Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) NOTE: The policies, guidelines, terms, and conditions stated in this Notice of Funding Opportunity (NOFO) may differ from those used by the NIH. Where this NOFO provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this NOFO. The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Objective Review Process.
Components of Participating Organizations	Human Foods Program (HFP)
Funding Opportunity Title	National Produce Safety Partnership Program
Activity Code	UF4
Announcement Type	New
Related Notices	None
Funding Opportunity Number (FON)	PAR-27-010
Companion Funding Opportunity	None

Number of Applications	See Part 2, Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)	93.103
Funding Opportunity Purpose	This funding opportunity aims to improve the safety of fresh produce and prevent produce-related illnesses.
Funding Opportunity Goals	The goal of this funding opportunity is to assist state and territory Produce Safety Programs with building and maintaining produce regulatory programs as part of a national Integrated Food Safety System (IFSS) focused on quality and national consistency, outreach and education to industry, and coordination across government agencies.

Key Dates

Posted Date	November 4, 2026
Open Date (Earliest Submission Date)	November 4, 2026
Letter of Intent Due Date(s)	December 18, 2026, for January 19, 2027, application due date. January 3, 2028, for March 1, 2028, application due date. January 2, 2029, for March 1, 2029, application due date.
Application Due Date(s)	January 19, 2027 March 1, 2028 March 1, 2029 All applications are due by 11:59 PM local time of applicant organization. **No late applications will be accepted for this Notice of Funding Opportunity (NOFO).**

Earliest Start Date	July 1, 2027
Late Applications	Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **No late applications will be accepted for this Notice of Funding Opportunity (NOFO).**
Expiration Date	March 02, 2029
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

Conformance to all requirements, both in the Application Instruction Guide and in the NOFO, is required and strictly enforced. When the program-specific instructions deviate from those in the Application Instruction Guide, follow the program-specific instructions.

Applications that do not comply with these instructions will not be accepted for review.

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Part 2. Full Text of Announcement
Section I. Notice of Funding Opportunity Description

Background
FDA's National Produce Safety Partnership Program advances implementation of the nation's Food Safety Modernization Act (FSMA)'s Produce Safety Rule (PSR) codified at 21 CFR Part 112. The PSR outlines science-based minimum standards for the safe growing, harvesting, packing, and holding of fresh produce grown for human consumption. These standards are designed to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce and provide a pathway for federal, state, and local agencies to work together to achieve our public health goals.

FDA began supporting state and territory agencies PSR implementation in 2016, providing awardees with funding and technical assistance to develop produce safety programs as part of a national Integrated Food Safety System (IFSS). In support of Executive Order 14212, recipients of funding under this Notice of Funding Opportunity will collaborate to protect a key component of healthy diets by enhancing the safety of fresh produce.

Program Structure
Recipient agencies of this cooperative agreement program will maintain a produce safety program within their jurisdiction with the overarching purpose to enhance produce safety and achieve high rates of compliance with the FDA's Produce Safety Rule. The objectives of this Cooperative Agreement Program (CAP) are holistically intended to support recipient produce safety programs and are focused on quality and national consistency.

This program is structured to allow applicants to select from defined **TRACKS**, **PATHS**, and data submission **OPTIONS**. All applicants are required to select:

- One Program **TRACK**, which identifies the foundational framework used to operate their produce safety program.
- One Program **PATH**, which identifies the regulatory authority under which produce safety inspections are or will be conducted; and
- One data submission **OPTION**, which identifies the method by which required data is submitted to FDA as outlined in Objective 4.

All applicants must choose only one Program TRACK (1 or 2)

TRACK 1: Recipients will enroll in **Produce Regulatory Program Standards (PRPS)** (see **Appendix G**) as the foundation of their produce safety regulatory program and will complete applicable program objectives (Objectives 1-6).

TRACK 2: Recipients will develop and maintain their own foundational framework (i.e., will not enroll in PRPS) for their produce safety regulatory program and will complete applicable program objectives (Objectives 2-6).

All applicants must choose only one Program PATH (B or C)

PATH B: Jurisdictions will conduct produce safety inspections under FDA's authority.

PATH C: Jurisdictions will conduct produce safety inspections under their own authority.

Note: PATH A, as included under PAR-21-174, is not an option under this cooperative agreement.

All applicants must choose only one data submission OPTION (A or D)

OPTION A (Aggregated Data Submission): Recipients will submit inventory, inspection, and compliance data in an aggregated form.

OPTION D (Disaggregated Data Submission): Recipients will submit inventory, inspection, and compliance data in a disaggregated form without farm identifying information.

Objective 1: Produce Regulatory Program Standards (PRPS) Enrollment

This objective is applicable to **TRACK 1** recipients only.

The Produce Regulatory Program Standards (PRPS) support the development of risk-based produce regulatory programs by establishing a uniform basis for measuring and improving the performance of these programs in the United States. By achieving and sustaining conformance of these program standards, federal and state produce regulatory programs can better direct their regulatory activities toward reducing risk and produce-related incidents.

The PRPS comprise ten standards which establish foundations for the critical elements that serve as an objective framework to evaluate and improve components of a produce regulatory program. These elements cover the produce program's regulatory foundation, training, inspection program, auditing, produce-related illness, outbreak and emergency response, enforcement program, outreach activities, program resources, program assessment, and laboratory support. Achieving and sustaining conformance with the PRPS will require comprehensive self-assessment on the part of a program and will encourage continuous improvement and innovation.

a. All applicants must demonstrate their program has the necessary management support and access to internal and external resources to achieve full conformance with the PRPS.

b. All enrolled produce regulatory programs will be expected to implement strategic improvement plans to ensure continuous improvement and demonstrate that they are moving towards full conformance of the PRPS. All produce regulatory programs receiving funding under this cooperative agreement for PRPS activities will be expected to achieve the following:

i. By the end of 5 years of funded PRPS enrollment, programs are expected to achieve full conformance with all 10 standards, utilizing the following prioritization:

- During the first 3 years of PRPS enrollment, programs should prioritize conformance with Standards 1, 3, 7, and 10, and prioritize implementation of Standards 2, 8, and 9. For this funding opportunity, “implementation” means a program has a particular element, system, program, and documentation as required in the PRPS, and “conformance” means fulfillment of a requirement; specifically, a program is using and can demonstrate the use of a particular element, system, or program listed in the PRPS.

ii. The FDA recognizes that the time required for achieving full conformance with the PRPS will vary between programs. The program must have a detailed strategic improvement plan on how to achieve conformance with the remaining PRPS elements and documentation of requirements not yet met in accordance with PRPS Standard 9.

Goals and Activities

Year 1 of enrollment:

1. Attendance and participation of key produce program managers and staff in an annual face-to-face or virtual national PRPS meeting, active participation in any required PRPS training and committee meetings, participation in the PRPS Alliance, and other initiatives supporting national and program specific conformance of the PRPS.
2. Conduct a comprehensive baseline self-assessment, including completion of all applicable appendices, worksheets, and other documents (or equivalent documents), as described in Standard 9.

