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PRODUCE SAFETY RULE

Incorporation by reference of federal produce safety regulations

The Department hereby incorporates by reference Title 21 of the Code of Federal Regulations, Part 112 (most current revision) regarding standards for the growing, harvesting, packing, and holding of produce for human consumption as provisions of this rule as though set forth herein line for line and word for word, except that unless the context otherwise dictates, references to “We”, “the United States Food and Drug Administration”, and “FDA” shall refer to the “Arkansas Department of Agriculture” or “Department”, and all words or terms defined or used in the federal regulations incorporated by reference shall mean the state equivalent or counterpart to those words or terms.

Definitions

The following words or terms, when used in this rule, shall have the following meaning, unless the context clearly indicates otherwise:

“Covered farm” means a farm or farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.

A farm is not a covered farm if it satisfies the requirements in 21 C.F.R. § 112.5 and the Department has not withdrawn the farm's exemption in accordance with the requirements of Part 112, Subpart R.

“Department” means the Arkansas Department of Agriculture.

“Produce” means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat,

amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Farm Registration

- (a) All covered farms shall register with the Department and provide a business name, mailing address, physical address, and telephone number.
- (b) Registered covered farms shall notify the Department of any change in the information provided at registration within ninety (90) days of the change.
- (c) Covered farms shall register with the Department no later than July 1 of each year.
- (d) The Department may post the inflation-adjusted annual threshold on its website.

Penalties

Any person who violates a provision of this rule may be subject to one or more of the following:

- (a) Actions detailed in the Compliance and Enforcement Penalty Matrix;
- (b) A stop sale order;
- (c) Civil penalties under the authority of the Arkansas Plant Act of 1917, A.C. A. Section 2-16-203.

**ARKANSAS DEPARTMENT OF AGRICULTURE
PRODUCE SAFETY ENFORCEMENT RESPONSE RULES**

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I. STATEMENT OF PURPOSE

Produce Safety is valuable to Arkansas' agricultural production and the protection of man from microbial contaminants attained during the growing, harvesting, packing and holding of produce for human consumption. It is essential to the public health and welfare that produce be handled properly to prevent adverse microbial effects on man.

The purpose of the rule is to provide a fair and consistent mechanism by which compliance with the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (CFR Title 21 Part 112), also known as the Produce Safety Rule (PSR), as amended, and the rules written pursuant thereto can be achieved.

II. DEFINITIONS (As used in this policy)

- A. **Base Civil Penalty:** The midpoint of a civil penalty range. [Example: The civil penalty range for a Minor Violation (1st level of enforcement) is \$100.00 to \$500.00. The base penalty is \$300.00]
- B. **Level of Enforcement:** The category by which a violative incident is considered a first, second, third, or fourth offense. For a violation to be considered as a second or subsequent offense, it must be a repeat of a violation for which a previous enforcement action has been taken by the Arkansas Department of Agriculture. The previous violation/violations must have occurred within the past 3 years.
- C. **Level 1 Violation:** A violative incident which does not involve human health and/or safety e.g. conditions that will not cause contamination of covered produce; or other incidents of non-compliance which do not create a competitive disadvantage for covered farms in full compliance.
- D. **Level 2 Violation:** A violative incident which affects human health and/or safety e.g. conditions that may cause contamination of covered produce if conditions or practices continue; or other incidents of non-compliance which create a competitive advantage over covered farms in full compliance; or a history of repetitive violative incidents.
- E. **Level 3 Violation:** A violative incident involving a practice, condition, or situation on a covered farm 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).
- Covered produce means: produce that is subject to the requirements of 21 CFR Part 112, in accordance with 21 CFR 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop (see 21 CFR 112.3).
- F. **Covered produce farm:** Any farm engaged in the growing, harvesting, packing, or holding of produce for human consumption which is subject to the requirements of the FDA Food Safety Modernization Act – Produce Safety Rule (21 CFR Part 112).
- G. **Produce:** Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible

reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

- H. **Respondent:** A covered produce farm charged with a violation of the Arkansas Produce Safety Law, as amended, and the rules written pursuant thereto.

III. LEGAL AUTHORITY

- A. "The Arkansas Plant Act" A.C.A. 2-16-203 et. seq. and Rules.

