302 KAR 60:010. Produce safety.

RELATES TO: KRS Chapter 260, 21 C.F.R. Part 112

STATUTORY AUTHORITY: KRS 260.020(3), 260.030(1)(d), 260.766, 260.769(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.769(1) authorizes the Department of Agriculture to promulgate administrative regulations for the efficient administration and enforcement of Kentucky's Produce Safety Rule for covered produce and covered farms. This administrative regulation establishes a uniform code for the growing, harvesting, packing, and holding of produce for human consumption.

Section 1. Definitions.

(1) "Adulterated" means covered produce in any growing, harvesting, packing, or holding area that has been subject to conditions whereby it could have become contaminated with filth or microorganisms of public health significance, or whereby it could have been rendered injurious to health.

(2) "Certificate of compliance" means a certificate issued by the department for covered farms that are inventoried and subject to regulatory inspection by the department.

(3) "Certificate of exemption" means a certificate of exempt status issued by the department pursuant to Section 5 of this administrative regulation for:

(a) Farms growing only produce that is rarely consumed raw,

(b) Farms growing only produce for personal consumption or produced for consumption on the farm,

(c) Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, or

(d) Farms where, during the previous three (3) year period, a farmers' average of all produce sales was $25,000 or less (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment.

(4) "Certificate of qualified exemption" means a certificate of exempt status issued by the department pursuant to Section 4 of this administrative regulation.

(5) "Covered farm" is defined by KRS 260.765(2).

(6) "Covered produce" is defined by KRS 260.765(1).

(7) "Department" is defined by KRS 260.765(3).

(8) "Egregious condition" means a practice, condition, or situation that is reasonably likely to lead to:

(a) Serious adverse health consequences or death from the consumption of or exposure to covered produce; or

(b) An imminent public health hazard if corrective action is not taken immediately.

(9) "Farm" is defined in 21 C.F.R. Part 112 and includes both a Primary Production Farm and a Secondary Activities Farm.

(10) "Farmer" is defined as the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements in 21 C.F.R. 112, KRS Chapter 260, and this administrative regulation.

(11) "Inspection" means an official regulatory visit conducted by the department for the purpose verifying compliance with 21 C.F.R. Part 112, KRS Chapter 260 and this administrative regulation.

(12) "Microorganisms" means microbial pathogens of public health significance.

(13) "No Action Indicated" or "NAI" means a farm inspection classification that indicates the farm is in substantial compliance, with no violating conditions or only minor violations noted at the time of inspection.

(14) "Official Action Indicated" or "OAI" means a farm inspection classification that indicates one (1) or more egregious violations materially related to food safety have been cited, or that an uncorrected VAI condition on a previous inspection has been cited.

(15) "Qualified exempt farm" means a farm that has met the eligibility requirements of KRS Chapter 260 for qualified exemption and has been issued a certificate of qualified exemption from the department.
(16) "Stop Use Order" means an order issued by the department declaring the cessation of a covered activity; use of a utensil, piece of equipment, or machinery; water distribution device; or room or area used for the production, handling, or storage of covered produce.
(17) "Voluntary Action Indicated" or "VAI" means a farm inspection classification that indicates a farm is generally in compliance, with only minor violations cited, which are not significant enough to pose an imminent health hazard.

Section 2. Right to Scheduled On-site Verification Visits. The department reserves the right to schedule, at any reasonable time, an on-site visit to verify if a farm is exempt, covered, or eligible for a qualified exemption.

Section 3. Produce Farm Survey. All covered farms and farms eligible for exemption shall be required to annually complete an Informational Survey.

