Contents

I. Documents included in LFFM the Sample and Activity Plan Proposal Request

The following documents are available to LFFM grantees on the Food Emergency Response Network (FERN) Portal (www.fernlab.org) with the LFFM Sample and Activity Plan Proposal Template (this spreadsheet) to assist in completing the LFFM Sample and Activity Plan Proposal (SAPP). References to these documents within these instructions are color coded, to help make it easy to identify which documents are being referenced.

- **LFFM Sample and Activity Plan Options by Track spreadsheet** – list of currently offered activities or sampling priorities for each Track
- **SRP-Lab Agreement Template** – word document example/template for the SRP-Lab Agreement, required for labs in Human and Animal Food Product Testing Tracks
- **Supplemental Instructions Documents** – some sampling priorities (e.g., Total Diet Study [TDS]) have an instructions document providing additional detail about the project (desired collections and testing). These are also posted in the FERN Portal.

II. Next Budget Period Proposal Submission

Labs are to submit, the following documents to: OM PO (Laurie Keppley), OP Project Manager (PM) and ORS LFFM Technical Program Manager (Lauren Yeung)

- Sample and Activity Plan Proposal (this spreadsheet) completed for all tracks you wish to participate in for the next budget period (note some tracks without activity or sampling options are not in the spreadsheet). Note that submitting this form does not constitute an official request for funding, grantees must request funds for these tracks via the RPPR.
- SRP-Lab Agreement (word document) – only for labs in M-HF, M-AF, C-HF, or C-AF Tracks; this agreement covers all commodity-hazard pairs for the M-HF, M-AF, C-HF, or C-AF Tracks included in this spreadsheet as the Sample and Activity Plan Proposal.

III. Completing the LFFM Sample and Project Plan Proposal (this spreadsheet).

A. Coversheet

Please provide the requested administrative information, including the appropriate contacts to receive communications about your LFFM Sample and Activity Plan proposal for the next budget period. ORS and OP will communicate with these contacts during the LFFM sampling plan/project negotiation phase.

Please indicate which Tracks your lab is proposing work for in the next budget period. With the following exceptions, laboratories must ONLY complete tabs (submit proposals) for tracks they were approved AND funded for in LFFM for the current budget period.

- The LFFM program will not be picking up any new labs to participate in the Food Defense, Human Food Testing, nor the Animal Food Testing tracks for the next budget period, with the following exception: Laboratories "Approved" and "Unfunded" for the M-AF Track in previous two budget periods may submit an M-AF Track proposal for the next budget period. This proposal can only include NARMS sampling work and cannot include state-proposed commodity-hazard pairs, or any other FDA-proposed commodity-hazard pairs offered for M-AF in the next budget period.
- LFFM grantees can propose a Micro or Chem Capability/Capacity Development Track project or Method Development/Validation Track project if they are "approved" for the track, regardless of whether you were funded in the current budget period.

Some Tracks do not have tabs in the spreadsheet because there are no projects to select from. This includes: SP-IT (ORA DX), SP-Sample Collection, Rad Capability/Capacity Development (not open this budget period). If you are approved for the SP-IT and SP-Sample Collection tabs, you can include those in your RPPR budget and continuation application in eRA commons. Your funding tier for SP-Sample Collection should match the funding tier for total M-HF, M-AF, C-HF, C-AF work proposed for the next budget period.

Track	Sample Load	Number of Samples	Funding

		(calculated using the sample numbers from the testing track(s) tier(s) your lab participates in – i.e., 100/250/500)	
Sample Collection	Low	100 – 500	$25,000
	Medium	501 – 1000	$35,000
	High	>1000	$45,000

IMPORTANT NOTE: LFFM grantees cannot increase their HAF Product Testing Track, WGS Track sample tier, or SP-Sample Collection Track tier beyond what the original LFFM application was approved for; however, grantees can reduce their tier voluntarily.