3. Following the baseline self-assessment, develop a strategic improvement plan that will result in conformance with the PRPS. Documentation related to the self-assessment and strategic improvement plan must be maintained. Strategic improvement plan(s) must include, at a minimum, all elements specified in Standard 9.
4. If applicable based upon assessment intervals, participation in in-person or virtual site visit(s) consisting of key state produce regulatory program and FDA personnel to discuss the conformance of program elements of the PRPS to prepare for assessment by the FDA /Human Foods Program/Office of Quality Assessment and Management/Quality Assessment Staff (Quality Assessment Staff). Participation includes providing meeting space for in-person activities; accessibility of key produce regulatory program management and staff; and access to records, databases, and other materials supporting PRPS conformance.

Years 2 to 5 of enrollment:

1. Participation in assessments conducted by the Quality Assessment Staff based upon regular assessment intervals determined by the FDA. Assessments evaluate accuracy of self-assessments, document the progress towards implementation and conformance, and determine whether milestones identified in the strategic improvement plan are met. Participation includes providing meeting space for any in-person activities; accessibility of key state produce program management and staff; and access to records, databases, and other materials supporting PRPS conformance.
2. Participation in in-person or virtual site visit(s) consisting of key state produce regulatory program and FDA personnel to discuss the conformance of program elements of the PRPS at intervals consistent with preparing for assessment by the Quality Assessment Staff. Participation includes providing meeting space for in-person activities, accessibility of key produce regulatory program management and staff, and access to records, databases, and other materials supporting PRPS conformance.
3. Attendance and participation of key produce program managers and staff in an annual face-to-face or virtual national PRPS meeting, active participation in any required PRPS training and committee meetings, participation in the PRPS Alliance, and other initiatives supporting national and program specific conformance of the PRPS.
4. Implementation of the strategic improvement plan. The strategic improvement plan should be updated to accurately reflect when specific objectives and tasks have been met and when new objectives and tasks are identified to achieve full conformance of the PRPS. Progress achieved should indicate that implementation and conformance of PRPS requirements can be expected by the timelines as outlined above in Objective 1(b)(i).
5. Review and update strategic improvement plan on an annual basis in accordance with Standard 9. Documentation related to the evaluation and strategic improvement plan must be maintained. The strategic improvement plan must include, at a minimum, all elements specified in Standard 9.

Objective 2: Program Administration

This objective includes elements of program administration needed to support the recipient's project. Unless specified otherwise, the goals and requirements under this objective are applicable to all recipients.

Goals and Activities

a. Recipients must develop and maintain a Program Workbook, utilizing a standardized template provided by the FDA (see **Appendix I**), to outline program objectives, annual goals and planned activities, track progress, and provide periodic progress reports as described in Section VI.

b. Recipients must maintain program staff and partners to accomplish the implementation, oversight, monitoring, and reporting of program objectives.

i. Recipients must develop a succession plan that supports a seamless transition if staff were to leave the program. Elements of this plan should include program standard operating procedures, training plans for each position, and existing agency succession planning strategies. **TRACK 1** recipients may accomplish this through their work under Objective 1.

c. Recipients must provide program personnel with appropriate training and resources commensurate with work duties.

i. The training curriculum for inspectors must be commensurate with the published FDA compliance program (CPGM 7303.080 Produce Safety Inspections, see **Appendix E**) or other applicable direction from the FDA.

d. Recipients must provide for key program personnel to attend and participate in the Annual National Consortium for Produce Safety and other initiatives supporting program implementation. These initiatives must be directly tied to CAP objectives.

e. Recipients must establish and maintain the capability to submit data to the FDA through electronic data exchange systems (e.g., FDA's Food Safety Data Exchange (FSDX) portal, see **Appendix F**).

f. Recipient agencies must establish and maintain 21 CFR 20.88 information sharing agreements with the FDA.

g. **PATH B** recipients must maintain FDA pocket credentials (with produce endorsement) for staff conducting Produce Safety Rule inspections.

h. **PATH C** recipients must follow their agency's credentialing and identification procedures for staff conducting Produce Safety Rule inspections.

i. **PATH C** recipients must adopt all Subparts of the Produce Safety Rule (21 CFR Part 112) in their entirety, by statute or administrative regulation; with exceptions as follows: recipients may omit any, or all, of the following:

i. Subpart M (Sprouts)

ii. Subpart P (Variances)

iii. Subpart Q (Compliance and Enforcement), provided the grantee agency has compliance and enforcement authority, or such authority will be obtained before conducting inspections

iv. Subpart R (Withdrawal of Qualified Exemption), provided that the state recognizes when FDA has withdrawn qualified exemption status

Additionally, **PATH C** recipients are responsible for ensuring that their statute and/or administrative regulation is updated to reflect applicable changes to the Produce Safety Rule resulting from FDA rule-making. Changes resulting from FDA rule-making must be incorporated into the grantee's statute or administrative regulation no later than the earliest compliance date that is applicable to the rule-making.

j. New applicants, and recipients previously funded through PAR-21-174 as PATH A (non-regulatory programs), must establish a mutually agreed-upon new applicant or transition plan with the FDA to include timelines, key milestones, and responsible parties. This plan must be established within the first 3 months of the recipient's first year and clearly document any alternate timelines required under Objectives 2-6 as a new regulatory program.

k. **TRACK 1** recipients will ensure that program elements developed under Objectives 2-6 are in conformance with the associated PRPS standards.

l. **TRACK 2** recipients will develop and maintain a foundational framework for their produce safety program. Written procedures must be established by the end of the recipient's first year, unless otherwise noted, to include the following:

i. Regulatory Foundation: recipients must evaluate the scope of their legal authority and regulatory provisions to ensure the protection of produce within their jurisdiction. The evaluation includes a determination of how the recipient's legal authority and regulatory provisions correspond to the applicable sections of the Federal Food, Drug, and Cosmetic Act (FD&C) and Code of Federal Regulations (CFR).

ii. Training Program: recipients must establish and maintain a written training plan that promotes staff development and demonstrates that all staff complete coursework, field training, and continuing education to adequately perform their work.

iii. Outreach and Technical Assistance Program: recipients must establish and maintain a written outreach and technical assistance plan, and include the elements outlined in Objective 3.

iv. Inspection Program: recipients must establish and maintain written inventory and inspection procedures appropriate to their chosen program **PATH**, and include the elements outlined in Objective 4.

v. Compliance and Enforcement Program: recipients must establish and maintain written compliance and enforcement procedures appropriate to their chosen program **PATH**, and include the elements outlined in Objective 5.

vi. Response Activities: recipients should utilize PRPS Standard 5 (see **Appendix G**), and must include the elements outlined in Objective 6, as the framework for their incident response activities and written procedures, to be established by June 30, 2032.

Objective 3: Outreach and Technical Assistance Program

This objective is intended to provide opportunities for outreach and technical assistance on the Produce Safety Rule and the jurisdiction's produce regulatory program to produce farms, prioritizing PSR covered farms. Outreach and technical assistance activities under this cooperative agreement provide an opportunity to promote safe farming practices that minimize human pathogens and protect a key component of healthy diets by enhancing the safety of fresh produce. Unless specified otherwise, the goals and requirements under this objective are applicable to all recipients.

