TO: Joint Committee on Dietary Supplements

FROM: Freddie Agyin, Chair of the Joint Committee

DATE: August 26, 2024

SUBJECT: Proposed revision to NSF/ANSI 173 – *Dietary Supplements* (173i111r1)

Revision 1 of NSF/ANSI 173, issue 111 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by September 16, 2024,** via the NSF Online Workspace <https://standards.nsf.org/home>.

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 is to update some normative references and definitions.

Background

Periodically the JC reviews all normative references and definitions. There was a task group created review the current standard. It was found that some of the references were out of date or no longer referenced in this standard. Some of the publication dates were updated while some were removed all together. The rule for references is that if there is no date then the most up to date version of that document is what is referenced, and if there is a date, that date is the version of that document that is referenced no matter if there is a newer version available. The TG discussed each reference, and the entire JC was polled. This ballot is the result of those discussions and JC poll.

The TG also reviewed every definition and made suggested changes. These changes were also sent as a straw ballot to the entire JC and there were no objections to these suggested changes. This ballot is identical to that straw ballot.

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 Dietary Supplements
c/o Rachel Brooker
Joint Committee Secretariat
Tel: (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 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 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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AHP, American Herbal Pharmacopoeia and Therapeutic Compendium

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Ashwagandha Root*, April 2000~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Astragalus Root*, August 1999~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Bilberry Fruit*, 2001~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Cohash Root*, 2002~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Haw Bark*, June 2000~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Chaste Tree Fruit*, 2001~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cramp Bark*, February 2000~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cranberry*, 2002~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Dang Gui Root*, 2003~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Echinacea Purpurea Root*, 2004~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Ginkgo Leaf*, 2003~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Goldenseal*, 2001~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Hawthorn Berry*, June 1999~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Hawthorn Leaf with Flower*, February 1999~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Reishi Mushroom*, September 2000~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *St. John's Wort*, July 1997~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Schisandra Berry*, October 1999~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Valerian Root*, April 1999~~[Error! Bookmark not defined.]

~~AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Willow Bark*, December 1999~~[Error! Bookmark not defined.]

AHPA, *Herbs of Commerce*~~, 2nd Edition, 2000~~[1]

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AOAC, *Official Methods of Analysis*, ~~20th Edition (2016)~~[2]

~~AOAC, *Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals*, 2002~~[2]

AOAC/FDA, *Bacteriological Analytical Manual*, (BAM) 8th edition, 1998[2,3]

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FDA, *Food Code ~~2017~~2022 Recommendations of the United States Public Health Service Food and Drug Administration*[3]

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[1] American Herbal Products Association. 8630 Fenton Street, Suite 918, Silver Spring, MD 20910. <www.ahpa.org>

[2] AOAC International. 2275 Research Boulevard, Suite 300, Rockville, MD 20850-3250. <www.aoac.org>

[3] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. 10903 New Hampshire Ave, Silver Spring, MD 20993. <www.fda.gov><https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam>

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Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021, Public Law 117-11[10]
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~~*International Code of Botanical Nomenclature* (Vienna Code), 2006~~ *International Code of Nomenclature for algae, fungi, and plants* [4]
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3 Definitions

Terms used in this standard that have special technical meaning are defined here.

