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Foreword

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 contains the following revisions, which allow NSF International increased flexibility in selecting finished product claims for analysis based on the number of finished product claims and ingredients present on the product label.

Issue 78

This revision relocates Tables 8.1 through 8.4 from Section 8 Good manufacturing practices (GMP) to Section 5.3.3 Microbiological contaminants. By placing the requirements under Section 8, is it implied that we are going to hold manufactures to the same testing requirements for their finished products and dietary ingredients. The intent was to certify products to these limits and not hold manufacturers to specific contaminant levels.

Issue 79

This revision fixes an error in the published equation for the pesticides list, as well as adjusts the significant figures for six of the pesticides.

Issue 80

This revision removes duplicate text from Section 5.5, as the same text was added during a previous revision to Section 4.1, where it fits more appropriately. It also updates the US FDA Food Code.

Issue 83

This revision expands the content of this Standard, with respect to its references to known toxic constituents, by establishing a maximum allowable level (MAL) for pyrrolizidine alkaloids (PAs) in dietary supplements and ingredients.

Issue 86

This revision adds glyphosate to the current pesticides list in Annex D.

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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, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.
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 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 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 shall 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