B. M-HF, M-AF, C-HF, C-AF Tracks

See "LFFM Sample and Activity Plan_Options by Track.xlsx" on the FERN Portal www.fernlab.org for a listing of all sampling and activity options for LFFM Tracks (M-HF, M-AF, C-HF, C-AF, Food Defense, Capability/Capacity Development, Method Development/Validation) for the next budget period.

Laboratories are to review these sampling options, including discussions with SRP partners for M-HF, M-AF, C-HF and C-AF Tracks, to determine what sampling projects to propose for the next budget period. The LFFM Sample Guide contains many suggestions on what to consider when discussing LFFM sampling options for the next budget period with SRP partners. See *LFFM Sample Guide section "Determining which Commodity-Hazard Pairs to Propose."*

Laboratories are to list the sampling projects they would like to pursue in the next budget period in the following tabs of this spreadsheet. All fields should be completed for each commodity-hazard pair. There are some changes to the proposal fields (compared to the previous budget period), so read the template carefully.

Considerations and guidelines for selecting commodity-hazard pairs for the next budget period

Laboratories should only propose commodity/hazard pairs for which they are already able to conduct analyses (e.g., it is not appropriate to propose work that requires use of a specific piece of equipment that will not be operational until 3-6 months into the budget period). It is permissible to propose work that requires limited work to validate/verify an existing method for a new matrix. No new major method validation or method development work will be allowed for proposed commodity/hazard pairs. If questions arise over effort of work for minor vs. major development work please reach out to LFFM Human and Animal Food Track Contacts for clarification.

Laboratories must use validated methods that are equivalent to official methods (see definition below). If methods used for LFFM Product Testing Tracks are not on the laboratory's scope of accreditation, validation data may be requested by ORS Technical Leads. All matrices must be validated or verified to be run with the intended method. Matrix verificationsmay also be requested by ORS Technical Leads.

Equivalent to Official Methods: *This phrase is used to describe the deliberative process used by ORS to ensure methods used by LFFM laboratories for LFFM work is technically sound and fit for use. Items considered include:*

- *Is the method fit for purpose (appropriate for the commodity/hazard pair; the purpose/intent of the sampling effort,*
- *Is the method an official method (FDA, AOAC, etc.); or if it is a modified official method or a method from another source (in-house, etc.), is it validated/verifiec*
- *Is the method validated for the matrix; are matrix spikes or inclusion of Standard Reference Material/Certified Reference Material (SRM/CRM) needed)*
- *If applicable, MLOD and MLOQ are available and appropriate for the commodity/hazard pair*
- *Is the method under ISO scope; if not, is it validated/verified in the lab?*

Laboratories should be proactive in identifying back-up commodity-hazard pairs in the event they are asked to replace or reduce the numbers for a commodity-hazard pair included in their proposal. Back-up commodity-hazard pairs can be noted in the M-HF, M-AF, C-HF, and C-AF tabs, columns F and G, respectively.

Although we are asking laboratories to submit a sampling plan that represents the entire sample load for the budget period (aligned with funding level; 100, 250, 500), requests to reallocate the sampling plan are allowed, especially to accommodate high priority national outbreak or emergency response testing priorities (see LFFM Sample Guide on the FERN Portal www.fernlab.org for information on how to request reallocation).

LFFM laboratories and state regulatory programs can propose commodity-hazard pairs outside those included on the "LFFM Sample and Activity Plan_Options by Track.xlsx" document, available on the FERN Portal www.fernlab.org. Please be aware that state-proposed commodity-hazard pairs may be considered lower priority or not recommended at all for LFFM work. State-proposed commodity-hazard pairs that are identified as low priority during the review process may still be approved with additional stipulations.

Items to keep in mind when considering state-proposed commodity-hazard pairs include:

- The summary of the purpose and public health need will be critical for the FDA to evaluate if the project aligns with the goals of the cooperative agreement. Not all hazard/commodity pairs will be approved.

- Depending on the justification, state-proposed commodity-hazard pairs could be approved on sample plans even if they are not of high priority to the FDA for food safety reasons.