IV. ENFORCEMENT ACTIONS

Under the preceding Arkansas Codes, the Arkansas Department of Agriculture has several options for enforcement action. These are:

- A. **Warning Letter:** For Level 1 Violation, 1st level of enforcement violations, the Arkansas Department of Agriculture will issue a Notice of Warning (NOW) letter. The letter will cite the specific violation. The letter will also identify any corrective action that may be needed and notify the respondent that further violations will result in more severe enforcement action.
- B. **Stop Use/Stop Sale:** The use or sale of contaminated covered produce; practices that will pose a significant risk to human health and/or safety; or at the request of FDA, etc., will remain in effect until violation is corrected.
- C. **Informal Agreement:** When a violation has been alleged, the respondent has the option of an informal hearing or a board/committee hearing. The purpose of the informal hearing is to resolve a complaint or incident. A hearing officer will meet jointly with the respondent and Arkansas Department of Agriculture staff. The group will seek consensus on an appropriate enforcement action for recommendation to the Board. Enforcement action based on the Penalty Matrix (Appendix A) will include Civil Penalty and/or further legal action. The Full Board acts on all recommendations resulting from the informal hearing.
- Excluding Level 3 violations.
- D. **Board/Committee Hearing:** If the respondent chooses to bypass the informal agreement process, or if an agreement cannot be reached during the informal hearing, a hearing will be held by the Food Safety Committee of the Board. Enforcement action will include Civil Penalty and/or further legal action. Following the Committee hearing, a written Finding of Fact, Conclusion of

Law, and recommendation will be submitted to the Board. The Full Board will act on all recommendations of the Committee.

- E. **Injunction:** The Board may apply for an injunction to any court of competent jurisdiction for violations of the Produce Safety Law. The court, upon hearing and for cause, has the option of temporary or permanent injunction restraining any person from violating any provisions of the Arkansas Produce Safety Law and rules.
- F. **Referral to Prosecuting Attorney:** The Plant Board has the option of referring violations of the Arkansas Produce Safety Law to the prosecuting attorney.

V. INCIDENT INVESTIGATION

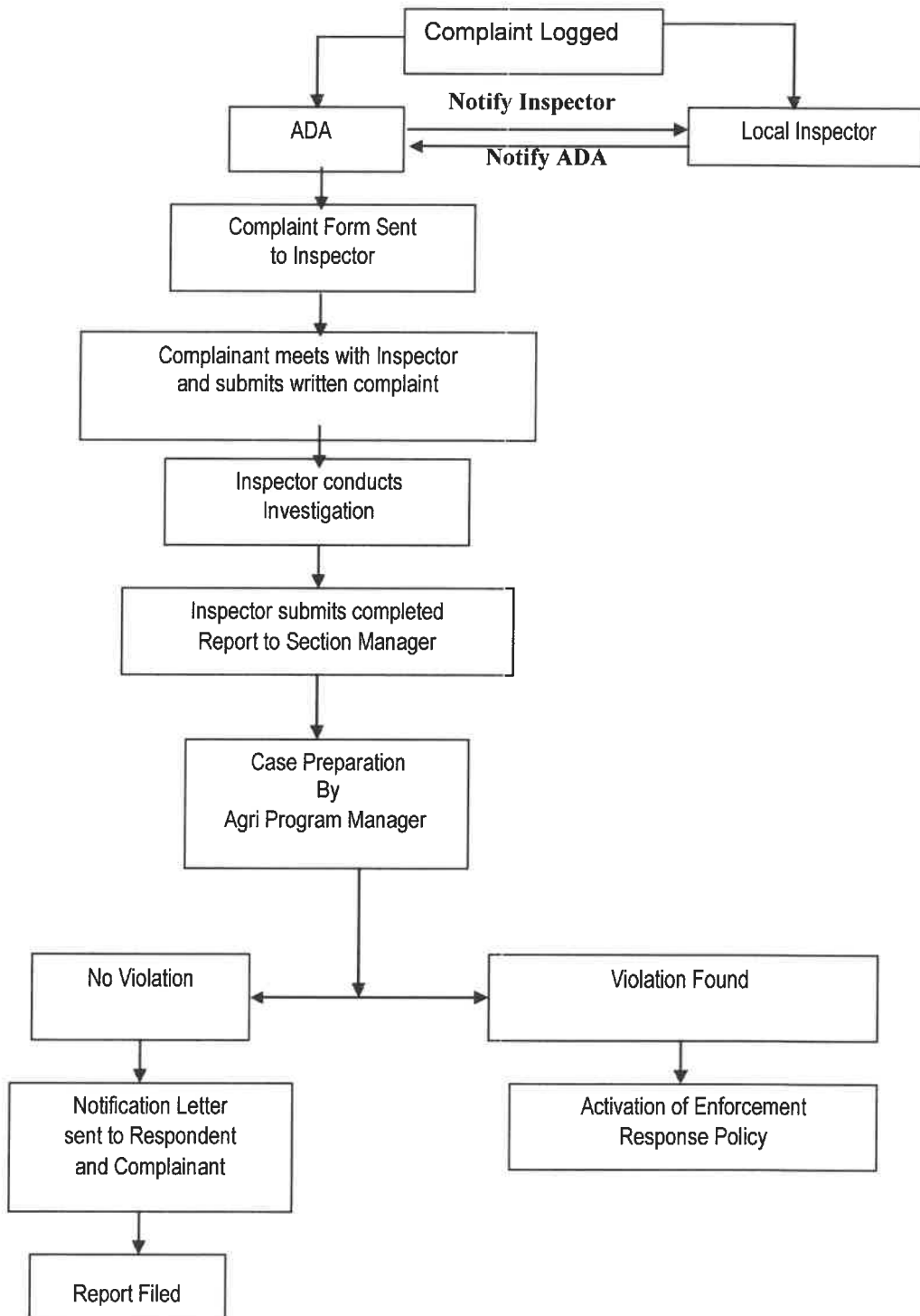
An incident investigation will be initiated when:

