

NSF/ANSI 173 – 2010

Dietary supplements

**NSF International Standard/
American National Standard**



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NSF International Standard/
American National Standard
for Dietary Supplements —

Dietary supplements

Standard Developer
NSF International

American National Standards Institute

Designated as an ANSI Standard
November 22, 2010

American National Standards Institute

Prepared by
The NSF Joint Committee on Dietary Supplements

Recommended for Adoption by
The NSF Council of Public Health Consultants

Adopted by
NSF International
January 2003

Revised July 2005
Revised August 2006
Revised July 2007
Revised April 2008
Revised September 2008
Revised April 2009
Revised November 2010

Published by

NSF International
PO Box 130140, Ann Arbor, Michigan 48113-0140, USA

For ordering copies or for making inquiries with regard to this Standard, please reference the designation "NSF/ANSI 173 – 2010."

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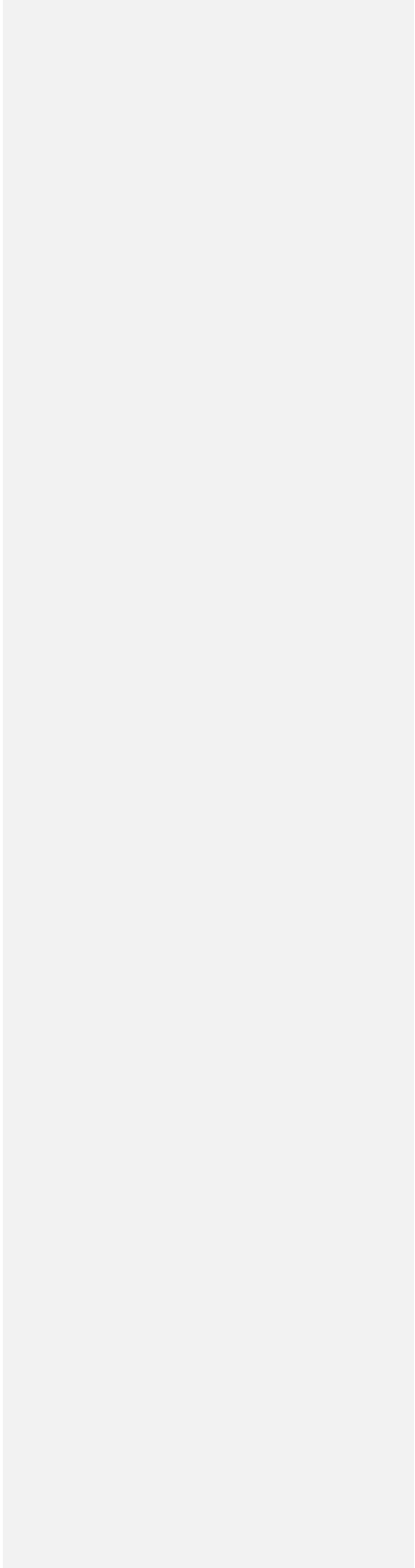
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Foreword²

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 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 173-2010) includes the following revisions:

Issue 31 - Diethylene glycol (DEG)

Sections 5.3.6.2 Contaminants in Glycerin and 7.5.2 Test methods for Glycerin have been added to the Standard.

Issue 33 - Section 7

Testing methodologies have been updated in Section 7.3 Test methods for microbiological contaminants.

Issue 34 – Dioxins

Acceptance levels for dioxins and dioxin-like PCBs have been updated in Section 5.3.6 Industrial Contaminants.

Issue 35 - Enteric Coated Tablets

Disintegration testing for delayed release/enteric coated capsules and tablets has been updated in Section 5.4 Disintegration.

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, c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan, 48113-0140, USA.

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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.

Compliance to this Standard does imply the product evaluated meets all applicable regulatory requirements.

This statement is intended to add clarification regarding the scope of this standard.

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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

- when available, an analytical method used to verify the claims listed on the label or certificate of analysis.

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.

21 CFR, Chapter 9, *Federal Food, Drug and Cosmetic Act* (FFDCA)³

40 CFR Part 141, *National Primary Drinking Water Regulations*³

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Ashwagandha Root*, April 2000⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Astragalus Root*, August 1999⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Bilberry fruit*, 2001⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Cohosh root*, 2002⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Haw Bark*, June 2000⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Chaste Tree Fruit*, 2001⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cramp Bark*, February 2000⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cranberry*, 2002⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Dang Gui Root*, 2003⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Echinacea purpurea Root*, 2004⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Ginkgo Leaf*, 2003⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Goldenseal*, 2001⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Hawthorn Berry*, June 1999⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Hawthorn Leaf with Flower*, February 1999⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Reishi Mushroom*, September 2000⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *St. John's Wort*, July 1997⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Schisandra Berry*, October 1999⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Valerian Root*, April 1999⁴

³ US Government Printing Office, Washington, D. C. 20402 <www.gpo.gov>.

