

## **Salmonella Set Definitions**

FSIS laboratories keep records of *Salmonella* test set results. Sets are described using the following terms.

- Set A is the first set of samples taken in a plant or one taken when the previous set passed.
- Set B is the set of samples taken after failure of one set (Set A) immediately prior to this set.
- Set C is the set of samples taken when two consecutive previous sets (Sets A and B) have failed.

## **Salmonella Set A Failures**

When there is a Set A failure, the District Manager (DM) sends a letter containing the following information to the establishment:

- The set completion date listed on the PREP report.
- The class of product.
- The sample test results (e.g., number of samples analyzed and number of positive samples in the set).
- A statement that the establishment needs to take immediate action to meet the standard in accordance with sections 310.25(b)(3)(i) or 381.94(b)(3)(i) of the regulations.
- A request for the establishment to respond to the Supervisory Veterinary Medical Officer (SVMO)/IIC to explain why it believes that it is operating in full compliance with the regulations or what immediate actions it intends to take.

## **Within 30 days of the date of the DM's letter:**

- The IIC will document the establishment's response to the DM's letter (i.e., corrective actions identified or an explanation of compliance). The IIC will maintain a copy of the documentation in the inspection files.
- The frontline supervisor and IIC will conduct and document an assessment of the establishment's HACCP and SSOP procedures and, where applicable, analyze data from the establishment's generic *E. coli* testing program, focusing on the corrective and further planned actions by the establishment. The IIC will maintain a copy in the inspection files.
- The frontline supervisor and IIC will develop, document, and implement a verification plan, using the 01 and 02 SSOP and HACCP procedure codes, to verify any corrective actions implemented by the establishment. The IIC and CSI will conduct verifications to evaluate the effectiveness of

corrective actions. The IIC will keep a copy in the inspection files.

- After the IIC and frontline supervisor have completed the above documents, the frontline supervisor will forward them to the DM.
- The frontline supervisor and IIC will correlate with in-plant inspection program personnel to ensure the plan is understood and executed. Based on findings of the verification activities, any warranted enforcement actions will be taken in accordance with the rules of practice (9 CFR Part 500). The frontline supervisor will inform the DM about any necessary enforcement action.
- The frontline supervisor, IIC, and in-plant inspection program personnel will consult with the Technical Service Center (TSC) for assistance in data analysis or technical questions that arise.

Collection of samples for set B (the next *Salmonella* set) begins immediately after an establishment completes corrective and preventive actions or within 60 days of the end of set A, unless an agreement between the DM and the establishment was made to allow more time to implement corrective and preventive actions. The DM communicates with the frontline supervisor and the IIC to ensure that the establishment progresses with their actions in a timely manner.

### ***Salmonella* Set B Failures**

When there is a Set B failure:

- The DM sends a letter to the establishment with the same specific sample information as that included in a Set A failure. The letter informs the establishment that FSIS expects the establishment to address its total food safety program by reassessing its HACCP plan for that product and taking appropriate corrective and preventive actions and by making any necessary corrective actions in its SSOP.
- The DM, in consultation with the frontline supervisor, IIC, and inspection program personnel, will determine whether the establishment conducted proper reviews of its total food safety program, including a reassessment of HACCP plans and necessary evaluation of the effectiveness of the SSOP. The DM will issue a Notice of Intended Enforcement (NOIE) action if the reassessment is not performed.
- After the establishment has performed a reassessment, validated modifications to the plan, and reevaluated and modified the SSOP, as necessary, the DM will initiate an In-Depth Verification (IDV) review. The DM will receive the report developed from the IDV, containing the team's findings. The DM's designee will analyze the findings and make

recommendations about how to proceed. FSIS may also decide to conduct an IDV at some or all of the establishment's suppliers.

- The DM makes one of the following decisions:
- If the establishment's actions addressing its total food safety program do not meet the requirements in the regulations, the DM will issue an NOIE.
- If the establishment's actions addressing its total food safety program raise concerns regarding the establishment's design and execution of the program, but the concerns do not indicate regulatory noncompliance, the DM will send a 30-day reassessment letter that outlines FSIS concerns. The 30-day reassessment letter will ask the establishment to produce records that address the concerns.
- If the establishment's actions addressing its total food safety program in response to the IDV meet the requirements in the regulations, or if in response to the NOIE or the 30-day reassessment letter, the establishment provides adequate evidence that it has not failed to meet the requirements in the regulations, the DM will schedule Set C to verify the successful operation of the establishment's total food safety program.
- The enforcement investigation and analysis officer (EIAO) develops a verification plan to be used by in-plant inspection program personnel to verify all modifications made by the establishment in response to the Set B failure and to assess corrective actions and further planned actions provided in response to an enforcement action. The EIAO sends a copy of the verification plan to the frontline supervisor and DM and a copy will be kept in the inspection files at the establishment.
- The IIC and CSI will conduct verifications to evaluate the effectiveness of establishment's actions. The EIAO, frontline supervisor, IIC, and in-plant inspection program personnel correlate to ensure the verification plan is fully understood and executed as intended.
- The frontline supervisor e-mails a report to the DM each month on the findings of the verification activities until the establishment has passed the next *Salmonella* sample set.

Collection of samples for set C begins immediately after an establishment completes corrective and preventive actions or within 90 days of the end of set B, unless an agreement between the DM and the establishment allows more time to implement modifications. The DM communicates with the frontline supervisor and the IIC to ensure that the establishment progresses with their actions in a timely manner.

## ***Salmonella* Set C Failures**

When there is a Set C failure:

- The DM sends a letter to the establishment with the specific sample information. The letter informs the establishment that FSIS will instruct a EIAO and a compliance officer (CO) to conduct a focused assessment of the establishment's total food safety program to investigate the reasons why, in light of previous reassessments and corrective actions, the establishment failed Set C.
- The EIAO and a CO focus on the reassessments and corrective and preventive actions that the establishment took after the Set B failure, and on whether there is a basis to find that the establishment's total food safety program is not adequate. The EIAO and the CO consult with the IIC and frontline supervisor. If the establishment requests, the EIAO and the CO will meet with the establishment and provide an opportunity for the plant to present evidence about why it believes it has not failed to meet the regulatory requirements. If warranted, the CO develops a case file for an enforcement action. For grinding establishments, FSIS may decide to conduct an IDV at some or all of the establishment's suppliers.
- Based on findings by the EIAO and the CO, the DM and officials from Headquarters will determine what actions the Agency will take, including enforcement actions.
- There may be rare instances in which the DM determines that the establishment should conduct an additional reassessment. In such cases, the DM will issue a 30-day reassessment letter, and the IIC and CSI will conduct in-plant verifications and follow-up *Salmonella* verification testing will occur.

FSIS adopted pathogen reduction performance standards for *Salmonella* to verify that plant HACCP systems are effectively reducing contamination with this pathogenic microorganism. FSIS believes that the production of raw meat with *Salmonella* prevalence below the current national level is readily achievable with available technology and production methods.