TO: Joint Committee on Dietary Supplements

FROM: Brian Zamora, Chair of the Joint Committee

DATE: October 27, 2022

SUBJECT: Proposed revision to NSF/ANSI 173: *Dietary Supplements* (173i66r1)

Revision 1 of NSF/ANSI 173, issue 66 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by November 17, 2022** via the NSF Online Workspace <www.standards.nsf.org>.

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 address probiotics.

Background

The Joint FAO/WHO Working Group defines probiotics as, "Live microorganisms which when administered in adequate amounts confer a health benefit on the host."[1] In the NDI Draft Guidance released by the FDA, the viability of live microbial dietary ingredients was discussed, "FDA will pay particular attention to the viability of microorganisms in the NDI. The per-serving level of a viable microorganism depends on both the mass (in grams) and the viability (e.g., number of colony-forming units) of the organism in the final product."[2] Currently within Standard 173, the quantity and identity of viable probiotics is not addressed. To ensure the quality of products and ingredients containing probiotics, it shall be confirmed whether or not there are viable microorganisms in the products and ingredients. Therefore, products and ingredients containing probiotics shall pass quantity and identity testing performed according to the methods proposed below in order to achieve Certification under Standard 173. This issue should be understood in the context that Probiotics claims must also comply with Section 8 of this Standard which requires 21 CFR 111 compliance. This means label claims must be met for the entirety of the product shelf life. Probiotics are categorized as Class I dietary ingredients.

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

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Chair, Joint Committee on Dietary Supplements
c/o Rachel Brooker
Joint Committee Secretariat
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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 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 Health Sciences –

Dietary Supplements

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2 Normative references

The following documents contain provisions that, through reference in this text, constitute provisions of this Standard. At the time this Standard was written, the editions indicated were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent edition of the document indicated below.

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ISO~~NTIS~~/IEC 17025:~~1999~~2017, *General requirements for the competence of testing and calibration laboratories*~~19~~

~~19 National Technical Information Service. 5301 Shawnee Road, Alexandria VA 22312. www.ntis.gov~~

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3 Definitions

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Probiotic- : Live microorganisms that when consumed orally in adequate amounts confer a health benefit on the consumer.

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4 Labeling and literature requirements

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4.2 Probiotics

For products and ingredients containing probiotics, the following information must be present on the label:
— minimum colony forming units (CFU) count of each strain of live microorganism at the time of the product or ingredient's expiration, or at time of production if no expiration date is applied; or
— minimum total CFU count for a blend of live microorganisms at the time of the product or ingredient's expiration, or at time of production if no expiration date is applied; ~~acceptable~~; and
— storage directions that guarantee the minimum CFU count(s) at the time of expiration, or at time of production if no expiration date is applied;; and
— identification of the ~~bacteria~~ probiotic including genus, species, and strain based on widely accepted

nomenclature. If a trademarked name is used to identify the bacteria, then the genus, species, and strain shall also be included on the label.

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5 Product requirements

5.1 Identity

5.1.1 Dietary ingredients

The identity of the dietary ingredient shall be verified in accordance with Section 6.1 or 8.7 using the test method(s) appropriate for establishing identity based on the manufacturer's claims.

5.1.2 Finished product

Manufacturers are responsible for ensuring that finished products shall contain each of the dietary ingredients and, if applicable, any subcomponent, such as marker constituents, declared on the label. The finished product identity claims shall be reviewed to determine if select claims shall be verified in accordance with Section 6.1 or 8.7.

5.2 Quantity

5.2.1 Dietary ingredients

COA claims for dietary ingredients shall be reviewed to determine a set of verification tests to confirm quantity of dietary ingredients and any claimed subcomponents such as marker constituents in accordance with Section 6.2 or 8.7.

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5.2.2 Finished products

Finished product claims shall be reviewed to determine a set of verification tests to confirm the quantity of dietary ingredients, claimed subcomponents ~~marker constituents~~ (if applicable), and nutritional declarations as declared on the label in accordance with Sections 6.2 or~~and~~ 8.7.

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6 Test methods used by testing laboratories for identification and quantification of ingredients – Dietary ingredients and finished products

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6.2 Quantification test methods

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6.2.4 Probiotics

Probiotics shall have identity and quantity evaluated using reference methods that are scientifically valid and suitable for the intended purpose. If no appropriate reference method exists, development of a new method is allowable. The use of any modified or new method shall require that a method validation be performed which includes recovery of the selected reference probiotic species.

Sources for methods may include AOAC International[6], USP[17] or other method sources. Modification of an existing method to better suit the sample under test is allowable.
Probiotics, as Class I dietary ingredients, shall meet minimum quantities (minus the measure of uncertainty of the analytical method) as stated as a specification in the COA or on the label of the finished product.

Default method uncertainty for probiotic quantitation, unless stated otherwise, is 0.5 Log_{10} of the measurement.

Example:
Total quantity of probiotic cultures claimed on the COA or on the label is 30 billion CFU/serving ($3x10^{10}$ CFU = 10.5 log_{10} CFU/serving).
Minimum acceptable level is $1x10^{10}$ CFU = 10 log_{10} CFU/serving.
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8 Good manufacturing practices (GMP)

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8.7 Alternate Means of Compliance

Under certain circumstances, alternate means of evaluation to Identity or Quantity requirements is permitted. This type of situation may arise in the following circumstances:

- **No scientifically valid method:** There is not a currently available scientifically valid method for the ingredient in the finished product. This may occur, for example, when an ingredient occurs at a low level in the finished product or when a finished product matrix is highly complex.

- **As part of an evaluation plan:** The certification body may designate specific identity or quantity specifications for Section 8.7 review.

Ingredient identification or quantification test data used for 8.7 may be generated by the applicant, applicant's qualified supplier, or applicant's third-party laboratory. When the applicant or applicant's supplier test data or manufacturing records is used as part of compliance evaluation, the applicant shall be responsible to arrange access to these records.

All data used to support compliance to any requirement of this standard, shall comply with the test method requirements of the standard.

Whenever ingredient test data is used as part of compliance evaluation, production records must document appropriate traceability between ingredient lots and finished product batches, as well as appropriate ingredient weighing, ingredient addition and second person verification of those operational activities.
Sample test data must be identified with a unique code or other clear identification that links the sample to the parent material from which it was taken. For this evaluation, the manufacturer must submit the relevant raw material test data and a representative batch production record. If an ingredient used in the product is itself a proprietary blend, the applicant must submit or arrange to have the ingredient manufacturer submit the relevant raw material test data and a representative batch production record for the proprietary blend ingredient.
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