- FDA may not have the capacity to provide technical support, analytical guidance or follow-up actions for the testing performed for state-proposed commodity-hazard pairs. Before approving state-proposed commodity-hazard pairs, the lab may be asked to document that the SRP with appropriate jurisdiction for the proposed samples agrees to provide compliance support and initiate any necessary follow-up on these samples in the absence of support/coordination/assistance from FDA.

- State-proposed microbiology commodity-hazard pairs for human and animal food should include at least one pathogen, and state-proposed chemistry commodity-hazard pairs should focus on food contaminants. Food quality and indicator test methods, such as aerobic plate count and coliform count, and Standard of Identity should not be included in sample plans.

- Do not submit proposals for the following (animal food testing):
  - Proximate analysis
  - Raw pet food
  - Hemp and hemp byproducts

· For a detailed list of commodity-hazard pairs provided as sampling projects and options for the next budget period under the M-HF, M-AF, C-HF, and C-AF tracks, see current guidance on the FERN Portal www.fernlab.org.

Notes and considerations for M-HF, M-AF, C-HF, and C-AF sampling projects/options for next budget period

"LFFM Sample and Activity Plan_Options by Track.xlsx" on the FERN Portal www.fernlab.org. Commodity-Hazard pair tab columns/data fields are organized into the following sections. Individual columns/fields may also have a hover over tool tips, with additional information about that field.

- Column Header/Section 1: Sample Designation
- Column Header/Section 2: Sample Numbers and Targets
- Column Header/Section 3: Regulatory Outlook
- Column Header/Section 4: Sample Collection Details
- Column Header/Section 5: Analytical Details
- Column Header/Section 6: Additional information

Notes and considerations related to Sections 1 and 2 (Sample Designation, Sample Numbers and Targets]

- Some commodities are listed several times (separate rows) with separate hazards (analytes). If desired, it is permissible for the SRP to work with the lab to collect 1 sample of sufficient size to support multiple analyses. This practice is neither encouraged nor discouraged and is intended to offer maximum flexibility to SRPs supporting LFFM testing.
  - Example: LFFM lab/SRP proposes:
    - 25 samples of poultry food for Salmonella
    - 25 samples of poultry food for mycotoxins (AFL, DON)
    - 25 samples of poultry food for macro mineral and moisture

- In this example, the SRP could collect 25 physical samples of sufficient size to support all analyses, and the sample is split at the lab and sent for the separate analyses

- Flexibility in selecting analytes: Commodity-Hazard Pairs may be offered for multiple analytes (e.g., dietary supplements for lead, folic acid and vitamin D). Unless otherwise noted, flexibility is offered for LFFM grantees to propose collection and testing for one or more listed analytes of interest.
  - Priority will be given to labs that can test for all of the requested analytes.
  - In some cases (chemistry) a minimum number of analytes are required to participate in a sampling project, this will be listed in the "Hazard (Analyte)" field
- Counting samples and analyses towards Sample Load

  - In "LFFM Sample and Activity Plan_Options by Track.xlsx" on the FERN Portal www.fernlab.org Commodity-Hazard pair tab, each commodity-hazard pair has a total number of requested samples (Column G) – this is the total number of samples desired/requested NATIONALLY - across all LFFM states for the budget period.
    - Your lab can propose any number of samples for the budget period that you feel is reasonable and fits with your lab and SRP capacity. We will look to combine testing efforts from multiple labs to total the requested number of samples, nationally, for the commodity-hazard pair.
  - Your lab's Sample Load is the number of samples associated with your M-HF, M-AF, C-HF, and C-AF funding tier (i.e., 100, 250, 500). This budget period, we are counting unique/discrete analyses towards the sample load instead of physical samples.
    - Each commodity-hazard pair has a # of unique analyses per sample (Column D) – This is used to determine how much each physical sample counts towards the LFFM tiered sample load for M-HF, M-AF, C-HF, or C-AF.
  - Within the following tabs of this spreadsheet, you will be asked for:
    - Number of Samples (annual) – this is the number of physical samples you propose to collect for the budget period