Goals and Activities

a. Farms conducting PSR covered activities on PSR covered produce are eligible to receive outreach regardless of produce sales or exemption status; however, PSR covered farms must be prioritized.

i. Recipients are encouraged to provide outreach on produce safety and the Produce Safety Rule to produce farms supplying PSR covered produce directly to schools and/or other institutions serving vulnerable populations (e.g., hospitals and long-term care facilities).

ii. Produce farms located on Tribal lands or owned by Tribes or Tribal entities may receive outreach through this cooperative agreement, at their request. When federally recognized Tribes or farms on Tribal lands initiate contact with the recipient, the recipient must contact the FDA to discuss and coordinate the available Tribal outreach options. Additionally, recipients must communicate with the FDA when they receive requests for an On-Farm Readiness Review (OFRR) from a farm with Tribal affiliation to determine the appropriate entity to conduct the OFRR.

b. Outreach activities may include:

i. General outreach to industry such as one-time or short duration contact to provide information.

ii. Education utilizing existing curriculum and materials recognized by the FDA and training partners; these may include but are not limited to curriculum and materials developed by the Produce Safety Alliance, Sprout Safety Alliance, and Regional Centers.

c. Technical assistance should be focused on PSR covered farms and may include individual assistance to interpret and apply the regulation to a specific situation, including on-farm (e.g., On-Farm Readiness Reviews) or off-farm/remote delivery (e.g., off-farm, in-person, or virtual technical assistance delivery). **TRACK 1** recipients should record OFRRs in PRPS Appendix 7.2.

d. Recipients may choose to distribute FSMA Food Traceability Rule (FTR) related educational and informational materials during PSR inspections and/or any other in-person or virtual outreach activities. See **Appendix H** for FTR resources.

e. Recipients must develop and maintain an annual Outreach and Technical Assistance Plan as part of the required Program Workbook (see **Appendix I**), including annual targets for outreach and technical assistance activities based on their jurisdiction's needs.

f. An Educational Needs Assessment (ENA) is required to be completed prior to the development of any new trainings and/or materials. The purpose of the ENA is to prevent duplicative efforts among recipients, ensure material alignment with the PSR, and promote broader sharing of aligned materials.

Objective 4: Inspection Program

This objective includes program elements for recipients to maintain an inspection program for produce farms under their jurisdiction. Unless specified otherwise, the goals and requirements under this objective are applicable to all recipients.

Goals and Activities

a. Recipients must maintain a verified inventory that captures at least the required data elements listed in **Appendix C1** for all Produce Farms with Produce Sales. "Verified" refers to data collected directly from the farmer (e.g., collected through direct mailing, phone, informational visit, inspection, voluntary online registration, or other direct interaction with the farm).

i. All produce farms that are covered by the PSR, not covered due to produce sales under $25k (adjusted for inflation), commercial processing exempt, grow only Rarely Consumed Raw (RCR) commodities or commodities under Enforcement Discretion (ED), or eligible for a qualified exemption are to be re-verified at a minimum of every 5 years. This is to ensure that all PSR covered farms are considered in work-planning, including those that may have previously been exempt.

ii. Recipients must establish procedures and timeframes for the identification and verification of new produce farms in their jurisdiction.

b. At a minimum, recipients must conduct routine inspections on 20% of their jurisdiction's non-exempt covered farms annually. If the recipient chooses to do more inspections than 20% of their covered inventory annually, that is allowed but will not be considered for additional funding eligibility.

i. Each covered farm in inventory must receive a routine surveillance inspection at a frequency of no greater than every five years.

ii. Recipients, regardless of their authority, may periodically receive FDA issued inspection assignments. Recipients must follow the requirements and conditions set forth in the assignment. These inspections may be counted towards the annual routine inspection goal or non-routine inspections as appropriate.

c. Annual funding is also allocated for non-routine inspections, including Follow-up and For-cause inspection types, estimated at 20% of all routine inspections conducted.

i. Recipients, regardless of their authority, may periodically receive FDA Follow-up or For-cause inspection assignments. Recipients must follow the requirements/conditions set forth in the assignment. These inspections may be counted towards non-routine inspections.

d. Recipients conducting inspections under Subpart M of the Produce Safety Rule under this cooperative agreement, must conduct these inspections jointly with FDA, in coordination with the FDA, and at the discretion of FDA.

i. Compliance and enforcement activities related to inspections under Subpart M of the Produce Safety Rule must be in coordination with the FDA.

ii. Personnel must complete FDA required training courses to conduct Subpart M inspection-related activities.

e. Recipients may implement and execute a produce safety inspection calibration program, in coordination with FDA, to ensure the consistent understanding, application, and communication of Produce Safety Rule requirements during inspections.

f. When appropriate, the recipient must coordinate with the FDA and other state or local agencies on multi-jurisdiction farm inventory activities and/or inspections (e.g., farm mixed-type facilities, farms crossing state borders, and Tribal lands), according to the most current FDA CPGM 7303.080, Produce Safety Inspections (see **Appendix E**) or other applicable direction from the FDA.

g. Recipients must utilize an electronic system for maintaining inventory and inspection data and required data elements; the system should be capable of extracting data into an .xml file format and facilitate reporting of required inventory, inspection, and compliance related data elements (see **Appendix C** and **Appendix D**).

h. Recipients must select one of the following data submission **OPTIONS (A or D)**, utilizing the associated reporting templates provided by the FDA (see **Appendix I**), to submit inventory and inspection data in the FDA's Food Safety Data Exchange Portal (see **Appendix F**) as outlined in Section VI, Additional Reporting Requirements.

i. Aggregated data submission **OPTION A**

- Recipients will submit data in aggregated form, using a format defined by FDA. See **Appendix C2** and **Appendix D1** for required data elements.

ii. Disaggregated data submission **OPTION D**

- Recipients will submit data in a disaggregated form, without farm identifying information, using a format defined by FDA. See **Appendix C3** and **Appendix D2** for required data elements.
- Additional funding may be available to recipients opting to provide data using the disaggregated data submission option to support IT development, IT system maintenance, and personnel to manage the data system (see **Table 4**).

i. **PATH B** recipients

i. Recipients must provide their farm inventory (see **Appendix C1**), with farm identifying information, to the FDA upon request.

ii. Recipients must conduct inspections according to the most current FDA CPGM 7303.080, Produce Safety Inspections (and attachments) (see **Appendix E**), and pertinent FDA guidance or operating instructions for conducting produce safety inspections.

iii. Recipients must prioritize inspections considering criteria listed in the most current FDA CPGM 7303.080, under Part II- Implementation, Inspection Priorities.

- **TRACK 1** recipients must include additional criteria as outlined in PRPS Standard 3.
- Recipients must demonstrate how they conduct their inspection work-planning and prioritization to FDA upon request.

iv. Recipients must submit all FDA 4056s with written observations, and full inspection reports for any potentially violative inspections. Refer to the most current FDA CPGM 7303.080, Produce Safety Inspections (see **Appendix E**), or other operating instructions provided by the FDA, for the required components and submission time frames of inspection reports by inspection classification.

