DECISION MEMORANDUM
INDIVIDUAL SANITARY MEASURE
Australia

E. coli O157:H7 detection in 375g raw ground beef with low volume enrichment medium and using commercially-available 8 test kits.

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EQUIVALENCE REQUEST:

As per letter dated November 13, 2008¹, and several e-mail correspondences (last e-mail August 2, 2010¹), Australia requested equivalence determination for the following:

1. E. coli O157:H7 detection in 375g raw ground beef with low volume enrichment medium i.e. 1L medium (2.7 volumes) using commercially-available 8 test kits. The 8 test kits are, 1) BioControl Assurance (8h), 2) BioControl Assurance (18-28h), 3) BioControl VIP (8h), 4) BioControl VIP (18-28h), 5) BAX MP (8h), 6) Reveal (8h), 7) Reveal (20h), and 8) Rapid check (15h).

BACKGROUND:

Australia submitted following documents (included in Tab5) to help FSIS in determining equivalence:

2) Validation of composite sampling for detection of E. coli O157:H7 in raw beef trim and raw ground beef.
3) Neogen recommends 11-hour incubations for E.coli O157:H7 testing if using 375g samples. Technical product information.

FSIS FOOD SAFETY MEASURE:
Samples taken to test for the presence of E. coli O157:H7 are analyzed in a FSIS laboratory using the Microbiology Laboratory Guidebook, Chapter 5 (MLG 5) analytical method.

¹ Highlighted information on pages marked with magenta and blue flags.
OBJECTIVE OF THE FOOD SAFETY MEASURE:
The objective for using the FSIS method of analysis is to use a scientifically validated method of analysis for the detection of E. coli O157:H7 in raw ground beef, beef trim/trim components, fermented sausages containing beef, and cooked beef patties.

EQUIVALENCE CRITERIA:
The following, are criteria used in making equivalence decisions for an E. coli O157:H7 testing method:

- The method is a scientifically validated method of analysis for E. coli O157:H7 approved or adopted by an international organization.

- The method ensures an opportunity for detection and identification of E. coli O157:H7 equal to or greater than the current FSIS method.

These criteria were re-evaluated by OPHS.

EQUIVALENCE EVALUATION:
I. The equivalence criteria for E. coli O157:H7 detection in 375g raw ground beef with low enrichment volume i.e. 1 L medium (2.7 volumes) using 8 test kits was that any modifications in the testing method had to be scientifically validated and the modified method should ensure an opportunity for detection and identification of E. coli O157:H7.

The validation study performed by Silliker Australia Pty. Ltd, and published as a research note in a peer-reviewed journal (Ahmed et al JFP 72:669) are included as supporting information. Briefly, 375g sample and low volume (1L) enrichment medium were enriched for 8 or 20 hours depending on the manufacturer’s recommendation. The authors concluded that for 5 test kits (Biocontrol VIP, 8 and 18 hr methods, Biocontrol Assurance 8 hr method, and BAX 8 hr method) recovery was statistically indistinguishable, and thus low volume enrichment could provide reliably sensitive results. The other 3 test kits (Reveal 8 and 20 hr, Rapidcheck 15 hr) either were not inoculated with target pathogen to a level resulting in fractional recovery, or recovery under the alternative conditions was statistically indistinguishable from the original conditions.

The validation data provided by Australia on low enrichment volume (1L medium i.e. 2.7 volumes) protocols does not provide adequate evidence demonstrating that the procedures are robust or repeatable for detecting E. coli O157:H7. Following, are the reasons:

a) The performance of the alternative methods was not validated against a reference cultural method. AOAC validation guidance recommends that the performance of alternative methods should be measured against a reference cultural method, defined as the appropriate AOAC, FDA/BAM or USDA/FSIS reference culture procedure.
b) Sensitivity was not determined by cultural confirmation.

c) Sample size does not provide adequate statistical power. In the current study 20 samples per condition were analyzed instead of 60 samples to achieve a good statistical power (80%)².

d) Existence of conflicting data on low volume enrichment procedures. An internal study by Biocontrol³ found that VIP 8h with 375 g sample and 1 L media resulted in partial recovery of E. coli O157:H7. While a 375 g sample with 1.5 L media at 10 or 12 h enrichment provided acceptable recovery of E. coli O157:H7. In another internal study conducted by DuPont-Qualicon, the BAX-MP (8h) assay did not perform well with a low volume enrichment procedure i.e. 375g with 1L enrichment medium¹,².

Therefore, it is not equivalent.

RECOMMENDATION:

The reviewers found that the request to use:

I. E. coli O157:H7 detection in 375g raw ground beef with low volume enrichment medium i.e. 1L medium (2.7 volumes) using commercially-available 8 test kits. The 8 test kits are, 1) BioControl Assurance (8h), 2) BioControl Assurance (18-28h), 3) BioControl VIP (8h), 4) BioControl VIP (18-28h), 5) BAX MP (8h), 6) Reveal (8h), 7) Reveal (20h), and 8) Rapid check (15h) does not meet the established criteria. Therefore, this request should not be granted.

APPROVAL:

[Signature]

Andreas Keller
Director
International Equivalence Staff
Office of International Affairs, FSIS

[Signature]

Mary Stanley
Director
International Policy Division
Office of Policy and Program Development, FSIS

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¹ Review document developed by Peter Evans (OPHS/MD) dated 8/22/2009

² Comparison of VIP® EHEC Enrichment Ratios with Composite Beef Trim Samples
CONCURRENCE/OIA:

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9-16-10
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CONCURRENCE/OPPD:

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9-20-10
Date