

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE	45-11	8/12/11
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THIS NOTICE CANCELS FSIS NOTICE 44-11 TO CHANGE THE EFFECTIVE DATE FROM AUGUST 22, 2011 TO SEPTEMBER 11, 2011

UPDATED: USING THE KIDNEY INHIBITION SWAB (KIS™) TEST TO DETECT ANTIMICROBIAL DRUG RESIDUES IN SWINE IN SELECTED ESTABLISHMENTS—PHASE III

I. PURPOSE

A. This notice informs inspection program personnel (IPP) that on September 11, 2011, the Agency will replace the Fast Antimicrobial Screen Test (FAST) with the Kidney Inhibition Swab (KIS™) Test for swine carcasses at slaughter establishments that slaughter both swine and cattle and where the KIS™ test is already in use for cattle. FSIS plans to replace FAST with the KIS™ test in all remaining establishments slaughtering swine during calendar year 2012. Establishments slaughtering sheep and goats will be added at a later time.

B. Carcasses for sampling and testing by the KIS™ test are selected in the same way as carcasses selected for FAST; see FSIS Directive 10,800.1, "Procedures for Residue Sampling, Testing, and Other Responsibilities for The National Residue Program" (<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10800.1.pdf>). Until further notice, FAST will continue to be used at the remaining establishments that slaughter swine only and at all other establishments in which FAST is currently used.

C. The Inspectors-in-Charge (IICs) are to conduct or assign IPP to conduct the tests as needed. Both Public Health Veterinarians (PHVs) and Consumer Safety Inspectors (CSIs) perform the FAST. Therefore, when the KIS™ test is implemented, either PHVs or CSIs may be assigned to conduct this test.

II. TRAINING

A. Current, revised training materials are available for use by PHVs and CSIs at establishments involved in KIS™ test Phase II and III, and are also available upon request for use by PHVs and CSIs at establishments that implemented the KIS™ test

DISTRIBUTION: Electronic

NOTICE EXPIRES: 9/1/12

OPI: OPPD

during Phase I using the original training materials.

B. As this phase of the implementation will occur in plants that already have the KIS™ test being used in cattle, there should already be IPP in these establishments trained to perform the KIS™ test. However, training materials on “Performing the KIS™ Test” in both CD-ROM and written formats will be sent from the FSIS Midwestern Laboratory to IICs at the slaughter establishments selected for KIS™ Test Phase III upon request. If needed, the IICs at the slaughter establishments at which the KIS™ test Phase III is to be implemented are to provide the training materials to those IPP designated by the IIC to conduct the test. Immediately after reviewing both the “Performing the KIS™ Test” CD-ROM and written instructional booklet, the designated IPP are to log onto AgLearn and affirm completion of the KIS™ training. An IIC at a selected establishment who wishes to receive additional training materials should contact CEDL@fsis.usda.gov and request the training materials in a timely manner.

III. RECEIPT OF TEST SUPPLIES

A. IICs at the establishments at which KIS™ test Phase III is to be implemented will receive additional KIS™ test supplies, including heating blocks (if extra heating blocks have been requested), by August 19, 2011. Those IICs are to begin using KIS™ test for swine as soon as IPP have been designated by the IIC to conduct the test but not before September 11, 2011.

B. In time, the KIS™ test will replace FAST for all livestock. FSIS will then phase out all FAST incubators and supplies and provide instructions on appropriate disposition. IICs at establishments selected for the first three phases of the KIS™ test implementation that no longer need the FAST incubator are to contact the Accountable Property Officer at the District Office for instructions on how to handle the excess equipment and to arrange for proper disposition. Some establishments that slaughter both cattle and swine may also slaughter sheep and goat, and IICs at these establishments are to keep the FAST equipment until KIS™ replaces FAST for those species in the future.

C. Additional FAST and KIS™ supplies can be obtained from the FSIS Midwestern Laboratory mailbox used for sampling supplies: <mailto:SamplingSupplies-MidwesternLab@fsis.usda.gov>. The following is the list of KIS™ supplies available from the Midwestern Laboratory:

- Digital Dry Block Heater (tests 20 units)
- KIS™ (Kidney Inhibition Swab) Tests (in packs of 25 tests)
- Negative Controls (4 tablets (approximately for 1 month testing, as each reconstituted tablet is good for 5 days)
- 15 ml Tube of deionized or distilled water (or equivalent)
- Timer
- Transfer Pipettes (in packs of 25-approximately for 1 month testing) or equivalent device for delivering 1ml of water
- Test Tube Rack (or equivalent device, to hold the KIS™ tests)

D. When requesting supplies, IICs are to include the establishment number, personal contact name and number, mailing address, and the specific supplies needed. Orders will typically be shipped within two business days.

