MICROBIOLOGICAL TEST FAILURE RESULTS QUESTIONNAIRE

PART A – These are RECOMMENDED actions following notification of any laboratory microbiological test result other than a fully conforming microbiological test result.

1. Now is the time to review your operations and gather data. The following actions are recommended when nonconforming microbiological test results are detected or a presumptive positive test result for *Salmonella*, *Escherichia coli* (*E. coli*), or other identified pathogens has been issued by the USDA National Science Laboratory performing the test.

2. Identify, segregate, and place suspect lot on medical hold.

3. Identify all ingredients used in suspect lot by manufacturer and lot number.

4. Identify all other products/lots with ingredients in common to the suspect lot. If other products/lots were produced with any of the same ingredients (manufacturer and lot number) as the suspect lot, locate, segregate, and place those lots on medical hold.

5. Do not produce any further products/lots with the same ingredients (manufacturer and lot number) as the suspected lot, place these ingredients on medical hold.

6. If currently producing with the same ingredients (manufacturer and lot number) as the suspected lot, ensure the product is identified, segregated, and placed on medical hold.

> Steps 2-6 are to ensure that suspect product and/or common ingredients from suspected lot do not enter the supply chain. Recommend a spreadsheet be developed listing end products by lots against ingredients by lots.

7. Identify all lots produced after the suspect lot for which the same equipment was used in blending, processing, and/or packaging.

8. Identify when involved equipment was wet washed and sanitized prior to and after the production of the suspect lot.

9. Review all production, maintenance, sanitation, and QA records for the day before and the day of suspect lot production.

10. Review visitor logs for the day before and day of production.

11. Review employee records for the day before and the day of production.

12. Review facility environmental conditions (e.g., temporary standing water due to heavy rains; broken windows or doors; storage areas, etc.) for the day before and day of production.

> Steps 7-12 are to determine if something happened the day of production or the day prior that may have lead to contamination of the product or its ingredients.

13. Consider conducting a full sanitation cycle (for example, wet wash and sanitize equipment/line) on the line the suspect lot was produced on. Also consider a full sanitation cycle on any other line that common ingredients (manufacturer and lot number) to the suspect lot were use in.

14. Determine relationships between the suspect lot all other products with respect to: a) equipment/environment; b) personnel; and c) ingredients.

15. Review collected data for completeness and await results of confirmation testing; you are now prepared should the presumptive be confirmed as an actual positive. In your review if you identify a probable/possible source of contamination you should take immediate corrective action and notify the government.

16. The government may require additional inspection/review prior to certification of products offered during the interim period between notification of presumptive positive and the results of the confirmation test. To include, but not limited, to certification/verification that the offered lot has no relationship (equipment/environment; personnel; ingredients) to the presumptive lot.

17. Review the collected data from recent environmental sampling to help identify a probable/possible source of contamination.

PART B – These are REQUIRED ACTIONS following notification of CONFIRMED POSITIVE laboratory analysis for *Salmonella*, *Listeria monocytogenes*, *Escherichia coli* (*E. coli*) or other identified pathogenic bacteria strains such as E. coli O157:H7, which can produce a Shiga-like toxin.

18. Ensure you have performed steps 1 through 17 above.

19. Develop a detailed report with the above gathered information. It is the responsibility of the contractor to provide the government a detailed report indicating the probable/possible source of contamination, relationships between the suspect lot and all other government products, and a corrective action plan to prevent recurrence.

20. Once the government has a full detailed report from the contractor the government will determine what further action(s) is/are required to ensure offered products meet government requirements.

21. Further actions may include, but are not limited to, increased auditing by the U.S. Army Public Health Center, additional product testing, tightened inspection requirements that could include increased sample sizes and modified testing procedures, additional testing of other lots/products, testing of raw ingredients, performing additional environmental sampling in production areas associated with the microbiological failure, submission of manufacturers certificates, or condemnation.

22. Any product lot found nonconforming due to microbiological testing will NOT be accepted by the government under any condition. Retesting or reworking confirmed positive lots is not authorized.