NSF Standard(s) Impacted: 173

Background:
Provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc., and any other reason why the issue should be considered by the Committee. Reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

Section 7.3.7.2.

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.

Recommendation:
Clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of strike-out and additions by highlighting or underlining; e.g., reference of the issue to a Task Group for detailed consideration, etc.

If the presence of E. coli is confirmed, then testing shall be performed based the FDA's Bacteriological Analytical Manual (BAM, Chapter 4A) to determine whether the product contains pathogenic E. coli, including but not limited to O157:H7.

If the presence of E. coli is confirmed, then additional testing shall be performed (i.e. serotyping) to determine whether the product contains pathogenic E. coli, including but not limited to O157:H7.

Supplementary materials (photographs, diagrams, reports, etc.):
If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.


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