## 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

Manage Event	Event Home	Lab Data Entry	New SitRep Entry	View SitRep	Documents	Meetings	Communications	Admin	
Contact Infor	mation								Enter Lab Data
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My Lab Personnel Testing PT Training 🖶 Lab Admin 🗰 Calendar 🦷 Storeroom 🍽 FERN Repository

Manage Lab Data: Virginia [	Division of Consolidated Laboratory Se	rvices			Activation Group Apps	
Get Blank Data Spreadshee Sample Data Entered	t Template				MANAGE EVENT EVENT HOME LAB DATA ENTRY	Forums Links Members
VES Supporting File Up	Tara Doran on Dec 7, 2020	Enter Lab Sample Data	Upload Supporting Files	Get Sample Data Spreadsheet Report	New SitRep Entry View SitRep Documents Meetings	Photos Polls Scheduler SecureSend
No current uploads					Communications Calendars FAOs	Teams Video Gallery Admin

Janage Lab Data: Virginia Division of Consolidated Laboratory Services						
Get Blank Data Spreadsheet 1	Template					
Sample Data Entered	Last Entered By		_			
YES	Tara Doran on Dec 7, 2020	Opening Data Entry Template Micro HF and AF LFFM Year 1 9.xlsx	Spreadsheet Rep			
		You have chosen to open:				
Supporting File Uploads		Data Entry Template Micro HF and AF LFFM Year 1 9.xlsx which is: Microsoft Excel Worksheet (90.7 KB)				
No current uploads		from: https://s3-fips-us-gov-west-1.amazonaws.com				

Open with Excel (default)	
⊖ <u>S</u> ave File	
Do this <u>a</u> utomatically for files like this from now on.	
OK Cancel	

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 3<sup>rd</sup> 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 3<sup>rd</sup> 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 3<sup>rd</sup> 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"

Manage Event	Event Home	Lab Data Entry	New SitRep Entry	View SitRep	Documents	Meetings	Communications	♡ More Apps	Admin	
										Enter Lab Data
Contact Inform	mation									
Laboratory	Activities Po	int of Contact /	Incident Comman	der						
Kirsten	Hirneisen									
Email: k	Kirsten.Hirne	isen@fda.hhs.g	gov							
Phone:	949-608-44	461								

#### 7. Click on "Get Blank Data Spreadsheet Template"

Manage Lab Data: Virginia Division of Consolidated Laboratory Services							
E 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							

- 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 Spreads	heet 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

REM LOST	ember to Г.	CLICK THE "SAVE DATA" BUTTON ABOVE THE GRID BEFORE Y	OU LEAVE THIS PAG	e or any update	ES WILL BE
Would Upload	<b>you like to</b> Spreadsheet	upload a spreadsheet template?			
Save I	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					
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14. Click "Select Files". Find the document you just saved and click "Open"

Lab Data Spreadsheet Upload			E Activation
			MANAGE E
To upload your spreadsheet, please	click the uploader, and highlig	ht the file you want to upload. Once selected, the upload will begin	EVENT HO
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	FERN PT Program	CO Collection 12042020TD1 V4.xlsx	12/4/2020 9:23 AM
	Personal	Comments on LFFM Applications - Project Scores ORS input Updated Food Defense.xlsx	8/13/2020 8:09 AM
		Copy of Biosafety Officer Details Scorecard.xisx	9/29/2020 11:38 AM
	Administrative	Copy of Data Entry Template Micro HF and AF LFFM Year 1 9.xlsx	12/7/2020 11:50 AM
	Surveillance	Data Entry Template Micro HF and AF LFFM Year 1 9:2020 to 6:2021 FINAL xlsx	12/7/2020 11:35 AM
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			Open Cancel

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

LabDIR : Virginia Division of Consolidated	I - h C
My Lab Personnel Testing PT Training 🔒 Lab Ad	Spreadsheet Upload Confirmation
Lab Data Spreadsheet Upload	The file was uploaded and processed successfully.
To upload your spreadsheet, please click the upleautomatically.	Close
Select files Copy of Data Entry Template Micro HF a 93	148
Next Cancel	

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.

Subr	mit l	_ab Data						
R	REMEMBER TO CLICK THE "SAVE DATA" BUTTON ABOVE THE GRID BEFORE YOU LEAVE THIS PAGE OR ANY UPDATES WILL BE LOST.							
Wou	Would you like to upload a spreadsheet template? Upload Spreadsheet							
Sa	ave (	Data Add Row	Delete Rows					
1	1	Sample Number (ID)	Product Description	Manufacturer/Brand	Product Code	Product Expiration Date	Collecting Entity	Date Collecte

#### 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 3<sup>rd</sup> 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 3<sup>rd</sup> 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.

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Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov* 

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.