§ Number of Unique Analyses per Sample (this must be taken from "LFFM Sample and Activity Plan_Options by Track.xlsx" available on the FERN Portal www.fernlab.org, depending on how many of the target analytes of interest you select)
- Count Towards Sample Load (this is the [# of samples] x [# of unique analyses])
- *Example: State A proposes collecting and analyzing 100 samples of dried mushrooms for Salmonella and Listeria monocytogenes. State A is a M-HF, annual sample load/target: 250. Collecting 100 dried mushroom samples and analyzing for both pathogens counts as 200 out of a 250 sample load for the budget period.*

Notes and considerations related to the SRP-Lab Agreement Template available on the FERN Portal www.fernlab.org (Regulatory Outlook)

· "Scope & Intent" and "Expectation for Regulatory Action" (Columns J, K): The SRP's agreement to follow-up on potentially violative samples (SRP-Lab Agreement Template available on the FERN Portal www.fernlab.org) applies to any commodity-hazard pairs marked "regulatory surveillance" (M-HF, C-HF) or "surveillance" (M-AF, C-AF). SRPs must have awareness of other (signals, TDS, NARMS) commodity-hazard pairs, especially if the SRP will be conducting collections.
  - **M-HF and C-HF Track**

    - Scope and intent: options consist of 'regulatory surveillance' (testing where published regulatory limits or action levels exist for the commodity-hazard pair); 'signals evaluation' (testing where these limits may not exist); and Total Diet Study.

    - The purpose of Signals Evaluation is to obtain additional information about the commodity/hazard pair, not to support immediate regulatory action on a sample-by-sample basis. Data will be received/reviewed in aggregate and may be used to inform future agency thinking. This may lead to shorter-term or longer-term follow-up including industry meetings, research, and inspections or sampling. Although the sampling is intended to be used for informational purposes at this time, findings of significant public health concern will be evaluated on a case-by-case basis for immediate follow-up.
  - **C-AF and M-AF Track**
    - Surveillance: sample collection occurs on an objective basis where there is no inspectional or other evidence of a problem with the product (IOM 4.4.10.3.48, Sample Basis)

· "FDA or State Sample Collections" and "Will Center issue an Assignment" (Columns L, N): See the FERN Portal www.fernlab.org for FDA-assignments (FDA collected samples, FDA-issued assignments) currently offered.
  - For TDS projects, refer to the Supplemental Instructions Documents referenced in Column N, and provided on the FERN Portal www.fernlab.org

· "Appropriate for retail collection by Lab Analysts" (Column M) – This field provides clarity regarding which commodity-hazard pairs are amenable for laboratory staff collection at retail. If laboratory staff will be collecting samples for commodity-hazard pairs marked "Regulatory Surveillance" (M-HF, C-HF) or "Surveillance (M-AF, C-AF), the laboratory must document agreement that the SRP will support follow-up on potentially violative samples (SRP-Lab Agreement Template available on the FERN Portal www.fernlab.org).

- "Is Center interested in tying collections to inspections done under food/feed contract or Produce CAP?" (Column O) – For some commodity-hazard pairs, there is specific interest from the Center in aligning the LFFM sampling with SRP inspection contract assignments, should the opportunity arise. For commodity-hazard pairs that say "yes", this is NOT a requirement, but rather a preference and a desire to see if aligning LFFM sampling plan and contract workplanning is possible. When proposing one of these commodity-hazard pairs, it is important to discuss whether the SRP would be willing to conduct sampling as part of an inspection contract assignment, should a contract inspection for an appropriate firm be assigned to the SRP. While the inspection itself would be reimbursed under contract, the sampling would not (the product sampling option under the contract is not active). Sampling can be supported using the LFFM Sample Collection Track (if your laboratory is approved/funded for this track) or using alternative funding sources available to the SRP where this activity is in scope.

