### Appendix B - Validated Test kits for sprout irrigation water

## **GUIDANCE FOR INDUSTRY**

# Sampling And Microbial Testing Of Spent Irrigation Water During Sprout Production

### **Microbial Testing**

#### **Testing Procedures**

The testing procedures described in this guidance are screening tests. They were chosen to obtain results as simply and quickly as possible (i.e., to provide answers in 48 hours or less) on the presence or absence of two major pathogenic bacteria, i.e., *Salmonella* and *Escherichia coli* O157:H7. Formal confirmation methods, which take longer than 48 hours, are described in the FDA Bacteriological Analytical Manual (published by AOAC International, Gaithersburg, MD).

The kits identified in this guidance are AOAC approved screening tests and/or FDA has experience with their use. These are also the tests that FDA plans to use as screening tests to monitor spent irrigation water at sprouting facilities. If screening methods, other than those described here are used, they should first be validated either by formal collaborative studies or by comparative studies with standard methods using the specific commodity in question, spent irrigation water or sprouts.

Procedures for determining the presence or absence of *Escherichia coli* O157:H7 and *Salmonella* species using the test kits listed below are provided at the end of this guidance. These procedures should be performed separate from the food production facility by a qualified laboratory, preferably an independent, certified lab.

The rapid test procedures described in this guidance all involve an enrichment step to encourage the selective growth of pathogens, if they are present, in order to make their detection possible. These test kits will NOT detect pathogens in irrigation water or sprouts if the enrichment step is not performed.

In addition, seasonal or regional differences in water quality, type of seed being sprouted, individual sprout production factors, and variations in sampling and analytical conditions may all impact on the effectiveness of the screening tests. Therefore, the lab should periodically run positive controls (i.e., sprout or water samples to which a known quantity of pathogens have been added) to ensure the tests used are capable of detecting pathogens when they are present in the samples being tested.

#### Test Kits

#### Escherichia coli O157:H7

1. VIP EHEC, Biocontrol Systems, Inc., Bellview, WA., (AOAC Official method # 996.09) or

2. Reveal E. coli O157:H7, Neogen Corp., Lansing, MI.

#### Salmonella

1. Assurance Gold Salmonella EIA, (AOAC Official method # 999.08)

or

2. Visual Immunoprecipitate (VIP) Assay for Salmonella, (AOAC Official method 1B 999.09)

(Both kits are manufactured by BioControl Systems, Inc., 12822 SE 32nd Street, Bellevue, WA 98005).

# New Rapid Test Kit validated December 2010:

## Neogen's rapid test for Salmonella receives AOAC approval

LANSING, Mich., Dec. 14, 2010 - Neogen Corporation today announced that its enhanced rapid test for

Salmonella has received approval from AOAC International.

Neogen's new test kit, Reveal 2.0 for Salmonella, provides the food industry a quick, accurate and easy method of detecting this pathogen without compromising sensitivity or specificity. The AOAC's process validated the accuracy of the Reveal 2.0 for Salmonella system when testing food, rinse water and environmental samples.

"The Reveal 2.0 for Salmonella system cuts the wait time for results to just 24 hours, with only 15 minutes of test development time following enrichment," said Neogen's Ed Bradley. "We are pleased that the AOAC-approval further validates our test as an invaluable tool to food producers."

In the AOAC study, Reveal 2.0 for Salmonella was found to be an effective procedure for the detection of *Salmonella enterica* in chicken carcass rinse water, raw ground turkey and beef, hot dogs, raw shrimp, ready-to-eat meal products, dry pet food, ice cream, fresh spinach, cantaloupe, peanut butter and sprout irrigation water, and on stainless steel surfaces.

"The Reveal 2.0 Salmonella test system greatly simplifies the *Salmonella* testing protocol by instituting comprehensive sample enrichment procedures that apply to most sample commodities," said Bradley. "In the case of raw poultry and meat samples and poultry carcass rinses, Neogen has developed a single enrichment protocol that eliminates the hands-on time and effort of multiple enrichments, while maintaining same-day results. This is the first AOAC-approved kit in a new line of pathogen test kits designed for accurate results with minimal steps for users."