Instructions for completing aggregate data reports for Inspections, Compliance, and Enforcement

Quick Guide

Version: September 2021
Version: December 2021

General Instructions

This spreadsheet contains five tabs; 1. General Inspection Data, 2. Inspection Classification, 3. Inspection Observations, 4. Compliance and Enforcement, and 5. Sprouts. This spreadsheet must be completed and submitted in ORAPP by all Path B and Path C CAP grantees by Dec 1; Feb 1; May 1; and Sept 1 annually. Please save your file locally before you upload it to ORAPP. Use the File Naming Convention: (state abbreviation_grant number last 4_YYYYMMDD_Document Title); Example: AL_1234_20211201_Inspection Aggregate Data.

Except in rows 1.1-1.3, all data reported will be reported for the **corresponding reporting period only, as follows:**

Dec. 1 includes data for Jul 1 - Oct 31
Feb. 1 includes data for Jul 1 - Dec 31
May 1 includes data for Jul 1 - Mar 31
Sept. 1 includes data for Jul 1 - Jun 30

Because all reporting periods start on July 1st, your data is expected to remain the same or increase with each report submission.

What to Report:

- Except in rows 1.1-1.3, all data reported will be reported for the corresponding reporting period.
- Only report completed inspections. For inspection aggregate data reporting, report the farm size category at the time of inspection. An inspection is considered “completed” when the inspector

has finished the inspection and issued the FDA 4056 or state equivalent to the farm, the inspection elements of the Produce Farm Summary Report or equivalent have been completed, and the inspection is classified with a final decision of NAI, VAI, or OAI.

- If the state does not classify inspections by OAI, VAI, NAI, coordinate with your FDA OP project manager and PSN staff to determine how to correlate state inspection classifications to the reporting categories.
- Only report activities funded under the CAP.
- Only report inspections where your agency issued the 4056 or equivalent (this applies to joint agency inspections); an exception to this is Table 5 - Sprouts.

Data Sources:

- The likely data source is noted for each row. Most data will be captured on the FDA Form 4056 (or state equivalent) and the Produce Farm Inspection Report Summary (PFIRS).

Farm types:

- Report qualified exempt and commercial processing exempt (CPE) farms in these categories and not in the farm size categories.
    - Only report a farm as commercial processing exempt if 100% of covered produce is eligible for exemption under 21 CFR Part 112.2(b). For example, if a small farm exercises the processing exemption for some covered produce but other covered produce is not subject to the processing exemption, data for the farm should be included in the Small category and not in the Commercial Process Exempt (CPE) category.
- Sprouts only farms' data will be reported only in Tab 5. As a reminder, sprouts inspections under the CAP must be conducted jointly with FDA.
- If the farm has both sprouts and non-sprout covered produce, include data for all non-sprout produce that was covered during an inspection in Tab 1-4, where appropriate.

Data Entry:

- Please only enter numeric data into the spreadsheet without making any other changes to the spreadsheet; please do not include 'NA' in cells, please do not rename the tabs, or add any cells, rows, columns.
- Where cells are greyed, please do not put an entry; a grey cell indicates this would not be an applicable entry.
- If you have a note or explanation about your submission, please provide that in a separate email correspondence to your Office of Partnerships (OP) Project Manager.

Table Columns

Large Covered: a covered farm as defined in the Produce Safety Rule (21 CFR Part 112), conducting covered activities on covered produce, and, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than $500,000. A farm that is not eligible for a qualified exemption. The produce handled by the farm is not eligible for the commercial process exemption.

Small Covered: a covered farm as defined in the Produce Safety Rule (21 CFR Part 112), conducting covered activities on covered produce, and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than $500,000; and the farm is not a very small business as defined in 21 CFR 112.3. A farm that is not eligible for a qualified exemption. The produce handled by the farm is not eligible for the commercial process exemption.

Very Small Covered: a covered farm as defined in the Produce Safety Rule (21 CFR Part 112), conducting covered activities on covered produce, and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than $250,000. Does not include farms that are not covered by the Produce Safety Rule because they have less than $25,000 average annual monetary value of produce. A farm that is not eligible for a qualified exemption. The produce handled by the farm is not eligible for the commercial process exemption.

Qualified Exempt farm: A farm eligible for a qualified exemption, as established in the Produce Safety regulation, 21 CFR 112.5. These farms will not routinely be inspected under the FDA or state CAP PSR inspection programs.

