DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

PRODUCE FARM INSPECTION OBSERVATIONS

Name of State and Department *(if acting under commission with FDA)*	DISTRICT OFFICE ADDRESS

DISTRICT OFFICE PHONE NUMBER	DATE(S) OF INSPECTION	FEI NUMBER

LAST NAME, FIRST NAME, MIDDLE INITIAL AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED *(Most responsible individual present)* TO:

FARM NAME *(include business name, if different)*

OWNER/OPERATOR

FARM MAILING ADDRESS	FARM PHYSICAL LOCATION, IF DIFFERENT FROM MAILING ADDRESS (*e.g., location identifiers such as GPS coordinates)*
TYPE OF INSPECTION: ☐ Initial ☐ Routine ☐ Follow-up ☐ For-cause ☐ Other *(please specify)*	CROPS OBSERVED DURING INSPECTION

This form lists factual observations made by the FDA representative(s) during the inspection of the farm's operation.

This is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule *(21 CFR Part 112)* or any other legal requirement.

Representatives of the regulatory agency should record their observations on this form as clearly and specifically as possible and should order their observations by significance within each area (most important first). In some cases, an observation may relate to more than one topic area. Representatives of the regulatory agency should record observations in the topic area listed below that, in the representatives' judgment, is the most appropriate topic. Not all topic areas may be applicable in every situation. In addition, representatives of the regulatory agency may not examine every aspect of the farm's operation during an inspection, so a topic area left blank should not be interpreted to mean the farm is in compliance, or not in compliance, with requirements related to that topic area.

Representatives of the regulatory agency should discuss all observations with the management of the farm or their representative as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when this form is issued. Discussion should include those observations which may be written on the form and those that will only be discussed with management during the closeout meeting. This form should be issued during the exit conference of all produce inspections, including when no observations have been recorded.

The farm may use this opportunity to ask questions about the observations or to request clarification. If the farm has implemented, or plans to implement, corrective action in response to an observation, this may be discussed with the representatives of the regulatory agency during the inspection. Representatives of the regulatory agency should annotate the form, as applicable, with any completed or promised corrections discussed during the inspection. FDA representatives are encouraged to verify the farm's completed corrective actions during the inspection as long as the verification does not unreasonably extend the duration of the inspection. Inclusion of annotations regarding corrective actions does not signify any conclusion by the regulatory agency regarding the sufficiency of the actions.

FARM NAME *(include business name, if different)*

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If you have any questions, please contact the regulatory agency at the phone number and address above.

Representatives of the regulatory agency should record observations consistent with procedures established for conduct of inspections, including additional instructions that appear in Chapter 5 of the IOM, available at https://www.fda.gov/ICECI/Inspections/IOM.

REPORTABLE OBSERVATIONS MADE DURING THE INSPECTION

Representatives of the regulatory agency should check one of the following options. As noted above, this is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule (21 CFR Part 112) or any other legal requirement.

☐ During an inspection of the operation (I) (we) did not observe any conditions and/or practices to be reported on this form.

☐ During an inspection of the operation (I) (we) observed the following conditions and/or practices as described below.

Personnel Qualifications and Training *(21 CFR Part 112, Subpart C)*

1. §§ 112.21 and 112.22: Qualifications and training for personnel who handle (contact) covered produce or food contact surfaces

   ☐ Observation ☐ Corrective action taken

   Description:

2. § 112.23: Assignment or identification of supervisors

   ☐ Observation ☐ Corrective action taken

   Description:

3. § 112.30: Record-keeping

   ☐ Observation ☐ Corrective action taken

   Description:

Health and Hygiene *(21 CFR Part 112, Subpart D)*

4. § 112.31: Measures to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance

   ☐ Observation ☐ Corrective action taken

   Description:

5. § 112.32: Hygienic practices of personnel

   ☐ Observation ☐ Corrective action taken

   Description:

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

6. § 112.33: Measures to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance

   ☐ Observation ☐ Corrective action taken

   Description:

Agricultural Water *(21 CFR Part 112, Subpart E)*

7. § 112.41: Quality of agricultural water

   ☐ Observation ☐ Corrective action taken

   Description:

8. § 112.42: Agricultural water sources, water distribution system, and pooling of water

   ☐ Observation ☐ Corrective action taken

   Description:

9. § 112.43: Treating agricultural water

   ☐ Observation ☐ Corrective action taken

   Description:

10. § 112.44: Microbial quality criteria applicable to agricultural water used for certain intended uses

    ☐ Observation ☐ Corrective action taken

    Description:

11. § 112.45: Corrective measures if agricultural water does not meet requirements of § 112.41 or § 112.44.

    ☐ Observation ☐ Corrective action taken

    Description:

12. §§ 112.46 and 112.47: Testing agricultural water that is subject to the requirements of § 112.44.