- Inspection reports include, but are not limited to: Form FDA 4056, Produce Farm Inspection Report (PFIR) or PFIR Summary (PFIRS) (as appropriate), Attachments and Exhibits.

j. **PATH C** recipients

i. FDA will not routinely request a recipient's farm inventory with farm identifying information. However, recipients must provide farm inventory data with farm identifying information to the FDA upon request.

ii. Recipients are encouraged to conduct inspections according to the most current FDA CPGM 7303.080, Produce Safety Inspections (and attachments) (see **Appendix E**), and pertinent FDA guidance or operating instructions for conducting produce safety inspections.

iii. Recipients must use a risk-based prioritization model and are encouraged to prioritize inspections considering criteria listed in the FDA CPGM 7303.080, under Part II- Implementation, Inspection Priorities.

iv. FDA will not routinely request detailed inspection reports. However, recipients must provide detailed inspection reports to the FDA upon request, within 15 business days of the completion of the inspection or within 15 business days of the request.

- Inspection reports include, but are not limited to, the state equivalent of: Form FDA 4056, Produce Farm Inspection Report (PFIR) or PFIR Summary (PFIRS) (as appropriate), Attachments and Exhibits, and/or supporting evidence.

k. New applicants and recipients previously funded through PAR-21-174 as PATH A (non-regulatory programs) must coordinate with the FDA on establishing an initial inventory of produce farms, and the development and implementation of an inspectional program, including initial work planning and participating in joint inspections. Additional requirements and timelines may be outlined and mutually agreed upon under Objective 2(j).

Objective 5: Compliance and Enforcement Program

This objective includes program elements for recipients to maintain a compliance and enforcement program for produce farms under their jurisdiction. It is recommended that all programs coordinate with local/state/federal agencies to utilize the compliance and enforcement action(s) that will result in the greatest protection of public health. Unless specified otherwise, the goals and requirements under this objective are applicable to all recipients.

Goals and Activities

a. **PATH B** recipients

i. Recipients' internal procedures on their preliminary review of inspection documentation must align with the FDA's Investigation Operation Manual (IOM) and other pertinent FDA guidance or operating instructions.

ii. Recipients must submit their internal procedures on their preliminary review of inspection documentation to the FDA for review by the end of their first year under this cooperative agreement, and as procedures are updated.

iii. Recipients must engage with the FDA on any compliance and enforcement activities according to the most current FDA CPGM 7303.080, Produce Safety Inspections (and attachments) (see **Appendix E**), and pertinent FDA guidance or operating instructions.

iv. In compliance cases, recipients must provide their inspection documentation to the FDA, and FDA will determine the compliance status and perform the enforcement action(s). Inspection documentation may include previous inspection reports as determined by the FDA.

v. Recipients may need to conduct follow-up inspections as determined by the FDA.

b. **PATH C** recipients

i. Recipients' written procedures for conducting compliance and enforcement activities should include:

- A risk-based process to determine when a directed investigation, follow-up, or re-inspection is needed.
- A framework for compliance and enforcement progressive actions, utilizing the current compliance and enforcement guidance available.

ii. Recipients must submit biannual reporting on OAI inspections, including the submission of the following data elements: inspection date(s), produce commodity/commodities observed, inspection type, full text of written observation(s) that led to OAI classification, enforcement action taken, farm's corrective action, and recipient's next steps (see **Appendix I**). This data submission requirement is not applicable to recipients submitting disaggregated data under **OPTION D**.

- Furthermore, if the recipient finds during an inspection that a farm has one or more conditions that have or could likely lead to produce contamination and there is impacted produce in the marketplace, or it is unknown whether impacted produce is in the marketplace, the recipient must inform the FDA, within 1 business day after the conditions are observed, and coordinate on any compliance and enforcement activities. In these situations, the recipient should continue to take the action they consider appropriate under their authority.

iii. New applicants and recipients previously funded through PAR-21-174 as PATH A (non-regulatory programs) must coordinate with the FDA on all compliance and enforcement activities until recipients have fully established regulatory authority. Additional requirements and timelines may be outlined and mutually agreed upon under Objective 2(j).

Objective 6: Response Activities

Each jurisdiction should have the capability to systematically detect, investigate, mitigate, document, and analyze produce-related incidents to stop, control and prevent hazards that are likely to result in a produce related illness, injury, or outbreak. Produce incidents include, but are not limited to, foodborne illness outbreaks, Laboratory Flexible Funding Model (LFFM) positive samples if the regulatory program is participating in an approved LFFM sampling plan, and significant weather events (e.g., flooding, wildfires). These capabilities can reside and be funded by other offices or agencies in the jurisdiction or may be headed by the produce program funded under this cooperative agreement. The expectation is that there is coordination across multiple offices and departments within a jurisdiction and there is not duplication of efforts or redundant funding allocated for these capabilities. Unless specified otherwise, the goals and requirements under this objective are applicable to all recipients.

Goals and Activities

a. Recipients should engage and coordinate response with funded or voluntary Rapid Response Teams (RRT) in their jurisdictions, where applicable. **TRACK 1** recipients must implement and conform with PRPS Standard 5 (see **Appendix G**).

b. In jurisdictions without a funded or voluntary RRT, **TRACK 1** recipients must implement and conform with PRPS Standard 5, and **TRACK 2** recipients should utilize PRPS Standard 5 as the framework for their incident response planning and field activities.

c. Recipients that plan on conducting produce response activities should ensure staff have the appropriate training (e.g., completion of ER220 Traceback Investigations course prior to conducting a traceback investigation).

d. If the recipient is part of the Laboratory Flexible Funding Model by signing on to an approved LFFM sampling plan, they will apply their Produce Safety Program response, enforcement, and regulatory framework, appropriate to their Program **PATH**, to conduct follow-up inspections, investigations (including traceback/forward) and enforcement actions (e.g., embargoes, holds, recalls, warning letters, closures, etc.) to positive samples identified as part of the LFFM cooperative agreement.

i. Recipients will commit to coordinating response and compliance follow-up on LFFM samples with the FDA in real-time, to include sharing findings and compliance actions or other follow-up activities discussing regulatory/compliance strategy with the FDA.

ii. If a potentially violative LFFM sample comes to a Produce Safety Program but is outside the Produce Safety Program's regulatory authority/jurisdiction, the program agrees to identify and notify the appropriate state/federal agencies with jurisdiction, and to notify the FDA.

iii. Potentially violative LFFM samples may come to the Produce Safety Program from any laboratory participating in the LFFM Human Food Product Testing track for microbiology. This includes samples collected by LFFM laboratories within the same state as the Produce Safety Program (may or may not be the primary servicing laboratory for the Produce Safety Program) and samples collected by other states/analyzed by other LFFM laboratories where the potentially violative product is traced back to the Produce Safety Program's state.

iv. Recipients will collect samples in accordance with the collection instructions for each hazard-commodity pair on the approved LFFM sample plan, as needed.