⁴ American Herbal Pharmacopoeia (AHP), P. O. Box 66809, Scotts Valley, CA 95067 <www.herbal-ahp.org>.

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Willow Bark*, December 1999⁴

AHPA, *Herbs of Commerce*, 2nd Edition, 2000⁵

AOAC International/Food and Drug Administration, *Bacteriological Analytical Manual*, (BAM) 8th edition, 1998⁶

AOAC International, *Official Methods of Analysis*, 18th edition (2005)⁷

American Oil Chemists' Society, AOCS Official Method Cd 18-90, *p-Anisidine Value, Sampling and Analysis of Commercial Fats and Oils*, 1997⁸

British Herbal Medicine Association, (BHMA), *British Herbal Pharmacopoeia*, 1996⁹

Compliance Services International, *Analytical Method for the Determination of Quintozene and Its Degradates and Impurities in Ground Dried Ginseng Root by Gas Chromatography* Laboratory validation of analytical method number CSI-023-01, 1999¹⁰

Dietary Supplement Health and Education Act of 1994 (DSHEA), Public Law 103-417⁶

GOED, *Voluntary Monograph*¹¹

Health Canada, *Fish Oil Monograph*¹²

INA, *Allicin by High-Performance Liquid Chromatography*¹³

INA, *Black Cohosh Assay by ELSD*¹³

INA, *Catechins and Gallic Acid in Green Tea by HPLC*¹³

INA, *Fatty Acid Content in Saw Palmetto by Gas Chromatography*¹³

INA, *Ginkgo Flavonol Glycoside Assay by HPLC*¹³

INA, *Ginkgoterpenoid Assay by HPLC*¹³

INA, *Kavalactone Assay by HPLC*¹³

⁵ American Herbal Products Association (AHPA), 8630 Fenton St., Suite 918, Silver Spring, MD 20910 <www.ahpa.org>.

⁶ US Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002 <www.fda.gov>.

⁷ AOAC International, 481 N. Frederick Avenue, Suite 500, Gaithersburg, MD 20877 <www.aoac.org>.

⁸ AOCS, 2710 S. Boulder, Urbana, IL 61802 <www.aocs.org>.

⁹ British Herbal Medicine Association, P.O. Box 583, Exeter EX1 96X UK <www.bhma.info>.

¹⁰ Compliance Services International, 7501 Bridgeport Way West, Lakewood, WA 98499 <www.complianceservices.com>.

¹¹ Global Organization for EPA and DHA Omega-3s (GOED), 1075 Hollywood Ave., Salt Lake City, UT 84105 <www.goedomega3.com>.

¹² Health Canada, Address Locator 0900C2, Ottawa, Ontario K1A 0K9 Canada <www.hc.sc.gc.ca>.

¹³ Institute for Nutraceutical Advancement (INA), c/o NSF International, 789 N. Dixboro Road, Ann Arbor, MI 48105 <<http://www.nsf.org/business/ina/index.asp?program=INA>>.

INA, *Phenolics in Echinacea by HPLC*¹³

INA, *St. John's Wort Assay by HPLC*¹³

INA, *Sterols Content in Saw Palmetto by Gas Chromatography*¹³

International Code for Botanical Nomenclature (St. Louis Code), 2000¹⁴

NTIS/IEC 17025: 1999 *General requirements for the competence of testing and calibration laboratories*¹⁵

The Merck Index: An Encyclopedia of Chemicals, Drugs and Biologicals (Annual)¹⁶

*NSF International White Book: Listing of Proprietary Substances and Nonfood Compounds*¹⁷

USEPA *Methods for the Determination of Metals in Environmental Samples – Supplement, 1 – EPA/600/R-94-111 – May 1994*¹⁸

USEPA *Microwave Assisted Acid Digestion of Sediments, Sludges, Soils and Oils*, EPA Method 3510 – September 1994¹⁸

USFDA, *Pesticide Analytical Manual* (PAM) Volume I. Multiresidue Methods, 3rd Edition, 1994⁶

USFDA, *Pesticide Analytical Manual* (PAM) Volume I. Updates. 2003⁶

USFDA, *Pesticide Analytical Manual* (PAM) Volume II. Methods for Residues of Individual Pesticides – 1991⁶

USFDA, *Food Code 2001 Recommendations of the United States Public Health Service Food and Drug Administration*⁶

USFDA, *A Multiresidue Pesticide Monitoring Procedure for the Determination of 112 Halogenated Pesticides Using Gas Chromatography with Mass Selective Detection and Selected ion Monitoring*. Laboratory Information Bulletin, 4304⁶

USFDA, *Determination of Aristolochic Acid in Traditional Chinese Medicines and Dietary Supplements*⁶

USFDA, *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, H.R.3448.ENR⁶

USP, *Dietary Supplements Compendium (DSC)*¹⁹

USP, *Glycerin Monograph*¹⁹

USP, *United States Pharmacopeia – National Formulary (USP-NF)*¹⁹

¹⁴ Koeltz Scientific Books, P.O. Box 1360, D-61453, Koenigstein, Germany <www.koeltz.com>.

