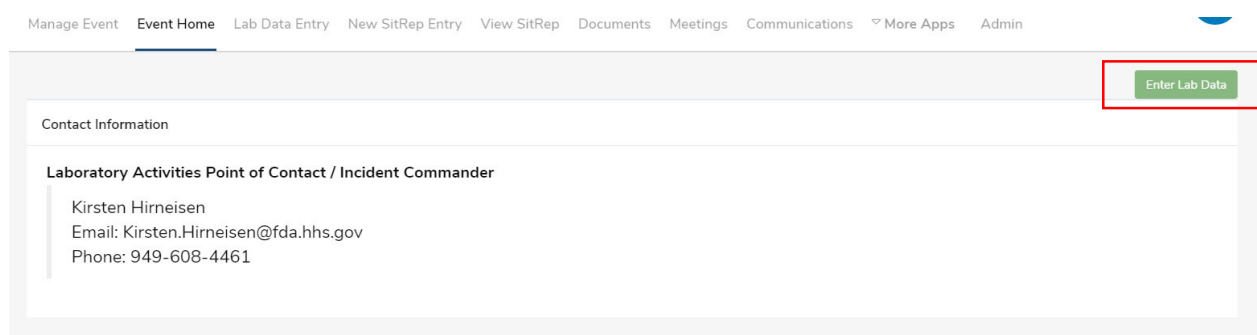
- If the sample ID is new, then it adds the new record
- If the sample ID is the same as another sample previously submitted, then it updates the data for that sample (overwrites it)

When submitting data in Q2-4, we recommend that you only submit the new quarter's samples (so you are only submitting new sample IDs to the system). However, we don't want to be burdensome, so if it is easier for you to have a single spreadsheet with the entire Budget period's samples and upload it at each quarter, that is acceptable.

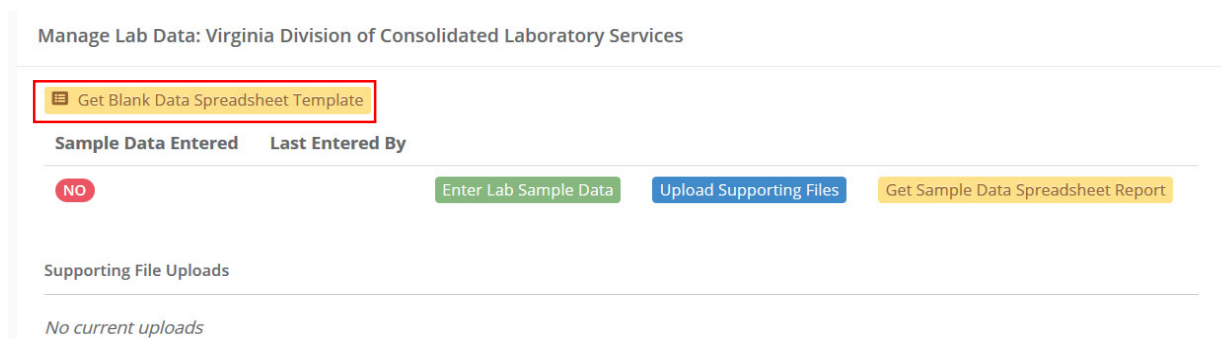
- If you opt to have a single spreadsheet (including all samples from the budget period) that you upload every quarter, please be aware that every time you submit data, you are overwriting data from a prior quarter (same sample IDs). This becomes important if ORS asked you to update or fix data elements during a prior quarters' data review. You **must** make sure those edits are reflected in both the FERNIab.org activation portal and your locally saved data spreadsheet, otherwise when you submit data in a future quarter, the fixed data elements will revert back to their prior state and need to be cleaned/updated again.

When you are ready to upload your surveillance data to the activation workgroup follow these instructions:

6. Go the activation workgroup and select "Enter Lab Data"



7. Click on "Get Blank Data Spreadsheet Template"



8. Open it with Microsoft Excel

9. Click on Enable Editing

10. Without changing anything about the blank data spreadsheet, copy and paste just the surveillance data from the template you had saved in your records. It works best if you only highlight the entire section of data instead of selecting entire rows. NOTE: You can attempt to skip steps 2-5 and just upload the spreadsheet you have in your files, but we find that starting fresh with a new template prevents errors.