    ☐ Observation ☐ Corrective action taken

    Description:

13. § 112.48: Water that is used during harvest, packing, and holding activities

    ☐ Observation ☐ Corrective action taken

    Description:

14. § 112.50: Record-keeping

    ☐ Observation ☐ Corrective action taken

    Description:

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

Biological Soil Amendments of Animal Origin and Human Waste *(21 CFR Part 112, Subpart F)*

15. § 112.52: Handling, conveyance, and storage of biological soil amendments of animal origin

☐ Observation ☐ Corrective action taken

Description:

16. § 112.53: Use of human waste

☐ Observation ☐ Corrective action taken

Description:

17. §§ 112.51, 112.54, 112.55, and 112.56: Determining status of biological soil amendment of animal origin; acceptable treatment processes; applicable microbial standards for such treatment processes; and, application requirements and minimum application intervals for biological soil amendments of animal origin

☐ Observation ☐ Corrective action taken

Description:

18. § 112.60: Record-keeping

☐ Observation ☐ Corrective action taken

Description:

Domesticated and Wild Animals *(21 CFR Part 112, Subpart I)*

19. § 112.83: Measures related to grazing animals, working animals, or animal intrusion

Observation Corrective action taken

Description:

Growing, Harvesting, Packing, and Holding Activities *(21 CFR Part 112, Subpart K)*

20. § 112.111: Measures related to growing, harvesting, packing, or holding both covered and excluded produce

Observation Corrective action taken

Description:

21. § 112.112: Measures to be taken immediately prior to and during harvest activities

☐ Observation ☐ Corrective action taken

Description:

22. § 112.113: Handling harvested covered produce

☐ Observation ☐ Corrective action taken

Description:

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DATE(S) OF INSPECTION	FEI NUMBER

23. § 112.114: Disposition of dropped covered produce

☐ Observation ☐ Corrective action taken

Description:

24. § 112.115: Measures related to packaging covered produce

☐ Observation ☐ Corrective action taken

Description:

25. § 112.116: Measures related to food-packing (including food-packaging) material

☐ Observation ☐ Corrective action taken

Description:

Equipment, Tools, Buildings, and Sanitation *(21 CFR Part 112, Subpart L)*

26. § 112.123: Equipment and tools

☐ Observation ☐ Corrective action taken

Description:

27. § 112.124: Instruments and controls used to measure, regulate, or record

☐ Observation ☐ Corrective action taken

Description:

28. § 112.125: Equipment used in the transport of covered produce

☐ Observation ☐ Corrective action taken

Description:

29. § 112.126: Buildings

☐ Observation ☐ Corrective action taken

Description:

30. § 112.127: Domesticated animals in and around a fully-enclosed building

☐ Observation ☐ Corrective action taken

Description:

31. § 112.128: Pest control in buildings

☐ Observation ☐ Corrective action taken

Description:

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32. § 112.129: Toilet facilities

☐ Observation ☐ Corrective action taken

Description:

33. § 112.130: Hand-washing facilities

☐ Observation ☐ Corrective action taken

Description:

34. § 112.131: Control and disposal of sewage

☐ Observation ☐ Corrective action taken

Description:

35. § 112.132: Control and disposal of trash, litter, and waste

☐ Observation ☐ Corrective action taken

Description:

36. § 112.133: Plumbing

☐ Observation ☐ Corrective action taken

Description:

37. § 112.134: Control of animal excreta and litter from domesticated animals

☐ Observation ☐ Corrective action taken

Description:

38. § 112.140: Record-keeping

☐ Observation ☐ Corrective action taken

Description:

Sprouts *(21 CFR Part 112, Subpart M)*

☐ Check here if entity does not engage in growing, harvesting, packing, and/or holding of sprouts

39. § 112.142: Seeds or beans used to grow sprouts

☐ Observation ☐ Corrective action taken

Description:

40. § 112.143(a): Fully-enclosed buildings

☐ Observation ☐ Corrective action taken

Description:

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41. § 112.143(b): Cleaning and sanitizing food-contact surfaces

☐ Observation ☐ Corrective action taken

Description:

42. §§ 112.144(a), 112.145, and 112.146: Environmental monitoring for *Listeria* species or *L. monocytogenes* (written environmental monitoring plan, collection and testing, corrective actions)

☐ Observation ☐ Corrective action taken

Description:

43. §§ 112.144(b) and (c), 112.147 and 112.148: Testing spent irrigation water or in-process sprouts for pathogens *(written sampling plan, collection and testing, corrective actions)*

☐ Observation ☐ Corrective action taken

Description:

44. § 112.150: Record-keeping

☐ Observation ☐ Corrective action taken

Description:

Records *(21 CFR Part 112, Subpart O)*

45. § 112.161 - 112.167:General record-keeping

☐ Observation ☐ Corrective action taken

Description:

Other Observations

46. Other

☐ Observation ☐ Corrective action taken

Description:

FDA REPRESENTATIVE SIGNATURE	FDA REPRESENTATIVE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED

FARM NAME *(include business name, if different)*

DATE(S) OF INSPECTION	FEI NUMBER

Continuation Sheet

Additional Observations and/or Comments

Continue

FARM NAME *(include business name, if different)*

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The observations of conditions and practices listed on this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug, and Cosmetic Act, or
2. To assist firms inspected in complying with applicable laws and regulations.

Any reference to this report in labeling, advertising, or other sales promotion by any person is prohibited under Section 301(n) of the Federal Food, Drug and Cosmetic Act.