Section 4. Qualified Exemption.
(1) A covered farm that meets the requirements for a qualified exemption may apply for qualified exempt status with the department by submitting an Application for Qualified Exemption.
(2) Upon the department's review of the Application for Qualified Exemption, a farm verified as having met the requirements for exemption status shall be issued a certificate of qualified exemption.
(3) A certificate of qualified exemption shall be non-transferrable.
(4) A certificate of qualified exemption shall only be issued:
(a) In the name of the applicant; and
(b) For the FSA location or locations identified in the application.
(5) Unless otherwise withdrawn, the certificate of qualified exemption shall be valid for up to three (3) years.
(6) Qualified exemption status shall be valid for the balance of the calendar year of issuance regardless of date, and for the two (2) calendar years ending December 31 thereafter. Renewals for an additional three (3) year period shall be upon submission of an Application for Qualified Exemption and accompanied by verification of the successful completion of an FDA-approved training course by the farmer.
(7) Failure to submit an updated Application for Qualified Exemption to the Department by the expiration date noted on the certificate of exemption shall result in forfeiture of the qualified exemption and the presumption by the Department that the farm shall be subject to all requirements of the KRS Chapter 260.
(8) All qualified exempt farms shall be required to complete a yearly evaluation of qualified exemption status. Once a farm's qualified exempt status changes to covered status, the farmer shall immediately notify the department.
(9) The epartment shall only withdraw a qualified exemption as established under 21C.F.R. Part 112, Subpart R or this administrative regulation. Withdrawal shall be by written notice to the farm.
(10) If a farm's qualified exemption is withdrawn by the department, the farm shall be considered "covered" and shall be subject to all requirements of 21 C.F.R. Part 112, KRS Chapter 260, or this administrative regulation.
(11) Any applicant whose application for qualified exemption has been denied or withdrawn by the department may appeal the action as established in Section11 of this administrative regulation.
(12) Any person whose qualified exemption has been withdrawn by the department may submit a written request for reinstatement of the qualified exemption.

(13) Within ten (10) days following receipt of a written request for reinstatement, including a statement signed by the farmer that, in the farmer's opinion, the condition causing the withdrawal of qualified exemption has been corrected, the department shall make an inspection, and if the inspection reveals that the condition causing the withdrawal has been corrected, the qualified exemption shall be reinstated.

Section 5. Certificate of Exemption:

(1) A farm that meets the requirements for an exemption, as established in KRS Chapter 260 may apply for a certificate of exempt status with the department by submitting an Application for Qualified Exemption.

(2) One (1) or more of the requirements established in paragraphs (a) through (d) of this subsection shall be met for a Certificate of Exemption.

(a) The farm shall only grow produce that is rarely consumed raw, specifically including: asparagus, black beans, great Northern beans, kidney beans, lima beans, navy beans, pinto beans, beets, garden (roots and tops) beets, sugar beets, cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill (seeds and weed), eggplants, figs, ginger, hazelnuts, horseradish, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, mature southern field peas (such as black-eyed peas, cowpeas, crowder peas, purple hull peas, sea island peas, silver peas, and speckled peas), winter squash, sweet potatoes, and water chestnuts as established in 21 C.F.R. Part 112.2.

(b) Produce grown shall only be used for personal consumption or produced for consumption on the farm as outlined in 21 C.F.R. Part 112.2.

(c) Produce grown shall receive commercial processing that adequately reduces the presence of microorganisms of public health significance as established in 21 C.F.R. Part 112.2.

(d) During the previous three (3) year period, a farmer's average of all produce sales was $25,000 or less (on a rolling basis) adjusted for inflation using 2011 as the baseline year for calculating the adjustment as established in 21 C.F.R. Part 112.4.

(3) Upon the department's review of the Application for Qualified Exemption, a farm verified as having met the requirements for exemption status shall be issued a Certificate of Exemption.

(4) A Certificate of Exemption shall be non-transferrable.

(5) A Certificate of Exemption shall only be issued:

(a) In the name of the applicant; and

(b) For the FSA location or locations identified in the application.

(6) Unless otherwise withdrawn, the Certificate of Exemption shall be valid for as long as the farm remains in exempt status.

(7) All exempt farms shall be required to complete a yearly evaluation of exemption status. If a farm's exempt status changes to covered status, the farmer shall immediately notify the department.

Section 6. Inspection Frequency, Notices, Records.