Appendices

Appendix A: Funding Band Descriptions and Determinations

Applicants will determine their eligible funding bands based on their actual verified farm inventory at the time of application. The following table describes the farm inventory numbers to include in each funding band determination.

Funding Band	Description	Verified farm inventory for funding band determinations
Program Base and Regulatory Funding (**Table 1**)	Includes program base funding applicable to all CAP objectives and additional funding for regulatory work based on the applicant's total number of verified non-exempt PSR covered farms in their jurisdiction.	# Non-exempt PSR covered farms
Farm Inventory Funding (**Table 2**)	Includes supplemental program funding for farm inventory work based on the applicant's total number of verified produce farms with produce sales (as detailed in Obj 4(a)) in their jurisdiction. This funding covers the maintenance and re-verification of existing farm inventory as well as the verification of new farms in their jurisdiction.	# Produce farms with produce sales: non-exempt PSR covered farms, farms not covered due to produce sales under $25k (adjusted for inflation), farms with commercial processing exemption, farms that grow only Rarely Consumed Raw (RCR) commodities or commodities under Enforcement Discretion (ED), and farms eligible for a qualified exemption

Outreach and Technical Assistance Funding (**Table 3**)	Includes supplemental program funding for outreach and technical assistance activities based on the applicant's total number of verified farms eligible to receive outreach and technical assistance (as detailed in Obj 3(a)) in their jurisdiction.	# Produce farms conducting PSR covered activities on PSR covered produce: non-exempt PSR covered farms, farms not covered due to produce sales under $25k (adjusted for inflation), and farms eligible for a qualified exemption

Appendix B: Key Timelines

The following table contains key timelines by program objective for reference. This is not an all-inclusive list of NOFO requirements and expectations. Key timelines for reporting are detailed under Section VI.

Program Objective	Key Timelines
Objective 1	Refer to Year 1 and Year 2-5 Goals and Activities as detailed under Objective 1.
Objective 2	2(a): Recipients must develop and maintain a Program Workbook, utilizing a standardized template provided by the FDA, to outline program objectives, annual goals and planned activities, and provide periodic progress reports as described in Section VI. 2(l): **TRACK 2** recipients will develop and maintain a foundational framework for their produce safety program. Written procedures must be established by the end of the recipient's first year, except for procedures for response activities which must be established by the end of the project period (June 30, 2032). 2(j): New applicants, and recipients previously funded through PAR-21-174 as PATH A (non-regulatory programs), must establish a mutually agreed-upon new applicant or transition plan with the FDA to include timelines, key milestones, and responsible parties. This plan must be established within the first 3 months of the recipient's first year and clearly document any alternate timelines required under Objective 2-6 as a new regulatory program.
Objective 3	3(e): Recipients must develop and maintain an annual Outreach Plan as part of the required Program Workbook, including annual targets for outreach and technical assistance activities based on their jurisdiction's needs.
Objective 4	4(a)(i): All produce farms that are covered, not covered due to produce sales under $25k (adjusted for inflation), commercial processing exempt, grow only Rarely Consumed Raw (RCR) commodities or commodities under Enforcement Discretion (ED), or eligible for a qualified exemption are to be re-verified at a minimum of every 5 years. 4(b): At a minimum, recipients must conduct routine inspections on 20% of their jurisdiction's non-exempt covered farms annually.
Objective 5	5(a)(ii): **PATH B** recipients must submit their internal procedures on the preliminary review of inspection documentation to the FDA for review by the end of their first year under this cooperative agreement, and as procedures are updated.
Objective 6	See Objective 2(l)(vi) Response Activities: recipients should utilize PRPS Standard 5, and must include the elements outlined in Objective 6, as the framework for their incident response activities and written procedures, to be established by June 30, 2032.

Appendix C: Farm Inventory Data Elements

Elements are included as a reference and are subject to minor changes. The required reporting forms and associated instructions will contain additional information on the options and format for each reported data element (e.g., free text, standardized list of entry options, Y/N) (see **Appendix I**).

C1: Farm Inventory Required Data Elements to be maintained in recipient's IT system

Unique Farm ID
Date Verified
Farm Name
Business Address Line 1
Business Address City
Business Address State Abbreviation
Business Address Zip code
Business Address County
Phone Number
Email Address
Farm Size based on average produce sales
Covered Produce (Y/N)
Commodities
Activities
Farm Type
Farm PSR Coverage Status
Seasonal Growing Period
Seasonal Harvest Period
Point of Contact Role
Point of Contact First Name
Point of Contact Last Name
Point of Contact Phone Number
*Additional data elements must be maintained (See **Appendix C3**) by recipients participating in the Disaggregated Data Submission **OPTION D**.*

C2: Aggregated Farm Inventory Data Submission (OPTION A)

Farms by Farm Size and Farm PSR Coverage Status
Farms conducting covered activities on national priority commodities as identified by FDA
Farms growing covered produce
Farms harvesting covered produce
Farms packing covered produce
Farms holding covered produce
Farms processing covered produce
Farms retailing covered produce
Farm Mixed-Type Facilities

C3: Disaggregated Farm Inventory Data Submission (OPTION D)

State Abbreviation
Unique Farm ID
Date Verified
Covered Produce (Y/N)
Farm Size based on average produce sales
Farm Type
Farm PSR Coverage Status
Activities
Commodities
Production Method*
Soil Amendments Utilized*
Agricultural Water Source(s)*
Agricultural Water Application Method(s)*
Livestock on the farm*
Livestock adjacent to the farm*
Manure or compost operation adjacent to the farm*
**applicable to PSR covered farms; not expected to be reported until the farm has received an inspection.*

Appendix D: Inspection and Compliance Data Elements

Elements are included as a reference and are subject to minor changes. The required reporting forms and associated instructions will contain additional information on the options and format for each reported data element (e.g., free text, standardized list of entry options, Y/N) (see **Appendix I**).

D1: Aggregated Inspection and Compliance Data Submission (OPTION A)

Total farms inspected
Total inspections
For reporting period:
Inspections completed
Farms inspected
Inspections with observations on the FDA 4056 or state equivalent
Inspections at farms that handle priority commodities
Farms with improved inspection classification from previous inspection
Observations corrected during inspection
Inspection classification for each inspection by inspection type and farm size
Farms having previous OFRRs/food safety audits/PSR training
Observations by Produce Safety Rule Citation
Inspections resulting in compliance actions
Farms inspected resulting in compliance actions and by compliance action taken
Recalls and volume of product recalled
Compliance follow-up inspections/#farms and by improved classification

D2: Disaggregated Inspection and Compliance Data Submission (OPTION D)

State Abbreviation
Unique Farm ID
Farm Size
Farm PSR Coverage Status
Inspection End Date
Date of Last PSR Inspection
Covered Activities Observed
Commodities Observed
Inspection Type
Previous Inspection Classification
Current Inspection Classification
PSR Training Source
On-Farm Readiness Review (OFRR) Conducted
Previous Food Safety Audit
Written Observation(s) text by Citation #
Other Observation(s)
Discussion Item(s) narrative text
Did this inspection result in Compliance and Enforcement Action?
Follow-up inspection planned?
Compliance and Enforcement Action(s) Completed
Recalls Resulting from PSR Inspection

