

Department of Agriculture, Food and the Marine

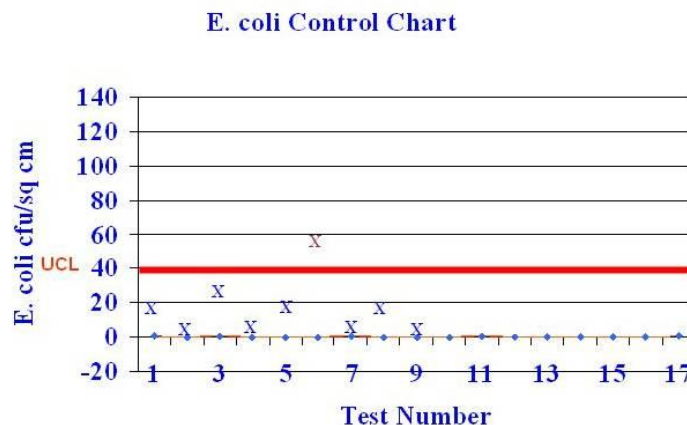
Trader Notice MH 17/2015

To: USDA Approved Plants

Subject: - The mandatory use of Statistical Process Control (SPC) in generic E coli testing and evaluation of test results in USDA certified establishments.

FBOs are obliged to maintain accurate records of all test results in terms of cfu/cm² of surface area sponged. The results should be recorded onto a process control chart showing at least the 13 most recent test results. In the example given here the establishment's process was out of control because the UCL was exceeded at test 6. The establishment took action after test 6 to identify and eliminate the cause and prevent its recurrence. Subsequent tests indicate process control.

Example SPC Chart



The current FSIS audit has brought to our attention establishments that have opted for the sponge method of sampling for generic E coli and have not been using **Statistical Process Control (SPC)** techniques to evaluate ongoing test results.

How to do a SPC or Statistical Process Control – example: -

FBO conducts a series of preliminary generic *E. coli* tests during normal operations and then charts the results for long enough to have a true picture of its performance - about 30 days is usual. The results are usually recorded in cfu/cm² – see example chart above. It is then necessary to determine the typical range of generic *E. coli* counts found under normal circumstance.

FBOs may (i) calculate their own statistics or (ii) hire a consultant company or (iii) use a software package to develop statistical process control values to determine the upper and lower control limits based on test results.

Once the values are determined, as long as the data points on the company chart stay within the control limits set by the company, the process is considered in control.

The range as determined by the maximum and minimum control limits must be reviewed annually, as a minimum, or more often where there are changes to

- (i) The HACCP or the Food Safety Management System or
- (ii) The sanitary dressing procedures.

Some FBOs may have already used SPC to establish limits in the past but should repeat the exercise to reflect current process controls