(1) Risk prioritization. The department shall assign a risk prioritization level to each farm based on:

(a) Commodities handled.

(b) Farm acreage.

(c) Annual produce sales.

(d) Farmer attendance at a Produce Safety Alliance or FDA-approved grower training.

(e) Compliance history.

(f) Participation in an on-farm readiness review.

(g) Agricultural water source.

(h) Presence of a farm food safety plan.

(i) GAP certification or recent participation in other food safety programs.
(j) Adjacent land use.
(k) Likelihood of wildlife or animal intrusion.
(l) Geographical location of the farm.

(2) Priority designation. Inspection frequencies shall be assigned as follows:
(a) Priority 1 farms shall receive a minimum of one (1) inspection per year.
(b) Priority 2 farms shall receive a minimum of one (1) inspection every two (2) years.
(c) Priority 3 farms shall receive a minimum of one (1) inspection every three (3) years.

(3) Regardless of a farm's priority designation, the department shall make as many additional inspections and re-inspections as are necessary for the enforcement of this administrative regulation.

(4) Inspection records. The department representative inspecting a covered farm shall record the findings on the Produce Farm Inspection Observations Report and shall provide a copy of the inspection report to the farmer.

(5) Issuances of notices. If an inspection reveals a violation of this administrative regulation, the department shall notify the farmer. In the notification, the department shall establish:
(a) The specific violations found; and
(b) A specific and reasonable period of time for the correction based on the nature of the violations found pursuant to this paragraph. The report of inspection shall state:
1. Failure to comply with a notice from the department, or with a time limit for correction of a violation, shall result in regulatory action up to and including civil penalties, as established in KRS Chapter 260, and
2. An opportunity for appeal from an adverse notice or inspection finding shall be provided if a written request is filed with the department within ten (10) days following service of notice.

(6) Service of notice. A notice provided for under this section shall be properly served if a copy of the Produce Farm Inspection Observations Report or other notice has been delivered personally to the farmer, or the notice has been sent by registered or certified mail, return receipt requested, to the last known address of farmer.

Section 7. Violations and Corrective Action Plans.

(1) If a farm has committed a violation of 21 C.F.R. Part 112, KRS Chapter 260, or this administrative regulation, an opportunity to correct the violation shall be provided in accordance with the following classifications:
(a) NAI - No changes in the inspection frequency shall be warranted under this classification;
(b) VAI - A follow-up inspection shall be warranted within a period of time not to exceed the date of the next routine inspection to determine if the violation causing this classification has been corrected; or
(c) OAI - A follow-up inspection shall be conducted within a period of time not to exceed thirty (30) days to determine if the violation causing the classification has been corrected. A farm shall also be classified as OAI if it continually fails to correct a violation previously classified under a VAI designation or if an egregious violation is noted during an inspection.

(2) Upon completion of the inspection, a recommended classification of NAI, VAI, or OAI and the timeframe for correction of the violation shall be specified on the Produce Farm Inspection Observations Report.

(3) A farm that receives an inspection classification of VAI or OAI shall submit a plan of corrective action to the department:
(a) VAI: Within thirty (30) days following the inspection; and

(b) OAI: Within ten (10) days following the inspection.

(4) Failure to submit a plan of corrective action to the department within the time frame established in subsection (3) of this section shall result in the initiation of enforcement provisions pursuant to KRS Chapter 260 and Section 10 of this administrative regulation.

(5) If, during the next inspection, the violation noted on the previous inspection has not been corrected within the timeframe established in subsection (3) of this section, the department shall:

(a) Extend the timeframe for corrective action if the department determines that progress towards compliance has been made;

(b) Issue a warning letter;

(c) Initiate enforcement provisions pursuant to Sections 8 and 10 of this administrative regulation; or

(d) Initiate enforcement provisions pursuant to KRS Chapter 260.

Section 8. Stop Use.

(1) If a duly authorized agent of the department finds, or has probable cause to believe, that a covered activity or the continued use of a utensil, piece of equipment or machinery, water distribution device, or room or area used for the production, handling or storage of covered produce could result in adulterated product, the department shall issue a Stop Use Order to the farmer.

