789 N. Dixboro Rd,
Ann Arbor, Michigan
48105-9753 USA

T +1 734 769 8010
E standards@nsf.org
nsf.org

Joint Committee on GMP for Dietary Supplements

April 18, 2024

Proposed revision to NSF/ANSI 455-2 – *Good Manufacturing Practices for Dietary Supplements* (455-2i62r1)

Revision 1 of NSF/ANSI 455-2, issue 62 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by May 9, 2024** via the NSF Online Workspace.

Please review all ballot materials. When adding comments, please include the section number applicable to your comment and add all comments under one comment number whenever possible. If you need additional space, please use the attached blank comment template in the reference documents and upload online via the browse function.

Purpose

The proposed revision will update the language in Section 4.5.84 to clarify the intent for the Environmental Monitoring Program.

Background

4.5.84 - The requirement is separated into two requirements to give focus on each.

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

Freddie Agyin

Chair, Joint Committee on GMP for Dietary Supplements
c/o Rachel Brooker, Joint Committee Secretariat
T +1 (734) 827-6866
E 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 grey 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 GMP for Dietary Supplements –

Good Manufacturing Practices for Dietary Supplements

•
•
•

4 Audit requirements

•
•
•

4.5 Operation

•
•
•

4.5.84 ~~Environmental Monitoring Program shall be risk-based to include controls to evaluate and mitigate the presence of nonpathogenic microorganisms in production areas and equipment. If an environmental monitoring program includes pathogen testing in product contact zones, the production area and equipment shall not be used until the area is cleaned and proven free of pathogens~~.
A risk-based Environmental Monitoring Program that includes controls to evaluate and mitigate the presence of nonpathogenic microorganisms in production areas and equipment shall be established.

4.5.85 If an environmental monitoring program includes pathogen testing and a positive result is found in product contact zones, then production area and equipment shall not be used until the area is cleaned and proven free of pathogens.

•
•
•