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Joint Committee on GMP for Dietary Supplements

March 7, 2024

Proposed revision to NSF/ANSI 455-2ARG – *Audit Requirement Guidelines for Good Manufacturing Practices for Dietary Supplements (455-2ARGi43r1)*

Revision 1 of NSF/ANSI 455-2ARG, issue 43 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by March 28, 2024** via the NSF Online Workspace.

Please note that this is an ARG ballot only. ARG guidelines are denoted in italics and only the italic language is open for comments. While this ballot may include some suggested changes to the standard this ballot is NOT on those changes. They are only included so that you can see how those suggested changes impact the ARG. If you have any comments on the included standard changes you MUST make those comments on that issue paper's ballot. The link to the ballot is included in the comments in the ballot. Any comments on the suggested standard changes shown in this ballot will be considered nongermane and will not be addressed.

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

Purpose

The proposed revision will group requirements together that are similar as well as open requirements to international companies for global reach.

Background

4.5.29 is currently under section 4.5 Operation however, other requirements pertaining to supplier qualification are under section 4.3 Planning. Moving the requirement together with related requirements makes for a more cohesive layout of the standard and ease of use.

The current language requires manufacturers to implement FSVP if they directly import materials or product. It is implied this refers to manufacturers manufacturing or distributing in the US. However, this requirement unintentionally excludes international companies that do not distribute or sell in the US. The proposed change is to have a more inclusive language for implementation of FSVP or recognized or equivalent programs based on regulatory requirements at the country of manufacture or sale.

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

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[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.]

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NSF/ANSI Standard
for GMP for Dietary Supplements –

Good Manufacturing Practices for Dietary Supplements

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4 Audit requirements

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4.3 Planning

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4.3.1 A risk-based supplier qualification program is established and implemented for all ingredients. The program includes a supplier / ingredient risk evaluation, appropriate qualification activities as determined by the risk evaluation, and assurance that only approved suppliers are used. [21 C.F.R. § 117.405 & 21 C.F.R. § 117.410]

4.3.2 Supplier qualification procedures shall include initial qualification, periodic examination (requalification), disqualification, and as necessary, expedited approval of suppliers on an emergency basis. [21 C.F.R. § 111.75(a2iiA)]

4.3.3 Where required by regulations in the country of manufacture or sale, direct importers of components, bulk dosage forms, or finished dietary supplements shall establish and implement a foreign supplier verification program (e.g. FSVP). [21 C.F.R. § 1.511].

*****The suggested change above is NOT part of this ballot.*****

***4.3.3.1** Facilities subject to FSVP in the US should establish risk-based foreign supplier verification activities according to 21 CFR 1.505, 21 CFR 1.506:*
- Evaluation of a foreign supplier's performance and the risk posed by the material,

Commented [ER1]: This suggested change is 455-2i61r1. To vote or comment on this suggested change proceed to the 455-2i61r1 ballot at:

https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=8883

- Use of approved foreign suppliers,
- Determination and performance of appropriate foreign supplier verification activities (e.g. onsite audits, sampling and testing of the product, review of the foreign supplier's relevant food safety records, other appropriate verification activities, etc),
- Periodic reevaluation of a foreign supplier's performance and the risk posed by the material

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4.5 Operation

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~~**4.5.29** Direct importers of components, bulk dosage forms, or finished dietary supplements shall be established and implemented a foreign supplier verification program (FSVP). [21 C.F.R. § 1.511].~~

*****The suggested change above is NOT part of this ballot.*****

~~***4.5.29.1*** *Records for the foreign supplier program should be maintained and retained at least 2 yr after the documents are created or 2 yr after the product is discontinued for use. For smaller suppliers, record retention should be for at least a 3-yr period preceding the applicable calendar year to support their status as a very small supplier.*~~

~~***4.5.29.2*** *Electronic records under FSVP should follow 21 C.F.R. Part 11.*~~

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Commented [ER2]: This suggested change is 455-2i61r1. To vote or comment on this suggested change proceed to the 455-2i61r1 ballot at:

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