NSF International

MEMORANDUM

TO: Joint Committee on Dietary Supplements

FROM: Brian Zamora, Chair of the Joint Committee

DATE: November 13, 2020

SUBJECT: Proposed revision to NSF/ANSI 173 – *Dietary Supplements* (173i93r1)

Revision 1 of NSF/ANSI 173 issue 93 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by December 4, 2020** via the NSF Online Workspace <www.standards.nsf.org>.

When adding comments, please use the comment template provided in the ballot and upload it online via the browse function.

Purpose

The proposed revision will create more consistency within the standard.

Background

Per BAM4A, test for Enterotoxigenic *E. coli* (ETEC) is applicable only to samples where *E. coli* count exceeds 1E+04 cells/g. This will require all *E. coli* positive samples tested qualitatively (cat. 1 and 2 of finished product, vitamin and/or mineral ingredient, botanical ingredient – extract / other dietary supplement ingredient) to be retested by applying a quantitative method. Retested sample results may not correlate with initial results due to differences in sample homogeneity.

BAM 4A utilizes PCR methods, which are known for producing false positive results (i.e. from DNA from dead cells). Thus the chances of having to retest are high which result in an increase of turnaround time as well as cost associated with supplies and labor.

From CDC: Recently approved nucleic acid amplification tests that detect genes encoding putative virulence factors associated with non-STEC *E. coli* pathotypes (ETEC, EPEC, EAEC, EIEC) are now available in some clinical laboratories. However, the combination of virulence factors necessary for an *E. coli* strain to be a pathogen has not been determined for all pathotypes. For example, one PCR-based test relies on the *eae* gene that encodes the adhesion factor intimin to produce an EPEC result. However, many case-control studies have detected this gene with similar frequency in *E. coli* isolated from healthy people as from those with acute diarrhea. Therefore, EPEC might not be the etiology of illness for a person with diarrhea and a PCR-based EPEC result.

If you have any questions about the technical content of the ballot, you may contact me in care of:

Brian Zamora
Chair, Joint Committee on Dietary Supplements
c/o Rachel Brooker
Joint Committee Secretariat
NSF International
Phone: (734) 827-6866
Email: rbrooker@nsf.org

[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of ~~strikeout~~ and additions by gray highlighting. Rationale statements are in *italics* and only used to add clarity; these statements will NOT be in the finished publication.]

NSF/ANSI Standard
for Dietary Supplements –

Dietary Supplements

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7 Test methods used by testing laboratories for detection of contaminants – Dietary ingredients and finished products

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7.3.1 Test methods for microbiological contaminants

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7.3.7.2 Pathogenic *E. coli*

If the presence of *E. coli* is confirmed, then additional testing shall be performed (e.g., serotyping) ~~based the FDA's *Bacteriological Analytical Manual* (BAM, Chapter 4A)~~ to determine whether the product contains pathogenic *E. coli*, including but not limited to 0157:H7.

Rationale: The proposed revision will create more consistency within the standard.