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January 11, 2000

Dockets Management Branch
5630 Fisher Lane
Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

These comments are being written in regard to the document entitled "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" (Docket No. 99D-4489) on behalf of Silliker Laboratories, Inc.

1. For most testing laboratories, the set up of the 42 C shaking incubation represents a significant capital investment. For detection of *E. coli* O157:H7, make allowance for use of 500-ml flasks instead of 1-L flasks in the 42 C shaking incubation of BPW+ACV. This would double the testing capacity in one run.
2. Justify the necessity for the shaking incubation step. Do preliminary results truly indicate a significantly ($p=0.05$) improved recovery of *E. coli* O157:H7 versus static incubation?
3. Allow more flexibility in the screening procedures for *Salmonella* and *E. coli* O157:H7. Are there other AOAC or AOAC-RI approved screening procedures that can be used without validation or with minimum validation (e.g., *Salmonella* Vidas, *Salmonella*-Tek, *Salmonella/E. coli* O157:H7 BAX)?
4. Provide additional guidance regarding the extent of validation studies (e.g., minimum number of samples or replications required).

Thank you for considering these comments.

Sincerely,



W. Payton Pruett, Jr., Ph.D.
Director of Microbiology, Analytical Services

99D-4489

266

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