E. Some older incubators may still contain mercury thermometers, which can be identified by their silver or metallic colored indicator material. All unbroken mercury thermometers are to be returned to the Midwestern Laboratory. New non-mercury thermometers will be provided for incubators that are still in use. For instructions on how to return unbroken mercury thermometers, and how to request non-mercury thermometers, contact the Midwestern Laboratory by calling 314-263-2680 or contact the Laboratory Safety Officer through LaboratoryInquiry-MidwesternLab@fsis.usda.gov. If a mercury thermometer is broken, it is deemed hazardous waste that requires special handling and is not to be shipped to the Midwestern Laboratory. Instead, contact the FSIS Environmental Health and Safety Branch in Beltsville MD at 301-504-4245.

IV. IN-PLANT PROCEDURE AND DECISION RESPONSIBILITY

A. In-plant PHVs will be responsible for conducting the test or assigning a trained CSI to conduct the test.

B. If a particular plant is part of a mini-circuit, the testing will be done in the central plant of this mini-circuit where the KIS™ Test material and supplies are housed, as is the current practice at that location, or otherwise at the discretion of the assigned PHV.

C. The PHV or CSI conducting the test is to read the results between 3 and 16 hours after incubation. The results for this KIS™ test are based on distinct color changes. If a KIS™ test is positive, the PHV or CSI is to send the kidney, liver, and muscle tissue samples to the laboratory for confirmation and retain the carcass for disposition. In assignments where the Public Health Inspection System (PHIS) has been implemented, the PHV or CSI is to follow the directions in FSIS Public Health Inspection System (PHIS) Directive 13,000.2 for reporting the results from both the KIS™ and FAST in-plant tests (http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/PHIS_13000.2.pdf). FSIS Form 6600-7, FAST Antimicrobial Screen Test Worksheet is not to be used to report test results for KIS™. PHVs or CSIs in assignments using the Performance Based Inspection System (PBIS) are to report KIS™ and FAST in-plant tests using the eSample reporting system. The CSI may print out an eSample report of samples tested for the PHV if necessary.

D. In cases where there is doubt as to the test outcome, the in-plant PHV assigned to cover that establishment is to verify the results. In establishments where there is no in-plant PHV available, the CSI performing the test is to take a digital picture and send it via Outlook to the PHV assigned to cover that establishment for final determination of the test reading. In establishments where there is no in-plant PHV and digital cameras are not already available, in case of an unclear reading of the KIS™ test, the PHV assigned to cover that establishment is to verify the results.

E. Disposition of a retained carcass is based on regulations and positive FSIS laboratory results, if the carcass is not already condemned for other pathology. Carcass condemnation is the responsibility of the PHV, based on final results from the FSIS laboratory.

V. DATA ANALYSIS

In order to monitor operational performance, effectiveness of program implementation, and scientific outputs of the drug residue program, a number of Agency offices analyze data from the in-plant KIS™ tests. The Office of Data Integration and Food Protection (ODIFP) evaluates program effectiveness and operational performance on a monthly basis. ODIFP analyzes sample collection and analysis rates nationally and by district and circuit. In addition, ODIFP analyzes the number of confirmed positive KIS™ test results and evaluates the relationship between KIS™ test results and establishment condemnation rates. ODIFP shares its analysis with other FSIS program areas, including the Office of Public Health Science (OPHS) Risk Analysis Division's Chemical Residue Risk Branch and the Office of Field Operations. The OPHS and the Policy Development and Risk and Innovations Management Divisions of the Office of Policy and Program Development (OPPD) consider KIS™ test results in designing the veterinary drugs part of the National Residue Program, in collaboration with the Food and Drug Administration (FDA). OPHS and OPPD also take the KIS™ test results into account in collaborating with FDA on drug residue enforcement matters, including the Residue Violation System (RVIS).

Direct all technical questions to the Policy Development Division and all sampling questions to the Risk Innovation and Management Division at 1-800-233-3935 or submit your questions through *askFSIS* at <http://askfsis.custhelp.com>.

A handwritten signature in black ink, appearing to read "Daniel J. Seibert". The signature is fluid and cursive, with a prominent initial "D" and a long, sweeping underline.

Assistant Administrator
Office of Policy and Program Development