

NSF International Standard / American National Standard

NSF/ANSI 173 - 2022

Dietary Supplements





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NSF/ANSI 173 - 2022

NSF International Standard / American National Standard for Dietary Supplements –

Dietary Supplements

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Abbreviations

The following table is provided as a reference for unit abbreviations for common forms of measurement used within NSF documents.

| | second | S |
|----------------|-------------------------|-----|
| | minute | min |
| | hour | h |
| time | day | d |
| | week | wk |
| | month | mo |
| | year | yr |
| | inch | in |
| | foot | ft |
| length | yard | yd |
| | micrometer | μm |
| | nanometer | nm |
| | millimeter | mm |
| | centimeter | cm |
| | meter | m |
| | kilometer | km |
| | milliliter | mL |
| | liter | L |
| | liters per day | LPD |
| | liters per minute | LPM |
| l' | ounce | οz |
| liquid measure | pint | pt |
| | quart | qt |
| | gallon | gal |
| | gallons per minute | GPM |
| | gallons per day | GPD |
| | microgram | μg |
| | picogram | pg |
| | nanogram | ng |
| weight | milligram | mg |
| | centigram | cg |
| | gram | g |
| | kilogram | kg |
| | pounds | lb |
| | tons | t |
| concentration | parts per million | ppm |
| concentration | parts per billion | ppb |
| miscellaneous | colony forming units | CFU |

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Foreword²

The purpose of NSF/ANSI 173 is to serve as an evaluation tool for analyzing dietary supplements. Certification to this standard serves as a communication tool between manufacturers of ingredients and finished product, retailers, healthcare practitioners, and consumers. This standard provides test methods and evaluation criteria to allow for the determination that a dietary supplement contains the ingredients claimed on the label, either qualitatively or quantitatively, and that it does not contain specific undeclared contaminants. In some instances, validated laboratory methods are not yet available for analyzing certain ingredients. In such cases, new methods will be added to this standard as they become available.

NSF/ANSI 173 was developed with participation from the dietary supplements industry, public health regulators, and distributors of dietary supplements. Participation and technical guidance were provided by representatives of the American Herbal Products Association (APHA), the American Pharmaceutical Association (APA), the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), the National Institutes of Health (NIH), and the National Nutritional Foods Association (NNFA).

This edition of the standard contains the following revisions:

Issue 66

This revision adds language regarding probiotics in Sections 4.2, 5.1, and 5.2, and created new sections 6.2.4 and 8.7. It also added a definition for *probiotics* in Section 3 and updated a normative reference in Section 2.

Issue 91

This revision reorganizes the tables in Section 5 for clarity.

Issue 92

This revision removed Section 7.3.9: *Pseudomonas aeruginosa* due to the determination that the pathogen is not of significant public health concern as a food borne pathogen. This change brings the standard in line with other public health documents.

Issue 95

This revision removes reference to *Pseudomonas aeruginosa* in Section 5.3.3: *Microbiological contaminants* to reflect the change made in Issue 92.

Issue 97

This revision modifies the language in Sections 5.3 and 7.2 regarding pesticide evaluation to permit alternate means of evaluation.

Issue 98

This revision updates language in Section 4.1 regarding caffeine to that currently in use by the American Herbal Products Association (AHPA).

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Issue 99

This revision will update Section 7.3.7.1: Generic E. Coli.

Issue 101

The proposed revision amends Section 5.3.1.2 to specify methylmercury as well as total mercury levels.

Issue 102

This revision removes "shall" from informative notes, adds missing references, changes "must" to "shall" in normative sections, and moves a requirement that is currently in a note.

Issue 103

This revision removes and/or statements throughout the standard.

Issue 106

This revision updates Section 1.2 to clarify that both finished dietary supplement products and dietary ingredients may be evaluated under the scope of the standard.

Issue 108

This revision corrects language in Section 7.2.1. An inadvertent overlap in balloted language was caused by the same section being in two different ballots open at the same time.

This standard was developed by the NSF Joint Committee on Dietary Supplements using the consensus process described by the American National Standards Institute.

This standard and the accompanying text are intended for voluntary use by certifying organizations, regulatory agencies, and/or manufacturers as a basis of providing assurances that adequate health protection exists for covered products.

Suggestions for improvement of this standard are welcome. This standard is maintained on a continuous maintenance schedule and can be opened for comment at any time. Comments should be sent to: Chair, Joint Committee on Dietary Supplements at standards@nsf.org, or c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan 48113-0140, U.S.A.

NSF/ANSI Standard for Health Sciences –

Dietary Supplements

1 General

1.1 Purpose

This standard provides test methods and evaluation criteria for dietary supplement products to allow for the determination that the ingredients in the product are accurately identified, that the product contains the quantity of dietary ingredients and marker constituents declared on the product label, and that the product does not contain unacceptable quantities of contaminants.

This standard provides criteria for determining that good manufacturing practices (GMP) were followed in the production of dietary supplements.

1.2 Scope

This standard contains requirements for dietary supplements and dietary ingredients that contain one or more of the following: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.

Products and ingredients deemed a hazard to public health or safety by a regulatory agency having jurisdiction shall be excluded from the scope of this document. Conventional foods are excluded from the scope of this standard.

Manufacturers shall exercise due diligence to ensure compliance with all applicable regulatory requirements, but compliance with this standard in itself does not imply that all regulatory requirements have been met.

1.3 Formulation submission

The manufacturer shall submit, at a minimum, the following information for each product:

- complete formulation information, which includes the following:

— the composition of the formulation (in percent or parts by weight for each ingredient in the formulation including excipients);

- NOTE Ranges may be considered acceptable.
- the reaction process, if applicable;

— the component ID number (if applicable), chemical / material name, trade name and supplier(s) for each chemical present in the formulation;

- a list of known or suspected impurities associated with the finished product; and