



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Office of Policy
and Program
Development

George Washington Carver
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Beltsville, MD 20705-5271

MAR 12 2010

Mr. Jared Bradley
President/CEO
Microbial-Vac Systems, Inc.
14621 South 800 West #100
Bluffdale, Utah 84065

Dear Mr. Bradley:

This letter is in response to your submission (Log No. 08-NT-0336-N-A) requesting a No Objection regarding the use of Microbial-Vac Systems' unique wet-vacuum sampling device (M-Vac) in Food Safety and Inspection Service (FSIS) inspected establishments to collect samples from meat surfaces and food contact surfaces.

Based on our review of your submissions, including the several sampling studies that compared the M-Vac to other sample collection methods, FSIS has no objection to the use of the M-Vac sampling device in official establishments to collect samples from meat and environmental surfaces, provided that M-Vac does not:

1. adversely affect the safety of product;
2. jeopardize the safety of Federal Inspection Program Personnel;
3. interfere with inspection procedures; and
4. be inconsistent with FSIS regulations.

The no objection is conditional, that use of the M-Vac complies with the four criteria listed above.

The results of the environmental monitoring study and carcass/primal sampling study demonstrated that the M-Vac system performed better than sponging techniques, recovering more bacteria from the sampled areas. In addition, when M-Vac was compared to excision, there was no statistical significant difference between M-Vac and excision in numbers of *E. coli* O157:H7 collected from the surface of the trim.

As mentioned in your notification letter, FSIS does not have specific regulatory requirements prescribing methodologies for the collection of surface or environmental microbial samples. In addition, there are no FSIS regulations that require establishments use the N-60 excision of 4-inch x 2-inch x 1/8-inch surface area method, when collecting trim or carcass samples for its *E. coli* O157:H7, Hazard Analysis Critical Control Point (HACCP) verification samples.

However, there is an FSIS expectation that establishments use sample collection and analytical methods comparable to those used by FSIS i.e. robust N-60 excision sampling when establishments collect and analyze beef samples for *E. coli* O157:H7.

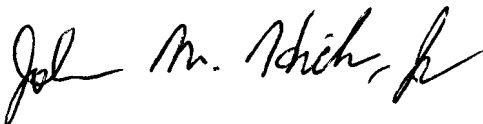
FSIS inspection program personal critically review an establishment's HACCP plan, including *E. coli* O157:H7 sampling and analytic methods. Thus, the use of the M-Vac system will be critically reviewed by FSIS inspection program personal if it is used by an establishment for collecting establishment's verification samples. Verification samples are used by an establishment to demonstrate that the establishment's HACCP food safety plan reduces the *E. coli* O157:H7 hazard associated with beef to below detectable levels.

Criteria that FSIS inspectors may evaluate include: 1) whether the surface area covered by the M-Vac system is comparable to the 4-inch by 2-inch by 1/8-inch excision method, and 2) whether the collection method combined with laboratory analyses is as sensitive as the method used by FSIS which has shown to detect 0.23 colony forming units (cfu)/g in a 25 g sample of 75/25 (lean/fat) ground beef (FSIS' Laboratory Guidebook http://www.fsis.usda.gov/PDF/MIg_5A_01.pdf)

It is our recommendation that the M-Vac System could be a very useful technology for regulated establishments and FSIS. The sample collection methods appear to be well-supported experimentally, using both indicators and pathogens. However, it would be important to evaluate this method against the N-60 excision method using a robust study design and to ensure that the study is well documented. In addition, training of sample collectors for any system is crucial to the overall efficiency of sampling. The use of the M-Vac collection system by collectors should be preceded by adequate training of collectors.

If you have any questions, please contact Robert Ragland Area Code (301) 504-0884 Fax: (3010 504-0876 or Email: robert.ragland@fsis.usda.gov)

Sincerely,



John M. Hicks, Jr., DVM, MPH
Director, Risk and Innovations Management Division
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