- A. Routine compliance monitoring indicates a violation has occurred.
- B. A formal complaint that an alleged violative incident has occurred (Filing of a written form by a complainant). In cases of apparent immediate endangerment to the public health, the written notification may be waived, and the investigation of the alleged incident will begin immediately).

The processing sequence for an incident investigation is outlined in Figure I.

FIGURE I

Processing Sequence



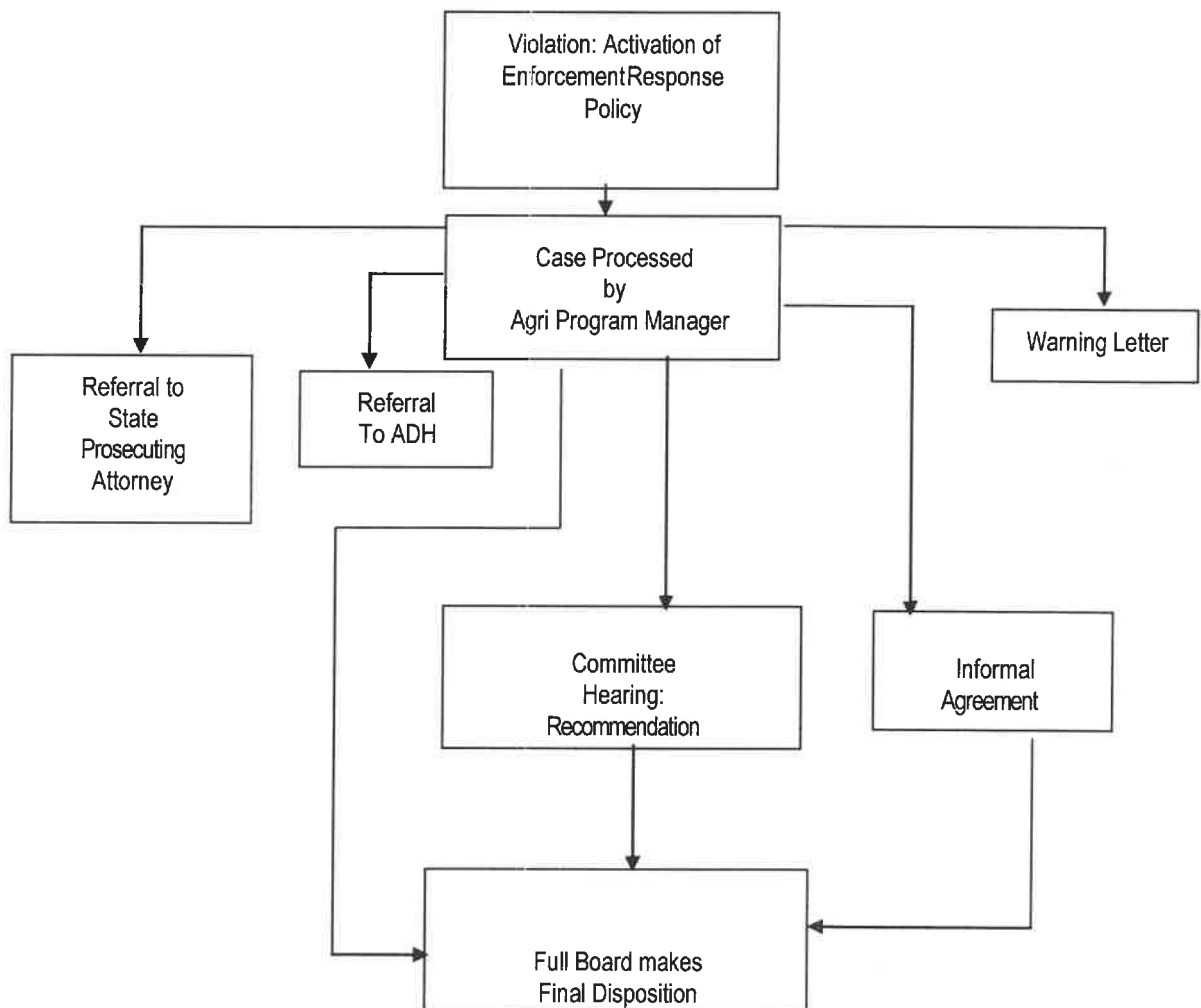
VI. ACTIVATION OF ENFORCEMENT RESPONSE POLICY

An apparent violation of law and/or rule must be documented to initiate an enforcement action.