Commercial processing exempt (CPE): A farm where all covered produce is eligible for exemption, as established in the Produce Safety regulation (21 CFR 112.2(b)). For the purposes of reporting inspection data, a farm would only be reported under "Commercial Processing Exempt (CPE)" if 100% of their covered produce is eligible for exemption. These farms will not routinely be inspected under the FDA or state CAP PSR inspection programs.

Farms Not Covered based on Produce Sales (<$25k): A farm verified to conduct covered activity on covered produce, but the farm is not covered by the Produce Safety regulation per 21 CFR 112.4(a). These farms cannot be inspected under the PSR because they are not subject to the regulation.

Tab 1. General Inspection Data

	Data Element	Explanation	Data source
1.1	**Total number of verified produce farms**	Cells E4, F4, and G4 should correspond to your Produce Farm Inventory aggregate data reported in Tab 1; cells C4, C5, and C6. The data should be current to reporting date. There is no need to report verified inventory for other produce farm types listed in other column headings.	Farm inventory
1.2	**Total number of farms inspected under CAP (cumulative through the end of the current reporting period)**	Total number of farms that have received a PSR inspection since 2018 through the end of the current reporting period using CAP funds. Do not include sprout only operations here. Farms would be counted only once, even if inspected multiple times.	FDA 4056 or state equivalent State data system

1.3	**Total number of inspections under CAP (cumulative through the end of the current reporting period)**		Total number of inspections that have received a PSR inspection since 2018 through the end of the current reporting period using CAP funds. Do not include sprout only operations here.	FDA 4056 or state equivalent State data system
All data below will be for the reporting period				
1.4	**Farms inspected this reporting period**	Total Farms	Total number of farms with completed inspections during the reporting period.	FDA 4056 or state equivalent PFIRS State data system
1.5		Primary Production Farms	Inspections of farms that meet the Produce Safety Rule (21 CFR Part 112) definition of this term. Farms cannot be both a primary production farm and a secondary activities farm.	
1.6		Secondary Activities Farms	Inspections of farms that meet the Produce Safety Rule (21 CFR Part 112) definition of this term.	
1.7		Farm Mixed-Type Facilities	Inspections of farms that meet the Produce Safety Rule (21 CFR Part 112) definition of this term. If a farm is both a mixed-type facility and either a primary production or secondary activities farm, it should only be reported as a farm mixed-type facility.	
1.8	**Inspections completed during this reporting period**		Report inspections completed during the reporting period. For joint agency inspections, report only if your agency issued the 4056 or equivalent.	FDA Form 4056 or state equivalent PFIRS
1.9	**Inspections completed during this reporting period with observations on the 4056 or state equivalent**		The number of inspections completed during the reporting period where one or more observations were noted on the FDA Form 4056 or state equivalent.	FDA Form 4056 or state equivalent
1.10	**Priority commodities observed during each inspection**	Priority commodity #1-7	Report each priority commodity observed for each inspection completed during this reporting period. Priority commodities can be found in the current FDA Produce Safety Inspection Program guidance documents. Two “Other Priority Commodity” lines are included to accommodate potential addition of new priorities at a later date. The current FDA Produce Safety Inspection Program guidance documents will list specific commodities for these rows when applicable. If no specific commodity has been identified please leave these rows	PFIRS or FDA Form 4056 or state equivalent

			blank. If more than one priority commodity was observed during an inspection, count “1” in each row/for each priority commodity covered (e.g. if cucumbers and tomatoes were observed on one inspection, count “1” in row 15 “cucumbers” and “1” in row 16 “tomatoes”; if kale and spinach were observed on one inspection, count “1” in row 14 “leafy greens”).	
1.11	**Farms with improved inspection classification from previous inspection** Previous inspection refers to previous inspection under state CAP.	From OAI to VAI or NAI	Immediate previous inspection was OAI (no matter when completed) and the inspection completed during this reporting period was VAI or NAI.	PFIRS State inspection data system (PFIRS from previous inspection).
1.12		No improvement from OAI	Immediate previous inspection was OAI (no matter when completed) and the inspection completed during this reporting period was also OAI.	
1.13		From VAI to NAI	Immediate previous inspection was VAI (no matter when completed) and the inspection completed during this reporting period was NAI.	
1.14		No improvement from VAI	Immediate previous inspection was VAI (no matter when completed) and the inspection completed during this reporting period was VAI or OAI.	

