Instructions for Completing the LFFM Lab-SRP Agreement

Laboratories must submit documentation of State Regulatory Program (SRP) agreement to lead response and follow-up, in coordination with FDA and following the LFFM Sample Guide, for any state-collected LFFM samples (this includes samples collected by either laboratory analysts or SRP staff). Specifically, this means the Manufactured Food program agrees to lead response and follow-up for samples collected at retailers/manufacturers/processors/distributors under the Human Food micro/chem tracks; and the Animal Food program agrees to lead response and follow-up for samples collected at retailers/manufacturers/processors/distributors under the Animal Food micro/chem tracks. SRP agreement should be from the regulatory program director/manager level or higher. A letter or an email is acceptable. **FDA will not approve commodity-hazard pairs unless there is documented SRP agreement to follow-up on any positive samples.** The following **SRP-Lab Agreement Template** is provided for Labs/SRPs to use in meeting this requirement.

Some commodity/hazard pairs offered under LFFM are non-regulatory in nature. Please refer Columns J and K ("Scope & Intent" and "Expectation for Regulatory Action") in the current **"LFFM Sample and Activity Plan_Options by Track.xlsx."** Non-regulatory work includes Total Diet Study (TDS), National Antimicrobial Resistance Monitoring System (NARMS), and Signals Evaluation (Human Food).

- There is a section within the LFFM Lab-SRP Agreement Template below that clarifies that there is no regulatory action expected for these commodity-hazard pairs, and asks if the SRP has regulatory limits, action levels, or other compliance thresholds that could result in SRP regulatory actions for this commodity-hazard pair. This information will be completed during the negotiations/approval phase.

When determining which commodity-hazard pairs to propose for the upcoming LFFM grant year, laboratories and SRPs should discuss capabilities and areas of common interest. It is important to ensure that ALL commodity-hazard pairs included in the LFFM Sample and Activity Plan proposal (**"LFFM Sample and Activity Plan_Proposal Template.xlsx"**) have been discussed between the Lab and SRP. Information in **"LFFM Sample and Activity Plan_Options by Track.xlsx"** Commodity-Hazard pair tab should be used by the Lab and SRP to determine which commodity-hazard pairs to propose for the year.

Per the Funding Opportunity Announcement (FOA), if the laboratory is the primary servicing lab for a MFRPS or AFRPS program, then at least 15% of LFFM samples for the Human Food or Animal Food Tracks must be collected by the MFRPS or AFRPS program.

See *LFFM Sample Guide section "Determining which Commodity-Hazard Pairs to Propose"* for more details.

LFFM Laboratory and SRP Agreement Template for Human and Animal Food Product Testing Tracks

[SRP] and **[LFFM laboratory]** have reviewed, discussed, and jointly submit this LFFM **[Year]** Sample and Project Plan Proposal.

Sample Collection Agreement

For Commodity-Hazard pairs where **[SRP]** is the collecting entity, **[SRP]** agrees to collect the samples outlined in the approved LFFM sampling plan, in accordance with the sample collection and documentation requirements laid out in the current version of the LFFM Sample Guide and submit to **[LFFM Laboratory]** for analysis.

For Commodity-Hazard pairs where **[LFFM Laboratory]** is the collecting entity, **[LFFM Laboratory]** agrees to collect the samples outlined in the approved LFFM sampling plan, in accordance with the sample collection and documentation requirements laid out in the current version of the LFFM Sample Guide and submit to **[LFFM Laboratory]** for analysis.

Sample Follow-up Agreement

[SRP or SRP in partnership with state RRT] agrees to lead the response, in coordination with FDA and following the current version of the LFFM Sample Guide, for any state-collected LFFM samples (whether collected by **[SRP]** or **[LFFM Laboratory]** staff). This includes inter-agency and multi-state coordination, including: notifying another SRP with jurisdiction over the responsible firm of laboratory findings if product was grown/manufactured/distributed in another state and found violative; coordinating with another SRP, if referral had occurred, to ensure violative findings are communicated with the responsible firm by one of the SRPs; and conducting follow-up activities per [SRP] policies, procedures, and regulatory authority.

Points of Contact

[LFFM Laboratory] – Name, position title, agency name, email, phone

[SRP] – Name, position title, agency name, email, phone

During negotiations and approval of the LFFM Sample and Activity Plan, additional information will be requested from the LFFM lab and SRP (this does not need to be included with the proposal):

Commodity-Hazard pairs marked Signals Evaluation, NARMS, Total Diet Study

No regulatory action is expected for these commodity-hazard pairs. If an SRP has regulatory limits, action levels, or other compliance thresholds that could result in SRP regulatory actions for this commodity-hazard pair, please disclose those here.

Commodity-Hazard Pair	Entity Collecting	Sample Collection Location	Number of samples	Name of SRP with jurisdiction	Does SRP have regulatory limits, action levels, other compliance threshold related to this commodity-hazard pair?
Lead in spices	*State A Dept. of Ag Food Program*	*Retail Grocery*	*100*	*State A Dept. of Ag Food Program*	*1ppm lead in spices action level; will result in recall*

All Other Commodity-Hazard Pairs

Commodity-Hazard Pair	Entity Collecting	Sample Collection Location	Number of samples	Name of SRP providing support for follow-up on potentially violative samples	Types of actions the SRP can take under their regulatory authority (specific to the commodity-hazard pair and the type of firm associated with sampling). If a retail collection, please indicate ability to collect traceback records (documents) and actions that could be taken at distributor or manufacturer, if located within the state. If commodity/hazard pair requires consultation with FDA prior to conducting follow-up (referring to another state for follow-up, notifying responsible firm), include statement confirming awareness.
Granola – Listeria monocytogenes	*State A Dept. of Health Food Program*	*Retail Grocery*	*100*	*State A Dept. of Health Food Program*	*Traceback record collection for violative product; stop sale at retail; if leads to distributor or manufacturer in State A, can conduct PC Rule inspection at facility, embargo product. Will notify responsible firm (manufacturer/distributor) in coordination with FDA and other SRP with jurisdiction (if firm is out of state) per LFFM Sample Guide.*