¹⁵ National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 <www.ntis.gov>.

¹⁶ Merck & Company, One Merck Drive, Whitehouse Station, NJ 08889 <www.merck.com>.

¹⁷ NSF International, 789 N. Dixboro Road, Ann Arbor, MI 48105 <www.nsf.org>.

¹⁸ USEPA, Washington, DC 20460 <www.epa.gov>.

¹⁹ United States Pharmacopeia (USP), 12601 Twinbrook Parkway, Rockville, Maryland 20852 <www.usp.org>.

World Health Organization, *WHO Guidelines for Drinking-Water Quality*²⁰

World Health Organization, *WHO Monographs on Selected Medicinal Plants*, Volume 1, 2 and 3²⁰

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.

3.2 adulteration: As defined by the Federal Food and Cosmetic Act, §402, adulterated food is defined in Title 21, USC §342.

3.3 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, and/or is produced according to a single manufacturing order during the same cycle of manufacture.

3.4 botanical ingredient (botanical): An ingredient consisting of, or derived from a plant or microorganism (e.g. fungi or cyanobacteria).

3.4.1 botanical ingredient - extract: The complex, multicomponent mixture obtained after using a solvent to dissolve components of the biomass. Extracts may be in dry, liquid, or semi-solid form. Excipients may be added to extracts to adjust the concentration, enhance stability, limit microbial growth, and to improve drying, flow, or other manufacturing characteristics. Extracts are not the same as expressed juices, pure chemicals isolated from an herb, or synthetically modified plant constituents.

3.4.2 botanical ingredient - non-extract: Crude botanical material (whole, cut or powdered herb).

3.5 chewable: Intended to be reduced through mastication.

3.6 dietary ingredient: An ingredient intended for use or used in a dietary supplement that is 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, or extract.

3.6.1 Class I (dietary ingredient): An added nutrient.

3.6.2 Class II (dietary ingredient): A naturally occurring (indigenous) nutrient.

3.7 dietary supplement: A product (other than tobacco) that:

- is intended to supplement the diet and bears or contains 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;
- is intended for ingestion in pill, capsule, tablet, powder, or liquid form;
- is not represented for use as a conventional food or as the sole item of a meal or diet;
- is labeled as a “dietary supplement” or has the word “dietary” deleted and replaced by the name of the dietary ingredient/s in the product (e.g., calcium supplement) or an appropriately

²⁰ World Health Organization, 1211 Geneva 27, Switzerland <www.who.int>.

descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins); and

– includes an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351, of the Public Health Service Act (42 U.S.C. 262), and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary (U.S. Department of Health and Human Services, USFDAP) has issued a regulation, after notice, and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f), and does not include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) or an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful.

3.8 finished product: A product requiring no further processing prior to sale to the consumer.

3.9 Good Manufacturing Practices (GMP): A system of procedures and documentation, written or analytical, to ensure that the product has the identity, strength, composition, quality, and purity that it is represented to possess.

3.10 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.

3.11 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.

3.12 manufacture or manufacturing: All operations associated with the production of dietary supplements, including packaging, labeling, testing, and quality control of a dietary ingredient or dietary supplement.

3.13 major food allergen: In accordance with the USFDA's Food Allergen Labeling and Consumer Protection Act of 2004⁶ 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.

3.14 marker constituent: A compound present in a botanical that is characteristic of the botanical and used for technical purposes, and that allows for the quantification of the ingredients incorporated into the product, e.g., identification of the botanical or process control.

3.15 measure of uncertainty: An estimation of the variability in an analytical result that can be reasonably expected based on the methodology employed. The estimate is based in part on parameters such as reproducibility, reference materials, and sample effects including matrix spike recoveries and scientific experience.

3.16 plant: A building or facility, or parts thereof, used for or in connection with the manufacturing, packaging, labeling, and/or holding of a dietary product.

3.17 pest: An objectionable animal or insect, e.g., bird, rodent, insect, or larva.

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

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

3.20 raw material: 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.

3.21 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.

3.22 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.