11. Once your quarterly data is populated into the blank data spreadsheet template, save it to your desktop or in your files, keeping the same name as what was given by the system (it may save as "copy of..." which is fine)

12. Click "Enter Lab Sample Data"

Manage Lab Data: Virginia Division of Consolidated Laboratory Services

Get Blank Data Spreadsheet Template

Sample Data Entered Last Entered By

NO

Enter Lab Sample Data

Upload Supporting Files

Get Sample Data Spreadsheet Report

Supporting File Uploads

No current uploads

13. Click "Upload Spreadsheet"

Submit Lab Data

REMEMBER TO CLICK THE "SAVE DATA" BUTTON ABOVE THE GRID BEFORE YOU LEAVE THIS PAGE OR ANY UPDATES WILL BE LOST.

Would you like to upload a spreadsheet template?

Upload Spreadsheet

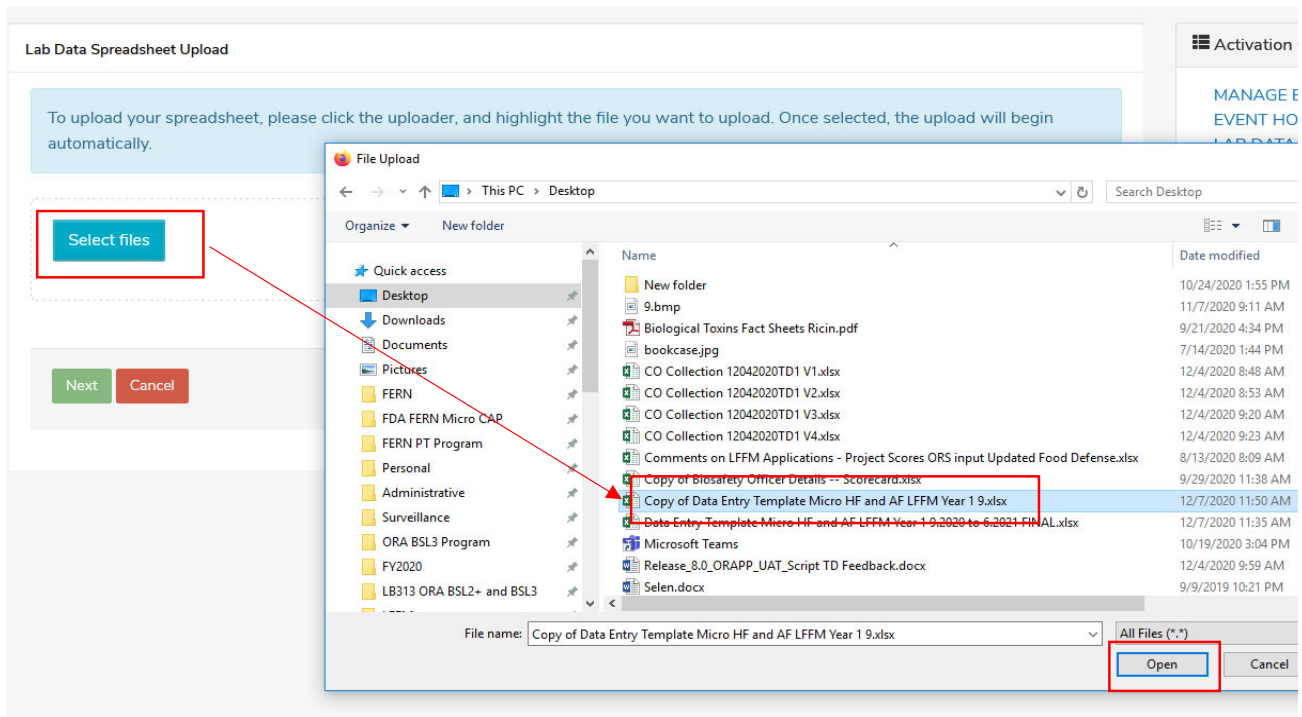
Save Data

Add Row

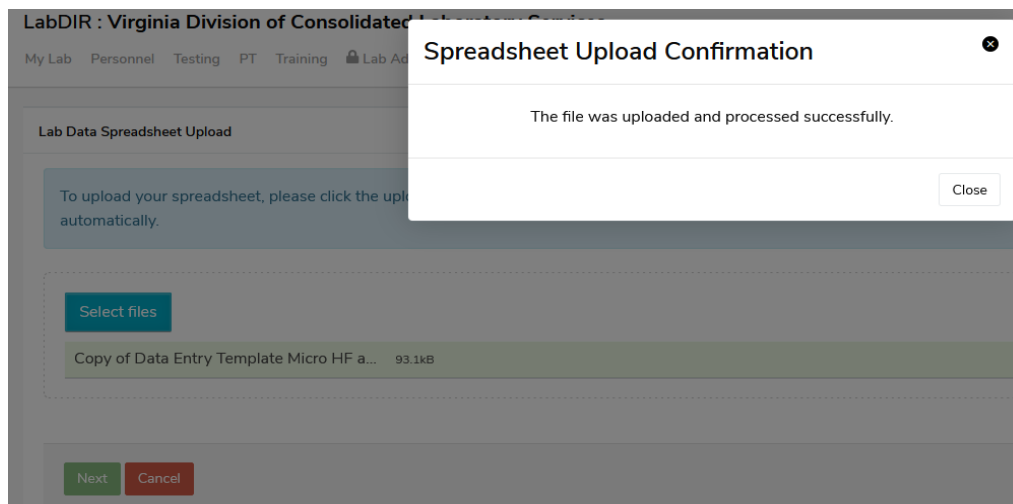
Delete Rows

| | Lab Name | State | Sample Number (ID) | LFFM Track |
|---|-----------|--|--------------------|----------------|
| 1 | Fake Data | 7065 - Alaska State Department of Environmental Conservation | AK | Micro Human Fo |
| 2 | | | | |

14. Click "Select Files". Find the document you just saved and click "Open"



15. When the document is done processing - Click Next. The system will check to see if your spreadsheet match



16. The data you copied should show in the data entry module on the screen. Check to be sure all your data was uploaded and then click "save data". If you forget to click save you will lose your data.

Submit Lab Data

REMEMBER TO CLICK THE "SAVE DATA" BUTTON ABOVE THE GRID BEFORE YOU LEAVE THIS PAGE OR ANY UPDATES WILL BE LOST.

Would you like to upload a spreadsheet template?

Upload Spreadsheet

Save Data Add Row Delete Rows

| | Sample Number (ID) | Product Description | Manufacturer/Brand | Product Code | Product Expiration Date | Collecting Entity | Date Collected |
|---|--------------------|---------------------|--------------------|--------------|-------------------------|-------------------|----------------|
| 1 | | | | | | | |

17. After your data is saved you can add rows to manually add more data, delete rows that had errors etc.