1.15	**Inspections where egregious conditions were observed** In this section, only inspections that noted egregious conditions will be reported. Egregious Conditions (working definition agreed upon within NASDA/FDA workgroup) as: A practice, condition, or situation on a farm or in a packing house that is reasonably likely to lead to: • Serious adverse health consequences or death from the consumption of or exposure to covered produce; • An imminent public health hazard is posed if corrective action is not taken immediately (example: edible portions of produce contacting a potential source of contamination).	# of farms	Number of farms where one or more egregious conditions were observed during an inspection. If a farm had multiple inspections where egregious conditions were noted, the farm would only be counted once.	FDA Form 4056 or state equivalent (analysis required)
1.16		# of inspections	Number of inspections completed during the reporting period during which one or more egregious conditions was observed.	FDA Form 4056 or state equivalent (analysis required)
1.17		# of egregious observations	Total number of egregious conditions-related observations observed during inspections completed during the reporting period.	FDA Form 4056 or state equivalent (analysis required)
1.18		# of egregious observations corrected during the inspection	Number of egregious conditions-related observations corrected during inspections completed during the reporting period.	FDA Form 4056 or state equivalent
1.19		# of egregious observations corrected after the inspection	Number of egregious conditions-related observations the farm corrected after the inspection and before a compliance action.	Compliance data system
1.20		# of egregious observations corrected after compliance action	Number of egregious conditions-related observations corrected after a compliance action.	Compliance data system

Tab 2. Inspection Classification – Current Reporting Period

Report inspections completed during the currently reporting period by inspection type, inspection classification, and farm size. The PFIRS is a data source for the inspection classification and farm size. The FDA 4056 or state equivalent is a data source for the inspection type. Refer to the FDA Produce Safety Inspection Program guidance documents for more information on inspection classification determinations. The greyed cells will auto-calculate; do not enter data in they greyed out cells.

	Data element	Explanation	Sourc

						e
All data below will be for the reporting period						
2.1		**Inspection classification by farm size for each inspection completed this reporting period**	**Do not report in this row, it will auto-calculate based on your other entries in this table. Please make sure the totals are correct. This row and Columns E, F, G, and H** will auto-calculate/populate. As a quality check, Cell E5 should be the same number as cell D12 in Table 1.			**PFIRS**
2.2		**Inspection type** These rows are mutually exclusive; therefore, each inspection should only be counted one time in rows 2.2-2.7. Terms are the same as those used on the FDA Form 4056.	**Initial PSR Inspections**	**Initial-routine**	Initial surveillance inspection at normally scheduled frequency	**FDA 4056 and PFIRS**
2.3				**Initial-for cause**	An inspection to follow-up on a specific issue, such as an outbreak, consumer complaint, or positive sample, etc., where the inspection is also the farm's initial inspection	
2.4			**Non-initial PSR inspections**	**Routine**	Surveillance inspection at the farm's normally scheduled frequency	
2.5				**Follow-up**	Follow-up to a violative inspection; this would include an inspection of a farm completed after the state or FDA took a compliance or enforcement action at the farm	
2.6				**For-cause**	A non-initial inspection to follow-up on a specific issue, such as an outbreak, consumer complaint, or positive sample, etc. This would include an inspection done at an expedited frequency due to possible conditions of concern	
2.7				**Other (# and type)**	Inspection does not meet one of the other categories (will be used very rarely). Discuss with your OP Project Manager or ORA PSN if you need to use this inspection type	

2.8	**OFRR**	**Yes**	Explanation for these fields is in the Produce Farm Inspection Report Summary Instructions.
2.9		**No**	
2.10	**Farm had a previous Food Safety Audit**	**Yes**	
2.11		**No**	
2.12	**PSR Training Source**	**PSA**	
2.13		**Alternate curricula**	
2.14		**None**	

Tab 3. Inspection Observations – Current Reporting Period

- For each FDA Form 4056 Item (in Column B), report the number of reportable observations checked on the FDA 4056 or state equivalent in Columns E-J, for each inspection completed during the currently reporting period.
- If the inspection has more than one observation for an observation row, tally all observations. For example, if the inspection cited two observations under 112.21 and 112.22, 4056 #1, the tally would report both observations.
- In Column L, report the number of corresponding corrective actions checked on the FDA 4056 or state equivalent.
- The FDA Form 4056 or state equivalent is a data source for the observed reportable observations documented on the FDA 4056 or state equivalent, and the corresponding corrective action.
- Tables 3 has N/A noted for the Subpart E – Agricultural Water items. The compliance dates for Subpart E were extended in a final rule dated 3/18/2019 (see 84 FR 9706).