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

4 Labeling and literature requirements

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Product labels shall declare the identity of dietary ingredient(s) and/or marker constituent(s) included in the product. Labels of products other than proprietary blends shall declare the quantity of each dietary ingredient and/or marker constituent, which shall be labeled by common name according to the Merck Index 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 *Herbs of Commerce* or the International Code of Botanical Nomenclature. The amount of active or desired ingredient shall be listed in addition to the total amount of the ingredient. Product literature may also include this information. ~~Labels shall comply with appropriate regulatory requirements.~~

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~~[This implies that the label meets all FTC and FDA requirements which is not a realistic expectation. In addition, unforeseen liability exists for NSF if a product is certified by NSF that may not meet the interpretations of the FDA or FTC].~~

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5 Product requirements – verified by testing laboratories

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~~All dietary supplements shall meet all applicable regulatory requirements.~~

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~~[This implies that the product meets all FTC and FDA requirements which may not be a realistic expectation. In addition, unforeseen liability exists for NSF if a product is certified by NSF that may not meet the interpretations of the FDA or FTC].~~

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~~The removal of "verified by testing laboratories" was removed because there are aspects of the product requirements that are verified by auditing and/or the testing that is performed by the client.~~

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5.1 Identity

5.1.1 Raw materials

The identity of the raw material shall be verified in accordance with 6.1 and/or 8-using the test method(s) appropriate for establishing identity based on the manufacturer's claims.

5.1.2 Finished product

~~All Manufacturers are responsible for ensuring~~ finished products shall contain each of the dietary ingredients and/or marker constituents declared on the label ~~when tested in accordance with 6.1.~~
The source of each ingredient shall be verified as listed on the label.

This change is being made because of the requirements that manufacturers of Dietary Supplements meet GMP requirements. When the Standard was originally written, these requirements were not in place. This is accomplished through compliance with Good Manufacturing Practices as indicated in section 8. Identity testing is a GMP requirement for each lot of raw material prior to incorporation into a finished product. Proof that adequate identity testing is in place shall be provided upon request to ensure compliance with the requirements herein.

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5.2 Quantity

5.2.1 Raw materials

The quantity of marker constituents shall be verified in accordance with 6.2 when declared on the certificate of analysis. Other declarations made in the certificate of analysis and/or the Raw Material Specification shall be verified in accordance with 6.2, 7.4, and/or 8.

5.2.2 Finished products

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“Finished product claims will be reviewed to determine a set of verification tests to confirm quantity of dietary ingredients, marker constituents and/or nutritional declarations as declared on the label in accordance with 6.2 and/or 8.”

The product shall contain at least 100% (minus the measure of uncertainty) of the quantity of each Class I dietary ingredient and/or marker constituent that is subject to verification testing.

The product shall contain at least 80% (minus the measure of uncertainty) of the quantity of each Class II dietary ingredient and/or marker constituent that is subject to verification testing.

~~The quantity of dietary ingredients and/or marker constituents declared on the label shall be verified in accordance with 6.2 and/or 8. Nutritional declarations shall be verified in accordance with 6.2 only when the quantity claimed is greater than 2% of the daily recommended value (DRV) (based on the reference caloric intake of 2,000 calories) as detailed in the following table (ref. is 21 CFR 101.9).~~

Table 1—Quantity of dietary ingredients required for testing

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| Component | DRV (units) | Level requiring testing |
|--------------------------|-------------|-------------------------|
| cholesterol | 300 mg | > 6 g/serving |
| Fat | 65 g | > 1.3 g/serving |
| fiber | 25 g | > 0.5 g/serving |
| potassium | 3,500 mg | > 70 mg/serving |
| protein | 50 g | > 1 g/serving |
| saturated fatty acids | 20 g | > 0.4 g/serving |
| sodium | 2,400 mg | > 48 mg/serving |
| total carbohydrate-sugar | 300 g | > 6 g/serving |

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~~The product shall contain at least 100% (minus the measure of uncertainty) of the quantity of each Class I dietary ingredient and/or marker constituent declared on the label.~~

~~The product shall contain at least 80% (minus the measure of uncertainty) of the quantity of each Class II dietary ingredient and/or marker constituent declared on the label. The product shall not contain quantities in excess of those permitted by GMP (manufacturer’s specifications):~~

This change is due to the recognition that testing for the substances in this table when they are present at ONLY 2% of the DRV may not be meaningful. In addition, testing these substances at that low of level can require significant resources due to difficulties with matrix effects which exceed the value of the test. In addition, This change is also being made because of the requirements that manufacturers of Dietary Supplements meet GMP requirements. When the Standard was originally written, these requirements were not in place. This is accomplished through compliance with Good Manufacturing Practices as indicated in section 8. Identity testing is a GMP requirement for each lot of raw material prior to incorporation into a finished product. Proof that adequate identity testing is in place shall be provided upon request to ensure compliance with the requirements herein.

5.3 Contaminants

5.3.1 Metals

5.3.1.1 Raw materials

Raw materials shall not contain undeclared metals in amounts greater than the following:

- arsenic content shall not exceed 5 parts per million (ppm);
- cadmium content shall not exceed 0.3 ppm;
- chromium (VI) content shall not exceed 2 ppm;
- lead content shall not exceed 10 ppm; and
- mercury content shall not exceed 0.2 ppm.