Troubleshooting:

The majority of data upload errors are because of changes to the spreadsheet template, blank rows, formatting changes, etc. If you receive an error message, please follow the instructions exactly and only copy and paste the cells with data into the downloaded template without selecting entire rows and columns. If you still experience issues reach out to your FDA technical lead(s).

Important:

This workgroup is used to track your state collected and state analyzed surveillance data. Any other data for other tracks or associated with FDA assignments or actual activations should be entered into the activations set up for that purpose and should not be double-entered in this activation workgroup. If you have questions reach out to your FDA technical lead(s).

- For the current budget period - if your laboratory participated in the FDA 3rd party (IEH) cereal assignment, record your samples against the category "RTE packaged/boxed cereals & granolas (not bulk)", even if it was not on your current budget period's approved sampling plan. In Comments (very last field), record "FDA 3rd Party Cereal Assignment". Record samples that were analyzed during the LFFM budget period/reporting period (7/1 or later).
- For the current budget period - If your lab chose to use LFFM funds to do Cronobacter testing for the recent event in Infant Formula, please report all LFFM funded Cronobacter samples. As there is no column for Cronobacter in the reporting template, please use the "Other Analyte" Column and write in "Cronobacter sakazakii" (NOTE: This is not an option in the drop down menu and must be typed in).

Change History

- 1/27/22 – clarified that calculation of turnaround time is done based on net work days (including federal holidays)
- 2/8/22 – added examples of how to interpret and record Country of Origin
- 4/4/22 – added information on how to report Cronobacter testing

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 36.67 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 PRAStaff@fda.hhs.gov

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