Appendix E: FDA Compliance Program 7303.080 Produce Safety Inspections

- FDA Website

Appendix F: FDA Food Safety Data Exchange (FSDX) Portal

- FSDX Portal

Appendix G: FDA Produce Regulatory Program Standards (PRPS)

- FDA Website

Appendix H: FSMA Food Traceability Rule (FTR) resources

- FDA Website

Appendix I: Required Program Reporting Forms

- FDA Website

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument	Cooperative Agreement: A financial assistance mechanism used when there is substantial Federal scientific or programmatic involvement. See Section VI.2 for additional information about the substantial involvement for this NOFO.
Application Types Allowed	New Only the application type(s) listed here are allowed for this NOFO.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for four (4) additional year(s) contingent upon annual appropriations, availability of funding, and satisfactory awardee performance and workload. FDA intends to fund an estimate of up to $34 million dollars for fiscal year (FY) 2027 in support of this cooperative agreement program. Funding for FY2028, FY2029, FY2030, and FY2031 will be contingent upon annual appropriations and availability of funding. It is anticipated that up to fifty-six (56) awards will be made, not to exceed $12 million in total costs (direct plus indirect), per award.

Award Budget

Application budgets need to reflect the actual needs of the proposed project. Proposed budgets should not exceed the maximum eligible funding (including direct and indirect costs) determined by combining the funding associated with the applicant's selected program **TRACK**, **PATH**, and additional optional funding as applicable (see **Tables 1-5**). Eligible First Time Applicants not previously funded under PAR-16-137 or PAR-21-174 should refer to **Table 6** for the TOTAL maximum eligible funding for their initial year.

Funding Structure

Each eligible applicant may apply for up to their maximum annual eligible funding, which is based on combining the maximum eligible funding from each funding band as outlined in **Tables 1**, **2**, and **3**, in addition to any applicable optional funding requested as outlined in **Table 4.** The applicant should select the funding bands that correspond to their actual verified farm inventory at the time of application (See **Appendix A**). Funding band determinations are based on the anticipated workload of each recipient. Additional one-time funding for applicants previously funded through PAR-21-174 as PATH A (non-regulatory programs) that will transition to a regulatory program is outlined in **Table 5**.

Table 1: Program Base and Regulatory Funding: Outlines program base funding across all applicable CAP objectives and additional funding for regulatory work based on the applicant's total number of verified non-exempt PSR covered farms in the recipient's jurisdiction.

Funding Band	Range of non-exempt PSR Covered Farms	Maximum Eligible Funding	Additional Funding for PATH C Compliance Programs
A	1–100	$320,000	$16,000
B	101–200	$440,000	$22,000
C	201–400	$680,000	$34,000
D	401–600	$920,000	$46,000
E	601–800	$1,100,000	$55,000
F	801–1,000	$1,340,000	$67,000
G	1,001–1,500	$1,850,000	$92,000
H	1,501–2,000	$2,450,000	$122,000
I	2,001–3,000	$3,500,000	$175,000
J	3,001–4,000	$4,700,000	$235,000
K	4,001–6,000	$6,800,000	$340,000
L	6,001+	$8,000,000	$400,000

Note: Recipients may utilize CAP funds for produce response activities under Objective 6. If additional response related funding is needed, recipients should contact their FDA Program Official for available options.

Table 2: Farm Inventory Funding: Outlines supplemental program funding for farm inventory work based on the applicant's total number of verified produce farms with produce sales (as detailed in Obj 4(a)) in the recipient's jurisdiction. This funding covers the maintenance and re-verification of existing farm inventory as well as the verification of new farms in the recipient's jurisdiction.

Funding Band	Range of Total Produce Farms	Maximum Eligible Funding
A	1-1,000	$20,000
B	1,001-2,000	$46,000
C	2,001–3,000	$72,000
D	3,001–5,000	$104,000
E	5,001–7,000	$156,000
F	7,001–10,000	$215,000
G	10,001–12,000	$286,000
H	12,001–16,000	$364,000
I	16,001+	$442,000

Table 3: Outreach and Technical Assistance Funding: Outlines supplemental program funding for outreach and technical assistance activities based on the applicant's total number of verified farms eligible to receive outreach and technical assistance (as detailed in Obj 3(a) and (c)) in the recipient's jurisdiction.

Funding Band	Range of Total Farms Eligible for Outreach and Technical Assistance	Maximum Eligible Funding
A	1-1,000	$45,000
B	1,001-2000	$105,000
C	2,001–3,000	$165,000
D	3,001–5,000	$240,000
E	5,001–7,000	$360,000
F	7,001–10,000	$495,000
G	10,001–12,000	$660,000
H	12,001–16,000	$840,000
I	16,001+	$960,000

Table 4 Optional Activities: Outlines additional funding for optional activities that may be added to the applicant's requested budget and application. The number of awards to receive this optional funding is dependent on the availability of funding.

Optional Activities	Maximum Eligible Funding
TRACK 1 Enrollment in Produce Regulatory Program Standards (PRPS)	$150,000
OPTION D Disaggregated Data Submission (Obj 4(i))	$25,000 (1-1000 total produce farms: **Table 2**, funding band A) $50,000 (1001-2000 total produce farms: **Table 2**, funding band B) $75,000 (2001-5000 total produce farms: **Table 2**, funding bands C - D) $100,000 (Over 5000 total produce farms: **Table 2**, funding bands E - I)

Table 5 Transitioning Applicants: Outlines additional one-time funding available to applicants previously funded through PAR-21-174 as PATH A (non-regulatory programs) that will transition to a regulatory program.

Eligible Applicants	Maximum Eligible Funding
PATH A recipient under PAR-21-174; transitioning to a regulatory program	$50,000 may be added as one-time funding (not annual) in addition to program funding as outlined in **Tables 1-4** to assist in the establishment of a regulatory program.

Table 6 First-time Applicants: Outlines maximum eligible total funding for the initial year of eligible First-time Applicants that did not receive funding under PAR-16-137 or PAR-21-174. Eligible funding in subsequent years will be based on the applicant's actual verified farm inventory at the time of application.

Eligible Applicants	Maximum Eligible Funding - Total Budget
First-time applicants that did not receive funding under PAR-16-137 or PAR-21-174.	$385,000

Award Project Period	The scope of the proposed project should determine the project period. The maximum project period is five (5) years.

HHS grants policies as described in the HHS Grants Policy Statement will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

Eligible Organizations

This funding opportunity is available only to state and territory government agencies with actual or potential regulatory oversight and responsibility over their respective jurisdiction's farms, produce commodities, and activities covered under FDA's Produce Safety Rule (21 CFR Part 112).

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the NIH Grants Policy Statement, **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the Application Instruction Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference the HHS Grants Policy Statement for additional information

- System for Award Management (SAM) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed project as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support.

The PD/PI should be an established in the area in which the application is targeted and capable of providing both administrative and technical leadership to the development and implementation of the proposed program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required.