5.3.1.2 Finished products

Finished products shall not contain undeclared metals at rates of intake greater than the following:

- inorganic arsenic content shall not exceed 0.01 milligrams per daily dose (mg/d);
- cadmium content shall not exceed 0.006 mg/d;
- chromium (VI) content shall not exceed 0.02 mg/d;
- lead content shall not exceed 0.02 mg/d; and
- mercury content shall not exceed 0.02 mg/d.

5.3.2 Pesticides

Unless a manufacturer has controls in place to screen for pesticides or use certified organic ingredients as demonstrated in the GMP audit, a broad pesticide screen shall be performed to confirm compliance with USFDA and USEPA regulated limits and the absence of banned pesticides in botanical products.

The purpose of this deviation is to assure all botanical products are tested for banned pesticides.

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Raw materials and finished products containing *Panax ginseng* or *Panax quinquefolius* shall not contain pesticides listed in 7.2.2 (limit of detection is less than 10 parts per billion (ppb)).

5.3.3 Microbiological contaminants

Raw materials shall not contain aflatoxins at levels greater than 20 ppb and shall not contain microorganisms in quantities greater than permitted in tables 5A and 5B.

Finished products shall not contain aflatoxins at levels greater than 20 ppb and shall not contain microorganisms in quantities greater than permitted in tables 6A and 6B.

Finished products in a liquid form with an alcohol content less than or equal to 50% shall not contain *Pseudomonas aeruginosa*.

Finished products with an alcohol content greater than or equal to 50% are exempt from microbial testing.

5.3.4 Natural toxins

Botanicals listed in Annex A shall not contain aristolochic acid (limit of detection is 0.5 µg/gm).

5.3.5 Known adulterants

Products shall be evaluated to ensure that they do not contain known adulterants including, but not limited to, the following:

- *Eleutherococcus senticosus* shall not contain *Periploca sepium* root.
- *Plantago lanceolata* shall not contain *Digitalis lanata* leaf.
- *Scutellaria lateriflora* shall not contain *Teucrium chamaedrys*.
- *Stephania tetrandia* shall not contain *Aristolochia fangchi*.

5.3.6 Industrial Contaminants

5.3.6.1 Contaminants in Fish Oil

For ingredients and products containing natural fish oil, manufacturers shall have controls in place to screen for polychlorinated biphenyls (PCBs), polychlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like PCBs in the oil ingredient.

The content of dioxins and furans expressed as the sum of PCDDs and PCDFs shall not exceed 2 pg WHO-TEQ per gram of oil and dioxin-like PCBs shall not exceed 3 pg WHO-TEQ per gram of oil.²¹ The dioxin-like PCBs shall include the IUPAC congeners 77, 81, 105, 114, 118, 123, 126, 156, 157, 167, 169 and 189.

In the event that the per gram limits for dioxins and furans or dioxin-like PCBs are exceeded, a daily dose based limit will be applied. The daily dose of the sum of the dioxins/furans and the dioxin-like PCBs shall not exceed 20 pg.¹²

NOTE – The acceptable daily dose of 20 pg/day is based on the Health Canada Fish Oil Monograph limit of 2 pg/kg b.w./day. Due to the targeted marketing of fish oils to children, a body weight of a child (10 kg) was used to derive the daily dose of 20 pg/day for dioxin/furan (PCDD and PCDF).

Total PCBs shall not exceed 0.09 mg/kg of oil (w/w). Total PCBs shall, at a minimum, include IUPAC congeners 28, 52, 101, 118, 138, 153, and 180.

5.3.6.2 Contaminants in Glycerin

For ingredients and products containing glycerin, manufacturers shall have good manufacturing controls in place to verify that any specific lot of glycerin used in the manufacture or preparation of products is tested for diethylene glycol (DEG).

Diethylene glycol in glycerin raw materials shall not exceed 0.1% as stated in the USP Glycerin monograph.¹⁹

5.3.7 Other product claims

Claims that a product is free of a particular contaminant or substance shall be verified in accordance with 7.4 and/or 8.

5.4 Disintegration

²¹ Global Organization for EPA and DHA Omega-3s, GOED Voluntary Monograph Omega-3, July 2006 Dioxin limits include the sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and are expressed in World Health Organization (WHO) toxic equivalents using WHO-toxic equivalent factors (TEFs). This means that analytical results relating to 17 individual dioxin congeners of toxicological concern are expressed in a single quantifiable unit: TCDD toxic equivalent concentration or TEQ.

5.4.1. Uncoated, film-coated, plain-coated, and hard and soft gelatin capsules

Supplements shall be verified as meeting the requirements for disintegration when tested using the equipment described in the currently promulgated version of the United States Pharmacopeia (USP) and in the USP monograph applicable to the product being evaluated. For products where no USP monograph applies, testing will be performed using deionized water as the immersion fluid for a time period of 60 min.