Tab 4. Compliance and Enforcement - Current Reporting Period

In this table report data related to compliance and enforcement actions. Contact CFSANOCProduce@fda.hhs.gov if you have questions about how to categorize a state compliance action.

	Data element		**Explanation**	**Data source**
All data below will be for the reporting period				
4.1	**Compliance and Enforcement actions completed this reporting period**	**Advisory actions (e.g. Regulatory letter, Regulatory meeting)**	A compliance tool that does not have the force and effect of law.	PFIRS and compliance system
4.2		**Administrative actions (e.g.**	A compliance action for which the authority is granted through legislation	

		Administrative detention, State embargo, State stop sale)	and is executed by the regulatory agency instead of the court system. Imposes a legal requirement on the recipient.	
4.3		**Fines/monetary penalties**	Monetary penalties imposed on a regulated body for non-compliance with a regulatory requirement.	
4.4		**Judicial actions (e.g. Seizure, Injunction, Prosecution)**	Judicial actions are implemented through the court system. Examples: seizure, injunction, prosecution	
4.5		**Other action (not inspection) (# and type)**	If a compliance action type does not fit under one of the other categories, report it in this section. Identify the type of action and the number. This section will not include re-inspections. If a re-inspection was assigned with no other actions, it would not be reported in this table.	
4.6	**Number of farms having a compliance and/or enforcement action completed this reporting period**		Number of farms at which one or more action (from rows 4.1-4.5) was taken during the reporting period. If more than one action took place at a farm, count that farm only once.	PFIRS and compliance system
4.7	**Compliance follow-up inspections that were completed this reporting period.** Compliance follow-up inspection: an inspection of a farm completed after the state or FDA took a compliance or enforcement action at the farm (see actions in rows 4.1-4.5 of this table). The inspection is generally performed to	**Compliance follow-up inspections**	Number of compliance follow-up inspections completed during the reporting period. If more than one compliance follow-up inspection took place at a farm during the reporting period, include all inspections. This cell should equal cell E9 in Table 2.	FDA Form 4056 or state equivalent PFIRS Will require comparison with previous inspection data
4.8		**Farms having a compliance follow-up inspection**	Number of farms where a compliance follow-up inspection was completed during the reporting period. If more than one inspection was completed at a farm during the reporting period, count the farm only once.	
4.9		**Compliance follow-up inspections resulting in an improved inspection classification from the previous inspection**	Inspections completed during the reporting period to follow-up to a compliance action where the inspection classification of the follow-up inspection improved.	

4.10	determine whether the farm has implemented corrective actions, or to confirm that the corrective	**Farms having a compliance follow-up inspections resulting in an improved inspection classification from the previous inspection**	Number of farms where inspections were completed to follow-up on a compliance action and where the classification of the follow-up inspection improved.	
4.11	**Recalls resulting from a PSR inspection**	**Number of recalls**	Number of distinct recalls initiated by farms during the reporting period as a result of PSR inspection findings. If a recall was expanded after the recall was initiated, but the expansion is considered to be part of the initial recall action, do not count the expansion as an additional recall. If a single recall included multiple products, count the action as one recall.	Recall system
4.12		**Total volume of products recalled**	If possible, report in pounds of produce recalled. This would be the amount of produce subject to the recall, not the amount returned or destroyed.	Recall system

Tab 5. Sprouts - Current Reporting Period

- Sprouts inventory data should be current to report date.
- Sprouts only farms' data will be reported only in Tab 5. As a reminder, sprouts inspections under the CAP must be conducted jointly with FDA.
- If the farm has both sprouts and non-sprout covered produce, include data for all non-sprout produce that was covered during an inspection in Tab 1-4, where appropriate.
- As a reminder, sprouts inspections under the CAP must be conducted jointly with FDA.
- Leave this tab blank if you have nothing to report.