Cost Sharing
This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement.

Additional Information on Eligibility
Number of Applications

Only one application is allowed per state or territory. Jurisdictions interested in involving multiple state or territory entities within their jurisdiction are required to internally coordinate and choose one entity to apply.

Section IV. Application and Submission Information
Requesting an Application Package
The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

Content and Form of Application Submission
It is critical that applicants follow the instructions in the Application Instruction Guide except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the Application Instruction Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Technical Session
Technical session(s) will be held for prospective applicants in November/December 2026. Subsequent technical sessions for future application due dates will be held as necessary. The technical session(s) will provide an overview of the submission requirements and allow prospective applicants an opportunity to ask questions regarding the application process. Participation in the technical session is optional but strongly encouraged.

To register for the technical session, please contact:

Adrianna Vargo
Office of Domestic Partnerships (ODP)
Email: Adrianna.Vargo@fda.hhs.gov

Letter of Intent
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows FDA staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Danielle Head
Office of Acquisitions and Grants Services (OAGS)
Email: Danielle.Head@fda.hhs.gov

Page Limitations

All page limitations described in the Application Guide must be followed.

Component	Form to use	Page limit
Project abstract	Project Abstract Summary form	1 page
Project narrative	Project Narrative Attachment form	30 pages
Budget narrative	Budget Narrative Attachment form	No

Instructions for Application Submission

The following section supplements the instructions found in the Application Guide and should be used for preparing an application to this NOFO.

Application for Federal Financial Assistance (SF-424)

All instructions in the Application Guide must be followed. In the "**Descriptive Title of Applicant's Project:"** field applicants must include the **TRACK** number, **PATH** letter, and State Organization Name/Abbreviation in the Project Title.

SF-424 A Budget Information - Non-Construction Programs Form

All instructions in the Application Guide must be followed.

Project/Performance Site Location(s)

All instructions in the Application Instruction Guide must be followed.

Project Abstract Summary

All instructions in the Application Guide must be followed.

The Project Abstract Summary must confirm the applicant's Program TRACK (1 or 2), confirm the applicant's Program PATH (B or C), and confirm the applicant's data submission OPTION (A or D).

Project Narrative Attachment

All instructions in the Application Guide must be followed.

As part of the project narrative, the applicant must address the following areas under each program objective for the applicable budget period utilizing the Program Workbook Outline. Refer to **Appendix I:** Required Program Forms.

Coversheet:

- Agency
- State or Territory
- Program **TRACK**
- Program **PATH**
- Data submission **OPTION**

Applicants must provide a numerical breakdown of their farm inventory used to determine their eligible funding in **Tables 1-3**, as further detailed in **Appendix A**.

- Number of verified farms to determine program base and regulatory funding band (**Table 1**)
- Number of verified farms to determine inventory funding band (**Table 2**)
- Number of verified farms to determine outreach and technical assistance funding band (**Table 3**)

Objective 1 PRPS (**TRACK 1** only):

- Planned activities related to Objective 1
- Describe the necessary management support and access to internal and external resources to achieve full conformance with the PRPS.

Objective 2 Program Administration:

- Planned activities related to Objective 2

- Staffing Matrix
- Subawards, including subaward name(s) and planned activities
- Contract entity/entities and planned services
- **PATH C**: Authority Statutes and Admin Regulations
- Information Sharing / 20.88

Objective 3 Outreach and Technical Assistance Program:

- Planned activities related to Objective 3
- Planned number of: PSA Trainings, OFRRs, and other Outreach and Technical Assistance activities (if known at the time of application)

Objective 4 Inspection Program:

- Planned activities related to Objective 4a Inventory
- Planned activities related to Objective 4b Inspections
- Inspection Work Planning Schedule, including time frames and minimum annual inspection goals based on verified covered farm inventory data

Objective 5 Compliance and Enforcement Program:

- Planned activities related to Objective 5

Objective 6 Response Activities:

- Planned activities related to Objective 6

Appendix: Only limited Appendix materials are allowed as described below:

Applicants must attach as Appendix #1, an organizational structure to accomplish the implementation, oversight, monitoring and reporting of program objectives. Roles and responsibilities must be outlined and must directly relate to accomplishing the applicable Program Objectives.

Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

Submission Dates and Times

Part I. contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, FDA's electronic system for grants administration. FDA and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the FDA Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the How to Apply - Application Guide.

Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

Funding Restrictions

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations, and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate: racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

Non-allowable costs:

1. Facilities and work covered under current contracts, cooperative agreements/grants, partnership funds, and other sources cannot be counted towards the fulfillment of the cooperative agreement and must remain distinct and separate from the cooperative agreement. The recipient must be able to account separately for fund expenditures from other sources of FDA funding and these cooperative agreements.
2. Vehicle purchases are not permitted.
3. New building construction.
4. Food may not be purchased.
5. Payment or reimbursement of any direct costs (including travel) for individual farms/farmers to attend grower training as a participant is not permitted.
6. Payment or reimbursement of any direct costs (including travel) for individual farms/farmers for audit costs or fees is not permitted.
7. Uniforms may not be purchased.
8. Any equipment or incentive type items that go to individual farms may not be purchased.

Additional funding restrictions may be part of the Notice of Award.

Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit the Application Guide. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to the FDA. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the assigned FDA Grants Management Specialist and responsiveness by components of participating organizations. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Section V. Application Review Information

Criteria

Applications submitted to the FDA are evaluated for technical merit. Only the review criteria described below will be considered in the merit review process.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Participation and Maintenance	**Maximum Points: 15**
Does the application demonstrate the applicant's ability to implement and maintain a Produce Safety Program that supports implementation of the Produce Safety Rule through the cooperative agreement program? Does the applicant demonstrate the ability to fully participate in initiatives supporting the cooperative agreement?	
Investigator(s), Key Personnel, and Resources	**Maximum Points: 20**
The applicant must provide an organizational structure and available resources to accomplish the implementation, oversight, monitoring and reporting of program objectives. Does the application outline roles and responsibilities and available resources that directly relate to accomplishing the applicable Program Objectives? Have adequate resources (including staff and infrastructure) been proposed in the application budget to meet the objectives of the cooperative agreement?	
Integration	**Maximum Points: 15**
Is there adequate demonstration of effectiveness in working with federal, state, and other appropriate organizations to implement the goals of the cooperative agreement?	
Approach	**Maximum Points: 50**
Does the applicant's Project Abstract Summary and Project Narrative Attachment, as outlined in "Part 2, Section IV. Application and Submission Information," demonstrate the ability to accomplish each of the objectives? Is the overall strategy, methodology, and analyses well-thought out and appropriate to accomplish the specific objectives? Has the applicant included annual goals, benchmarks, and associated timelines to accomplish the specific objectives? Have potential obstacles to achieving and maintaining objectives been identified, along with approaches to overcome these obstacles?	

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed project.

Renewals

Not applicable.

Review and Selection Process
Applications will be evaluated for technical merit by (an) appropriate Objective Review Committee convened by the FDA, using the stated review criteria. Assignment to an Objective Review Committee will be shown in eRA Commons.