5.4.2. Delayed release (enteric coated tablets)

Supplements which are claimed to be “delayed release” or “enteric coated” shall be verified as meeting the disintegration requirements for delayed release (enteric coated tablets) using the method described in the currently promulgated version of the United States Pharmacopeia (USP). The method employs simulated gastric fluid for one hour, followed by simulated intestinal fluid for a time period no greater than 8 h or for the time specified in the USP monograph if applicable to the product being evaluated. The tablets shall not disintegrate within the first hour of immersion.

5.4.3 Timed or slow release

Supplements which claim “timed release” or “slow release” shall be tested for disintegration using the equipment described in the currently promulgated version of the United States Pharmacopeia (USP). Testing will be performed using 0.1 M hydrochloric acid as the immersion fluid for a time period no greater than 8 h or for the time period indicated on the product label. The tablets shall not disintegrate within the first hour of immersion.

5.4.4 Other products

Chewables, powders, and liquids are exempt from disintegration testing requirements.

5.5 Oils

Supplements containing oils at greater than 2% by weight of the formulation shall demonstrate non-rancidity of the ingredients by having a peroxide value (PV) less than 10 milliequivalents/Kg oil, a p-anisidine value (p-AV) less than 20, and a total oxidation (Totox) number (p-AV + 2PV) less than 26.

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

6.1 Identification test methods

6.1.1 Botanicals

6.1.1.1 Macroscopic test methods

The identity of products shall be evaluated by an appropriate qualified individual based on the information contained in the monographs listed in table 3.

6.1.1.2 Microscopic test methods

The identity of products shall be evaluated by an appropriate qualified individual based on the information contained in the monographs listed in table 3.

6.1.1.3 Chemical test methods

The identity of dietary ingredients shall be evaluated in accordance with the methods in table 3. If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline⁷ as a minimum, which includes an evaluation of specificity and reproducibility. More rigorous validation could follow according to the guidelines of ICH²², USFDA⁶, GLP⁶, CEN²³, and/or AOAC⁷, as appropriate.

6.1.2 Vitamins

The identity of vitamins shall be evaluated in accordance with the methods listed in the currently promulgated version of the United States Pharmacopeia (USP). If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline⁷ as a minimum, which includes an evaluation of specificity and reproducibility. More rigorous validation could follow according to the guidelines of ICH²², USFDA⁶, GLP⁶, CEN²³, and/or AOAC⁷, as appropriate.

6.1.3 Minerals

The identity of minerals shall be evaluated in accordance with the methods listed in the currently promulgated version of the United States Pharmacopeia (USP). If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline⁷ as a minimum, which includes an evaluation of specificity and reproducibility. More rigorous validation could follow according to the guidelines of ICH²², USFDA⁶, GLP⁶, CEN²³, and/or AOAC⁷, as appropriate.

6.1.4 Other dietary supplement ingredients

~~An effort shall be made to seek out the most appropriate method to~~ **The most appropriate method available would be selected to** confirm claims for the product under evaluation, ~~t.~~ The source of these methods may include AOAC International, USP, AHP, European, German, Japanese monographs, INA, etc. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline⁷ as a minimum, which includes an evaluation of specificity and reproducibility. More rigorous validation could follow according to the guidelines of ICH²², USFDA⁶, GLP⁶, CEN²³, and/or AOAC⁷, as appropriate.

The purpose of this change is to add transparency regarding the limits of the available methodology regarding the testing of dietary supplements. The language that states "an effort shall be made" presents an onerous barrier to completing the analysis and testing of these products. The matrixes are variable and complex and many times completing the tests are not achievable.

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6.1.5 Quality assurance for identification test methods

Identification test methods shall be performed using certified reference standards or materials when available. These shall include vouchered specimens, certified reference materials, and/or single chemicals with established identity. To the extent to which it is feasible, the reference standard or material shall be prepared in the same manner as the sample being evaluated.

6.2 Quantification test methods

²² ICH Secretariat, c/o IFPMA, 15, chemin Louis-Dumant, P.O. Box 195, 1211 Geneva 20, Switzerland <www.ich.org>.

²³ European Committee for Standardization (CEN), Avenue Marnix 17, B-1000, Brussels <www.cen.eu>.

6.2.1 Botanicals

If declared on the label, the identity of marker constituents shall be evaluated in accordance with the methods in table 4. If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline⁷ as a minimum, which includes an evaluation of specificity, linearity, reproducibility, accuracy, spike recovery, and method detection limit (if applicable). More rigorous validation could follow according to the guidelines of ICH²², USFDA⁶, GLP⁶, CEN²³, and/or AOAC⁷, as appropriate.