~~**3.1 active ingredient: The principal ingredient identified in a product's name or on its principal display panel.**~~
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3.4 batch ~~or lot~~: ~~A specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, or is produced according to a single manufacturing order during the same cycle of manufacture.~~ a specific quantity of a dietary supplement that is uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture.
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3.9 component: ~~An ingredient intended for use in the manufacture of a dietary ingredient or dietary supplement, including those that may not appear in such finished product.~~ any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Component includes dietary ingredients (as described in section 201(ff) of the Federal Food, Drug, and Cosmetic Act) and other ingredients.
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3.11.1 Class I (dietary ingredient): ~~An added nutrient.~~ a nutrient that is added or whose content is adjusted or controlled.
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[4] Turland, N. J., Wiersema, J. H., Barrie, F. R., Greuter, W., Hawksworth, D. L., Herendeen, P. S., Knapp, S., Kusber, W.-H., Li, D.-Z., Marhold, K., May, T. W., McNeill, J., Monro, A. M., Prado, J., Price, M. J. & Smith, G. F. (eds.) 2018: *International Code of Nomenclature for algae, fungi, and plants (Shenzhen Code) adopted by the Nineteenth International Botanical Congress Shenzhen, China, July 2017*. Regnum Vegetabile 159. Glashütten: Koeltz Botanical Books. DOI https://doi.org/10.12705/Code.2018.

3.13 dry weight basis: A basis for expressing the measurement results for a substance in a material after subtracting the moisture content from the mass of the material, e.g., 1 g of a material that has a moisture content of 10% would have a dry weight of 0.9 g as determined using the equation:

$$C_{dry} = C_{wet} \times \frac{100}{100 - \text{moisture}}$$

The dry weight is then used to correct the results from another analysis such as HPLC analysis.

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~~**3.18 in-process material**: A material fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way that is produced for, and used in, the preparation of a dietary ingredient or supplement prior to packaging as ready for sale.~~

~~**3.19 lot number**: A distinctive combination of letters, numbers, or symbols, or any combination thereof from which the complete history of the manufacture, processing, packaging, holding, and distribution of a batch or lot of a finished dietary ingredient, dietary supplement, or other material can be determined.~~

3.X lot: a batch, or a specific identified portion of a batch, that is uniform and that is intended to meet specifications for identity, purity, strength, and composition; or, in the case of a dietary supplement produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.

3.20 major food allergen: ~~In accordance with the FDA's Food Allergen Labeling and Consumer Protection Act of 2004,[3] and for the purposes of this standard, major food allergens are considered milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. Highly purified oils are exempt by law.~~ In accordance with the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021, and for the purposes of this standard, major food allergens are considered milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame. Highly purified oils are exempt by law."

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~~**3.25 pest**: An objectionable animal or insect, e.g., bird, rodent, insect, or larva.~~

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~~**3.30 quality control system**: A planned systematic procedure for taking all actions necessary to produce consistent, unadulterated dietary ingredients or dietary supplements.~~

~~**3.31 quality control unit**: A person or organizational element designated by a firm to be responsible for duties relating to quality control operations.~~

3.XX **reportable food**: an article other than an infant formula for which there is a reasonable probability that the use of or exposure to such article of food will cause serious adverse health consequences or death.

~~**3.32 representative sample**: A sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and is intended to ensure that the sample accurately portrays the material being sampled.~~

~~**3.33 rework**: Clean, unadulterated material that has been removed from processing for reasons other than unsanitary conditions, or that has been successfully reconditioned by reprocessing, and that is suitable for use in the manufacture of a dietary product.~~

3.34 specifications: The quality parameters to which the products or materials ~~shall~~ conform and that serve as a basis for quality evaluation.

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4 Labeling and literature requirements

Product labels shall declare the identity of dietary ingredient(s) or marker constituent(s) included in the product. The quantity of dietary ingredient claimed on the label shall correspond to the quantity of the dietary ingredient per serving; if the claimed nutrient is only a part of the source component, then the amount shall correspond to the claimed part of the component. Labels of products other than proprietary blends shall declare the quantity of each dietary ingredient or marker constituent, which shall be labeled by common name according to the Merck Index19 or in accordance with the appropriate regulatory agency guidance when available. Labels of products containing botanicals shall include the part of the plant from which the ingredients are derived. Common names of botanicals shall be in accordance with the most current versions of *Herbs of Commerce or the International Code of Botanical Nomenclature*.[15] ~~The amount of active or desired ingredient shall be listed in addition to the total amount of the ingredient. Product literature.~~

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