(a) The reason for the Stop Use Order shall be documented on the Notice to Stop Use.

(b) The Notice to Stop Use shall notify all persons to discontinue a covered activity or use of a utensil, piece of equipment or machinery, water distribution device, or room or area used for the production, handling, or storage of covered produce until conditions causing the Stop Use Order have been corrected and permission for use is given by a duly authorized agent of the department.

(2) A person shall not, without department permission, utilize a piece of equipment, room, or area used for the production, handling, or storage of covered produce for which a Stop Use Order has been issued.

(3) If the department has evidence that a farmer has violated the provisions contained in this section, enforcement provisions shall be initiated pursuant to KRS Chapter 260 and Section 10 of this administrative regulation.

Section 9. Egregious Conditions, Examination, and Detention of Foods.

(1) The department shall have the authority to examine and collect water, produce, and environmental samples as often as necessary for the enforcement of this administrative regulation.

(2) A farmer shall take immediate steps to correct any egregious condition.

(3) If a duly authorized agent of the department finds or has probable cause to believe that covered produce in any growing, harvesting, packing, or holding area has been subject to conditions whereby the covered produce could have become contaminated with filth or microorganisms of public health significance, or whereby the covered produce could have been rendered injurious to health as established by KRS Chapter 260, the department shall issue a Stop Movement Order to the farmer.

(a) The reason for the order shall be documented on the Stop Movement Order.

(b) The Stop Movement Order shall give notice that the covered produce is, or is suspected of, being contaminated or injurious to health and notifying all persons not to remove or dispose of the produce by sale or otherwise until permission for removal, disposal, or diversion is given by an agent of the department or the court.

(4) The department shall issue a Notice of Voluntary Destruction to a farmer who elects to voluntarily destroy covered produce for which a Stop Movement Order has been issued.

(5) If covered produce for which a Stop Movement Order has been issued can be safely diverted by the farmer for alternative uses that do not pose a risk to human or animal health, the department, if requested, shall issue a Notice of Diversion/Change Order to the farmer.

(6) In all other instances, the department shall comply with KRS Chapter 260 regarding the disposition of produce for which a Stop Movement Order was issued.

(7) If the department has evidence that a farmer has failed to act to correct an egregious condition, enforcement provisions shall be initiated pursuant to KRS Chapter 260 and Section 10 of this administrative regulation.

Section 10. Enforcement Provisions.

(1) If the department has substantial reason to believe that a covered farm has failed to act to correct an egregious condition; if a farm owner, operator, or agent in charge has interfered with the department in the performance of its duties after its agents have duly and officially identified themselves; or if a farm has failed to comply with an OAI inspection notice within the timeframe granted, the department shall:

(a) Issue a stop work order for that portion or portions of the covered farm affected by the egregious condition;

(b) Issue a stop movement order; or

(c) Seek civil or criminal penalties under KRS Chapter 260.

(2) In all other instances of violation of this administrative regulation, the department shall serve the registered farm with a written notice specifying the violation and afford the holder of the registration an opportunity to correct.

(3) Notices provided for under this administrative regulation shall be deemed to have been properly served if:

(a) A copy of the inspection report or other notice has been delivered personally to the registration holder or the farm person-in-charge, or

(b) The notice has been sent by registered or certified mail, return receipt.

(4) Failure to comply with any provision of this administrative regulation, 21 C.F.R. Part 112, or KRS Chapter 260 shall subject the farmer to civil penalties pursuant to KRS 260.990.

Section 11. Appeals. All appeals of KDA determinations shall be in accordance with KRS Chapter 13B.

Section 12. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Informational Survey", 06/2020;

(b) "Application for Qualified Exemption", 06/2020;

(c) "Produce Farm Inspection Observations", 06/2020;

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Agriculture, 111 Corporate Drive, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

(47 Ky.R. 226, 714; eff. 11-18-2020.)