6.2.2 Vitamins

The quantity of vitamins shall be evaluated in accordance with the methods listed in the USP-NF. If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline⁷ as a minimum, which includes an evaluation of specificity, linearity, reproducibility, accuracy, spike recovery, and method detection limit (if applicable). More rigorous validation could follow according to the guidelines of ICH²², USFDA⁶, GLP⁶, CEN²³, and/or AOAC⁷, as appropriate.

6.2.3 Minerals

The quantity of minerals shall be evaluated in accordance with the methods listed in the United States Pharmacopeia (USP). If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline⁷ as a minimum, which includes an evaluation of specificity, linearity, reproducibility, accuracy, spike recovery, and method detection limit (if applicable). More rigorous validation could follow according to the guidelines of ICH²², USFDA⁶, GLP⁶, CEN²³, and/or AOAC⁷, as appropriate.

6.2.4 Other dietary supplement ingredients

~~An effort shall be made to seek out the most appropriate method. The most appropriate method available would be selected~~ to confirm claims for the product under evaluation. The source of these methods may include AOAC International, USP, AHP, European, German, Japanese monographs, INA, etc. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline⁷ as a minimum, which includes an evaluation of specificity, linearity, reproducibility, accuracy, spike recovery, and method detection limit (if applicable). More rigorous validation could follow according to the guidelines of ICH²², USFDA⁶, GLP⁶, CEN²³, and/or AOAC⁷, as appropriate.

The purpose of this change is to add transparency regarding the limits of the available methodology regarding the testing of dietary supplements. The language that states "an effort shall be made" presents an onerous barrier to completing the analysis and testing of these products. The matrixes are variable and complex and many times completing the tests are not achievable.

6.2.5 Quality assurance for quantitative test methods

6.2.5.1 Calibration

Quantification test methods shall be performed using certified reference standards as calibration standards. The standards are typically purchased as single chemicals with greater than 95% purity. If a

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high-purity standard is not available, a lower-purity material shall be used if there is a means by which the actual purity can be measured (e.g., UV absorbance).

6.2.5.1.1 Multi-level calibration curves

Multi-level calibration curves shall be prepared with a minimum of three concentration levels such that any sample preparations under evaluation would be bracketed by a calibration standard. Curves shall give a correlation coefficient of 0.995 or higher.

6.2.5.1.2 Single-level calibration curves

If a single level calibration is employed, the standard shall be run in triplicate and the relative standard deviation between these runs shall not exceed 2%. The detector response of the prepared sample shall be within 90-110% of that of the standard.

6.2.5.1.3 Blanks

A method/reagent blank shall be included in each analytical run.

6.2.5.1.4 Reproducibility/accuracy

All unfamiliar matrices shall be prepared in triplicate.

Whenever possible, two additional preparations shall be spiked with the reference standard(s) to assess recovery/accuracy. The reproducibility between the two spiked samples as measured by percent relative difference shall be no greater than 20%.

NOTE – When spiking with the reference standard is price prohibitive, a control sample with a known result shall be tested as part of the analysis run; this shall include a certified reference material or a sample that has been analyzed in the past.

6.2.5.1.5 Continuing Calibration Verification (CCV)

Continuing Calibration Verification (CCV) standards shall be run after every 10 sample preparations and/or at the end of the run. The recovery for the CCV shall be within the uncertainty of the method for the data to be acceptable. CCV standards, which are run to confirm an existing calibration, must show recovery of 90-110%. If the result falls outside this range, a new calibration shall be run.

7 Test methods used by testing laboratories for detection of contaminants – raw materials and finished products

7.1 Test methods for metals

The presence of arsenic, cadmium, chromium (total) (see following note), lead, and mercury (elemental) shall be measured in accordance with the following methods:

- sample preparation method: Samples shall be prepared by microwave-assisted acid digestion using a closed cell unit equipped with temperature monitoring. The temperature program and the selection of reagents shall be modified or optimized as appropriate for the product being evaluated; and
- analytical method: USEPA 200.7 *Metals: Inductively Coupled Plasma-Atomic Emission Spectrophotometric Method for Trace Element Analysis of Water and Wastes*. Alternate methodologies, such as graphite furnace atomic emission spectrophotometry, ICP-MS, and flow injection analysis may be used for specific samples at the discretion of the analyst.

NOTE – If the chromium (total) result exceeds the pass/fail criteria (5.3.1), levels of Cr (VI) will be determined using a liquid chromatography method based on EPA Method 218.6.¹⁸ Modifications to the sample preparation and extraction procedures will be employed based on the dietary supplement product or ingredient matrix.

7.2 Pesticides

7.2.1 Multi-residue method

The multi-residue method contained in the USFDA's Pesticide Analytical Manual (PAM I) shall be used to evaluate botanical products unless manufacturers have controls in place to screen for pesticides or use certified organic ingredients as demonstrated in the GMP audit.

