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Foreword[2]

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 was provided by representatives of the American Herbal Products Association, the American Pharmaceutical Association, the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the National Institutes of Health, and the National Nutritional Foods Association.

This edition of the Standard (NSF/ANSI 173-2011) includes the following revisions:

Issue 28/29 – Methods/QC Update
Includes updates to: (1) 6, Test methods used by testing laboratories for identification and quantification of ingredients – raw materials and finished products; (2) 7.4, Test methods for chemical contaminants; (3) the quality assurance sections related to verification testing performed to evaluate compliance with the Standard; and (4) Tables 3 and 4 have been removed.

Issue 30 – Aristolochic Acid
Includes updates to: (1) 5.3.4, Natural toxins; (2) 7.4, Test methods for chemical contaminants; and (3) Table A1, Botanicals known or suspected to contain Aristolochic Acid.

Issue 36 – Lead
Updates the lead limit for finished products from 20 to 10 mg/d.

Issue 37 – Cadmium
Updates the cadmium limit for finished products from 6 to 4.1 mg/d.

Issue 38 – Normative References and Definition
Updates 2 and adds a definition for “qualified individual” in 3.

Issue 39 – Macroscopic Test Methods
Updates 6.1.1.1.

Issue 40 – 7.4 Test methods for chemical contaminants
Eliminates discrepancies with 7.4 language approved in the Issue 29 and 30 ballots; achieves consistency with language in paragraphs related to method selection and development; ensures that all language meets ANSI requirements.

Issue 41 – Mercury
Corrects the mercury limit for finished products to 0.002 mg/d.

Annex B – Reference information for contaminant level acceptance criteria has been updated.

[2] The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI’s requirements for an ANS. Therefore, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

NSF offers a certification program to this Standard. Products certified by NSF carry the NSF Mark, the leading mark in public health and safety certification around the world. The NSF Mark on a product gives consumers and retailers assurance that the product meets the requirements of the NSF Standard. For more information on the NSF certification program, please contact the General Manager of Dietary Supplements, P.O. Box 130140, Ann Arbor, Michigan 48113–0140 or at 734-769-8010.

Suggestions for improvement of this Standard are welcome. Comments should be sent to Chair, Dietary Supplements at standards@nsf.org or, c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan,48113-0140,USA.

NSF International Standard
for Dietary Supplements —

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 also provides criteria for determining that Good Manufacturing Practices were followed in the production of dietary supplements.

1.2 Scope

This Standard contains requirements for dietary supplements that contain one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. This Standard does not include products represented for use as conventional foods.

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.

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 shall be considered acceptable.

  - the reaction process, if applicable;
  - the raw material 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