Notes and considerations related to Sections 4 (Sample Collection Details)

- "Imported or domestic product (or both) of interest?" (Column R) – this column indicates whether domestic or imported product is of interest for sampling. An imported product is one that was manufactured by a foreign firm and is now in domestic commerce; a domestic product is one that was manufactured by a domestic firm.

- "Sample Collection Location(s)" (Column S) – Sample Collection Location is the type of facility from which the sample was collected. Column T further breaks down what percent of samples (nationally) are desired per collection location type.
  - C-AF and M-AF Collection Locations:

    - **Retail**: A facility in which commodities or complete feeds are available to the public for purchase. Examples include grocery stores, big-box stores like Walmart, and farm or agriculture supply stores like Southern States, Tractor Supply Co., Highland Feed & Seed Co., Mid Kansas Coop, etc. **Online sampling like Chewy or Amazon is not permitted.**

    - **Manufacturer**: A facility where ingredients or complete feeds are processed, manufactured and/or mixed. Examples include soybean processors, ethanol plants, feed mills, and pet food manufacturers.

    - For some commodity-hazard pairs, only Manufacturer is listed, but column T indicates that other collection locations may be considered and approved on a case-by-case basis. This is intended to allow for flexibility in sampling proposals when state inventory of manufacturing facilities is low. States should indicate their ability to collect all or portions of the proposed commodity-hazard pair at alternative locations (i.e., retail) accordingly.

  - When completing the column for "Collection Location" in this spreadsheet, please select from this list of values: Distributor, (G) Grower, (M) Manufacturer/Processor, (R) Packer/Repacker, (D) Retail – Farmer's Market, (D) Retail – Grocery, (D) Retail – Online/Internet, (D) Retail – Other, (P) Retail – Restaurant, (W) Warehouse, Other - Not Listed
    - The only options for C-AF and M-AF are "(D) Retail" and "(M) Manufacturer/Processor"

- "Aseptic Sampling (Finished/Packaged Product or Aseptic Sampling from Larger Quantities)" (Column U) – Aseptic sampling is an important consideration for microbiological testing. Whenever possible, collect intact, unopened containers, and utilize aseptic sampling technique when necessary and appropriate.

  - See LFFM Sample Guide available on the FERN Portal www.fernlab.org, Section Sample Collection Best Practices - Sample Collection Techniques for information on sample collection techniques and aseptic sampling.

· "What are the expectations around representative sampling?" (Column V) – When the SRP is collecting the sample, the SRP's existing procedures for sample collection should be utilized. When collecting single retail units of product, it is important to ensure that a single unit is of sufficient size to support the testing to be conducted; if a larger sample size is needed, multiple units may need to be collected for a single sample (units must be from the same lot). SRPs collecting at a manufacturer are encouraged to conduct sampling that is representative of the lot. See LFFM Sample Guide available on the FERN Portal www.fernlab.org, Section Sample Collection Best Practices - Sample Collection Techniques for information on sample collection techniques and representative sampling.

Notes and considerations related to Sections 5 (Analytical Details)

- MLOD/MLOQ minimum requirements (Chem) – Column Z – because flexibility in use of equivalent methods is offered, this field indicates minimum method limit of detection and limit of quantitation that must be met for any method used in this commodity-hazard pair.

- Reference material (Chem) – Column AA – Consistent with past training on analytical worksheet packages given to C-HF and C-AF labs by ORS Track Leads, the expectation is that all methods utilize a suitable reference material (i.e., the matrix is similar to the samples being tested and the reference materials have the target analyte(s) at levels reasonable for the testing). Reference materials may be an SRM/CRM or other control material, such as appropriately evaluated PT samples (AAFCO, FAPAS, etc.). For some commodity-hazard pairs, a specific SRM/CRM material is recommended. For some commodity-hazard pairs, multiple SRM/CRM or Control Materials may be necessary. Where an SRM/CRM or Control Material is not available, spike recoveries may be necessary. Reach out to ORS Track Leads if your lab wants to discuss selection of an appropriate reference material for a commodity-hazard pair.