Review and Selection Process
As part of the objective review, all applications will receive a written critique.

Funding Preference for Alignment with Agency Priorities
Before final funding decisions are made, agency leadership will review awards for consistency with applicable laws and alignment with FDA's Public Health Pillars. To the extent permitted by law and applicable court orders, award applications which are aligned with agency pillars will receive a funding preference. For example, applications that explicitly align with FDA's Public Health Pillars will be eligible for a funding preference.

Appeals of objective review will not be accepted for applications submitted in response to this NOFO.

Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. The following will be considered in making funding decisions:

- Technical merit of the proposed project as determined by objective review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

Anticipated Announcement and Award Dates
Successful applicants will be notified of additional information that may be required or other actions leading to an award. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any FDA or HHS official or board.

Information regarding the disposition of applications is available in the HHS Grants Policy Statement.

Section VI. Award Administration Information
Award Notices
A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the HHS Grants Policy Statement.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in FDA-funded studies, the recipient must provide FDA copies of documents related to all major changes in the status of ongoing protocols.

Administrative and National Policy Requirements
The following Federal wide and HHS-specific policy requirements apply to awards funded through FDA:

- The rules listed at 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

- All FDA grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in the HHS Grants Policy Statement.

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. FDA may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination and HHS Grants Policy Statement.

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it to learn more.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework, to protect HHS systems and data. Please refer to HHS Grants Policy Statement for additional information.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (HHS) grant administration regulations at 2 CFR Part 200, and other HHS, PHS, and FDA grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial FDA programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the FDA purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the FDA as defined below.

The Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA staff being substantially involved as a partner with the PD/PI, as described below.

The PD/PI will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff have sufficient clearance and/or background checks to work on this project. This individual will work closely with designated officials within the recipient organization and with partner organizations to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge federal support in publications, announcements, news programs, and other media; and ensure compliance with other federal, regulatory, and organizational requirements.

FDA Program Staff will have substantial programmatic involvement that is above and beyond the normal oversight, monitoring, and stewardship of awards, as described below:

- FDA produce subject matter experts (SMEs) will assist recipients implementing the Produce Safety Rule (PSR) and conducting related regulatory activities. FDA will dedicate staff and resources to assist with the program activities described below.
    - Provide regulatory interpretation to PSR questions via the Technical Assistance Network (TAN) and direct interaction with FDA SMEs.
    - Collaborate to ensure high quality, nationally consistent produce inspections, such as developing inspection instructions and other inspection resources, coordinating on calibration (i.e., quality of inspections) of inspection staff, and performing joint inspections.
    - Conduct the compliance program for **PATH B** recipients, advise **PATH C** recipients on compliance strategies when requested, and collaborate with all recipients to implement appropriate enforcement responses.
    - Collaborate on produce response activities to ensure the best public health outcome.
    - Collaborate on educational materials to develop high-quality products and reduce duplication of effort to utilize resources in the most efficient manner. Provide review and approval for the proposed development of new educational content.
    - Conduct data analysis to improve future inspection and inventory work and compare data analysis findings (federal and state) to ensure continuous program improvement.
    - During the project period, FDA will provide continuous specialized technical assistance to help **TRACK 1** recipients achieve conformance with the Produce Regulatory Program Standards (PRPS); FDA SMEs will actively review, assess, verify, and guide self-assessments, strategic improvement plans, and implementation activities.
        - Assessments: recipients are required to participate in formal assessments, in which FDA will evaluate and verify the status of PRPS conformance, representing decision-making authority at critical project milestones.

Expected outcomes from collaboration include meeting **TRACK 1** and **TRACK 2** program objectives as applicable, high-quality inspections ensuring safe and healthy produce, inventory development and maintenance, and analyzing data for continuous program improvement.

Data Management and Sharing

Consistent with the FDA Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the HHS Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

Reporting

When multiple years are involved, recipients will be required to submit an annual report as outlined below and financial statements as required in the HHS Grants Policy Statement.

Reporting Requirements:

This award has additional financial and performance reporting requirements as outlined below.

Financial

Recipients are expected to provide budgetary information during mid-year monitoring activities, including funds expended (total and by category), planned expenses (total and by category), and funds remaining.

Performance

Performance progress reports, data reports, and monitoring calls are required for this award. Reports should be submitted via eRA and FDA's Food Safety Data Exchange (FSDX) Portal (see **Appendix F**). Recipients are required to use the excel reporting forms provided by FDA under OMB#0910-0909 (see **Appendix I**), for the following reporting and data submissions:

Due Date	Progress and Data Reporting
Sept 1	**Year 1:** • CAP Program Workbook detailing plans for the current budget period. **Years 2-5:** • CAP Program Workbook detailing accomplishments from the prior budget period (July 1 – June 30). • Current Farm Inventory (Aggregated or Disaggregated according to **OPTION A** or **D** selected). • Inspection and Compliance Data (Aggregated or Disaggregated according to **OPTION A** or **D** selected) covering the prior budget period (July 1 – June 30). • **PATH C** recipients participating in **OPTION A** data submission must submit data on OAI inspections as detailed in Objective 5(b)(ii) covering the prior budget period (July 1 – June 30).

Dec 1	• Inspection and Compliance Data (Aggregated or Disaggregated according to **OPTION A** or **D** selected) covering July 1 – October 31.
	• **PATH C** recipients participating in **OPTION A** data submission must submit data on OAI inspections as detailed in Objective 5(b)(ii) covering July 1 – October 31.
	• **TRACK 1** Recipients:
	  • Completion of Self-Assessments and Appendix 9.2 (Self-Assessment Summary Report), completed and submitted after year 1 of enrollment and annually thereafter on December 1.
	  • Submission of a strategic improvement plan that contains all PRPS required elements; accurately reflects when specific objectives and tasks have been, or will be, completed and/or implemented; and when new objectives and tasks are identified to achieve full conformance of the PRPS. Progress achieved should indicate when full conformance of the PRPS can be reasonably expected. This should be completed and submitted after year 1 of enrollment and annually thereafter on December 1.

May 1	• CAP Program Workbook detailing plans for the upcoming budget period and accomplishments from the current budget period to-date.

	• Current Farm Inventory (Aggregated or Disaggregated according to **OPTION A** or **D** selected)

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement. FDA will review and measure performance as described at 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over the threshold. See the HHS Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 2 CFR Part 200.113 and Appendix XII to 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (Responsibility/Qualification in SAM.gov, formerly FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

Program/Technical Contact

Adrianna Vargo
Office of Domestic Partnerships (ODP)
Email: Adrianna.Vargo@fda.hhs.gov

Financial/Grants Management Contact(s)

Danielle Head
Office of Acquisitions and Grants Services (OAGS)
Email: Danielle.Head@fda.hhs.gov

Section VIII. Other Information

Recently issued policy notices may affect your application submission. A full list of policy notices is provided in the Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Section 1004 of the Food and Drug Administration Amendments Act (21 USC 2104) and under Federal Regulation 2 CFR Parts 200 and 300.