Documentation must conform to the requirements of the Plant Industries Division.

The sequence of events within the enforcement response policy is as follows:

FIGURE II



VII. INTERNAL REVIEW

Staff will carefully review all documentation and records to determine:

- A. That apparent violation / violations have occurred.
- B. Whether the apparent violation or violations are **Level 1, Level 2** and/or **Level 3** violations.
- C. The correct level of enforcement based on the penalty matrix and the documented history of the respondent.

Concurrence with the Program's finding by the staff must be unanimous before further action can be taken on the case.

VIII. HEARINGS

The informal hearing officer and/or the appropriate Committee and/or the Full Board will carefully review the documentation and hear cases of alleged violations.

Should it be determined a violation(s) has occurred, the severity and level of enforcement of each violation will be determined by the three (3) factors in Section VII; as they are applied to the Penalty Matrix (Appendix A).

If a violation is determined in this sequence; the following factors will be considered:

- A. Cooperation of the respondent.
- B. Other extenuating/mitigating circumstances.

The Hearing Officer/Committee/Board may use these factors to accelerate or mitigate enforcement action. When a civil penalty is the preferred action, the base penalty may be increased or decreased based on these factors. The civil penalty will not be more or less than the range for the specific violation listed in Appendix A.

The Full Board will take action to determine the final disposition of the case.

IX. RIGHT OF APPEAL

Any person aggrieved by any action of the Full Board may obtain a review thereof, by filing in circuit court within 30 days of notice of the action, a written petition praying that the action of the Full Board be set aside.

APPENDIX - A

PENALTY MATRIX

ADA Produce Safety Compliance and Enforcement Penalty Matrix

Compliance History

SEVERITY	Initial Inspection	Routine Inspection	Non-Compliance
<p>Level 1</p> <p><i>Conditions that will not cause contamination of produce</i></p>	<ul style="list-style-type: none"> - The observation is discussed with the farm during the inspection and potentially documented on an inspection form. - A timeline for corrective actions and preventive measures is established. The observation may be reviewed during a follow-up inspection. 	<ul style="list-style-type: none"> - The observation is discussed with the farm during the inspection and documented on an inspection form. - A timeline for corrective actions and preventive measures is established. A follow-up inspection may be scheduled within 30, 60, or 90 days. - A Notice of Warning (NOW) letter may be issued detailing possible enforcement actions that may be taken if the observation is not corrected. 	<ul style="list-style-type: none"> - The uncorrected observation is discussed with the farm during the inspection and documented on an inspection form. - A timeline for corrective actions and preventive measures is established. A follow-up inspection may be scheduled within 30, 60, or 90 days. - Additional enforcement actions may be taken to ensure compliance, which may include issuing a Notice of Warning (NOW) letter or Notice of Violation (NOV) with administrative penalties of up to \$500 per violation.
<p>Level 2</p> <p><i>Conditions that may cause contamination of produce if conditions or practices continue</i></p>	<ul style="list-style-type: none"> - The observation is discussed with the farm during the inspection and reviewed at the next routine inspection. 	<ul style="list-style-type: none"> - The observation is discussed with the farm during the inspection and documented on an inspection form. - A timeline for corrective actions and preventive measures is established. A follow-up inspection may be scheduled within 30, 60, or 90 days. - A Notice of Warning (NOW) letter may be issued detailing possible enforcement actions that may be taken if the observation is not corrected. 	<ul style="list-style-type: none"> - The uncorrected observation is discussed with the farm during the inspection and documented on an inspection form. - A timeline for corrective actions and preventive measures is established. A follow-up inspection may be scheduled within 30, 60, or 90 days. - Additional enforcement actions may be taken to ensure compliance, which may include issuing a Notice of Violation (NOV) with administrative penalties of up to \$1,000 per violation.
<p>Level 3</p> <p><i>Produce is contaminated, or conditions will likely cause an imminent public health hazard if not corrected</i></p>	<ul style="list-style-type: none"> - The observation is discussed with the farm during the inspection and documented on an inspection form. - An evaluation is made to determine whether contaminated produce has entered commerce and whether an embargo, stop sale, or recall is required. Immediate actions must be initiated to ensure adequate mitigation and correction of the egregious conditions. A timeline for further corrective actions and preventive measures is established and a follow-up inspection is scheduled within 10, 30, 60, or 90 days. - Additional enforcement actions may be taken to ensure compliance, which may include issuing a Notice of Violation (NOV) with administrative penalties of up to \$1,000 per violation. 		