Notes and considerations specific to Animal Food Tracks (C-AF, M-AF)

- Labs already participating in NARMS are **not eligible** for M-AF NARMS sampling projects
- **Surveillance**: sample collection occurs on an objective basis where there is no inspectional or other evidence of a problem with the product (IOM 4.4.10.3.48, Sample Basis)
- **Complete Feed**: A nutritionally adequate feed for animals other than man; by specific formula is compounded to be fed as the sole ration and is capable of maintaining life and/or promoting production without any additional substance being consumed except water. (AAFCO OP)
- **Wet Pet Food**: Foods with a high moisture content. These include cans, foil trays and pouches.
- **Sample Location**: Type of facility from which the sample was collected.

○ **Retail**: A facility in which commodities or complete feeds are available to the public for purchase. Examples include grocery stores, big-box stores like Walmart, and farm or agriculture supply stores like Southern States, Tractor Supply Co., Highland Feed & Seed Co., Mid Kansas Coop, etc.**Online sampling like Chewy or Amazon is not permitted.**

○ **Manufacturer**: A facility where ingredients or complete feeds are processed, manufactured and/or mixed. Examples include soybean processors, ethanol plants, feed mills, and pet food manufacturers.

- C-AF Track – macro mineral + moisture testing. FDA's intent with these commodity-hazard pairs is aggregate data and not identifying label violations. This may represent a mutually advantageous commodity-hazard pair, as the SRP is interested in these samples for label verification and FDA is interested in aggregate data.

○ Analytical findings should be submitted quarterly. SRP can take any action deemed necessary and appropriate based on the violative finding under their own state authority. These findings do not need to be submitted to LFFM inbox, Division inbox, etc. However, in the case of complex compliance cases, labs are encouraged to contact FDA for further discussions on coordinated approaches that may include joint actions.

C. SP-MDV Track

When completing the Special Project/Method Development Method Validation (SP-MDV) Track tab in this spreadsheet, please list all MDV projects for the next budget period that your laboratory is eligible for and interested in pursuing. Your lab will not be chosen for every MDV project selected but this will allow FDA to better determine how many labs may be interested and decide which projects are priority. You will be notified which, if any, projects will be funded during the LFFM negotiations phase.

In "LFFM Sample and Activity Plan_Options by Track.xlsx" available on the FERN Portal www.fernlab.org Micro and Chem CC_MDV Projects tab, some MDV projects are listed as 'carryover' (see Column D) – these are projects funded in a prior budget period, organized by FDA, and were not completed on schedule. In these cases, FDA will allow LFFM grantees to carryover MDV track funds to the next budget period and allow those LFFM grantees to apply for a new MDV project in the next budget period (and receive new funds to support). LFFM grantees must indicate their intention to continue the carryover project in the SP-MDV Tab of this spreadsheet.

Other parameters:

- Labs may only be funded for 1 MDV project per budget period (micro or chem). If your lab is very interested in a second MDV project, you may select it and indicate that you are willing to conduct 2 projects for the budget period, within the $35,000 cap for the MDV track
- If your lab is willing to continue carryover MDV project from this budget period, that must be indicated on the proposal for the next budget period – there is a column to indicate whether an MDV project is a carryover project
- State-proposed MDV projects (not on the list) **are** allowed. There is a column to indicate whether a MDV project is FDA or state proposed
- If you are willing to participate in multiple MDV projects, please indicate which is your first choice, and which are back-up choices

D. Capability/Capacity Development Track

When completing the CC Dev Track tab of this spreadsheet, please list any C/C projects for the next budget period that your laboratory is eligible for and interested in pursuing. Some projects offered under C/C track this budget period are MDV in nature, but require additional resources to complete, hence offering under C/C Track.

Other parameters:

- Labs may select one C/C Development project per budget period, per discipline (micro, chem)
- Please note that each C/C Development project has a specific funding level (not all projects have the same funding level)
- State-proposed C/C Development projects **are not** allowed

If you are willing to participate in multiple C/C Development projects, please indicate which is your first