7.2.2 Test methods for pesticides in *Panax ginseng* and *Panax quinquefolius*

Products containing *Panax ginseng* or *Panax quinquefolius* shall be evaluated based on the FDA Pesticide Monitoring Procedure using Gas Chromatography with Mass Selective Detection and Selective Ion Monitoring method or the "Analytical Method for the Determination of Quintozone and Its Degradates and Impurities in Ground Dried Ginseng Root by Gas Chromatography" as validated by the Council for Responsible Nutrition/ American Herbal Products Association Joint Task Force, December 14, 2000. The testing determines the presence of the following pesticides:

Table 2 – CAS numbers for pesticides present in *Panax ginseng* and *Panax quinquefolius*

| Analyte | CAS # |
|--------------------------------------|---------------------|
| alpha-benzene hexachloride | (CAS # 319-84-6) |
| beta-benzene hexachloride | (CAS # 319-85-7) |
| delta-benzene hexachloride | (CAS # 319-86-8) |
| difenoconazole | (CAS # 119446-68-3) |
| hexachlorobenzene | (CAS # 118-74-1) |
| Lindane (gamma-benzene hexachloride) | (CAS # 58-89-9) |
| pentachloroaniline | (CAS # 527-20-8) |
| pentachlorobenzene | (CAS # 608-93-5) |
| pentachlorothioanisole | (CAS # 1825-19-0) |
| quintozone (pentachloronitrobenzene) | (CAS # 82-68-8) |
| Technazene | (CAS # 117-18-0) |
| tetrachloroaniline | (CAS # 3481-20-7) |

7.3 Test methods for microbiological contaminants

7.3.1 Reference methods

Testing shall be performed based on the currently promulgated version of the United States Pharmacopeia (USP). With the exception of *Pseudomonas*, testing methods shall adhere to those described in USP <2021> Microbial Enumeration Tests – Nutritional and Dietary Supplements and USP <2022> Microbiological Procedures for Absence of Specified Microorganisms – Nutritional and Dietary Supplements. For *Pseudomonas*, testing methods shall adhere to those described in USP <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.

NOTE – Methods that have been validated using established guidelines, such as those described by AOAC and USP, and have been demonstrated to yield equivalent or better results compared to the aforementioned USP methodologies may be substituted.

7.3.2 Preparatory Testing

Preparatory testing, as specified in the currently promulgated version of the United States Pharmacopeia (USP) shall be performed on all products. Certain products may themselves inhibit the multiplication of microorganisms that might be present, thus interfering with quantitative and qualitative microbiological assays detailed in section 7.3. Products shall be inoculated with the challenge microorganisms specified in USP <2021> and USP <2022>. For the quantitative assays, at least a 70% bioburden recovery compared to a control medium must be demonstrated. For the qualitative assays, the challenge organism must be recovered on the applicable selective media. If a product fails to meet the recovery limit, a suitable neutralizer (e.g. soy lecithin, 0.5%; or polysorbate 20, 4.0%) shall be added to the culture medium to neutralize inhibitory substances.

NOTE – In lieu of performing preparatory testing, a suitable neutralizer may be automatically added to the product and testing for the individual indicator organisms and pathogens may proceed as described in the following sections.

7.3.3 Total Aerobic Microbial Counts

Per the United States Pharmacopeia (USP), the Membrane Filtration Method or Plate-Count Method shall be used for products that are freely soluble. Moderately soluble and translucent products shall be processed via the Plate-Count Method. The Multiple-Tube Method shall be used for all other products. The media, diluent and incubation conditions specified by the USP shall be used.

7.3.4 Total Combined Molds and Yeasts Count

Per the United States Pharmacopeia (USP), the Membrane Filtration Method or Plate-Count Method shall be used for products that are freely soluble. Moderately soluble and translucent products shall be processed via the Plate-Count Method. The Multiple-Tube Method shall be used for all other products. The media, reagents and incubation conditions specified by the USP shall be used.

7.3.5 Enterobacteriaceae

Per the United States Pharmacopeia (USP), the sample shall be dissolved or suspended in Phosphate buffer or Fluid soybean casein digest medium and diluted to 100 mL with Fluid soybean casein digest medium. The suspension shall be pre-incubated and subsequently processed using the media, reagents and incubation conditions stated by USP.

7.3.6 *Salmonella* spp.

Testing shall be performed based on the USP Test for the Absence of *Salmonella* spp. (USP <2022>).

7.3.7 *Escherichia coli*

7.3.7.1 Generic *Escherichia coli*

For finished products, testing shall be performed based on the qualitative USP Test for the Absence of *Escherichia coli* (USP <2022>).

7.3.7.2 Pathogenic *Escherichia coli*

If the presence of *E. coli* is confirmed, then testing shall be performed based the US FDA's Bacteriological Analytical Manual (BAM, Chapter 4A) to determine whether the product contains pathogenic *Escherichia coli*, including but not limited to 0157:H7.

7.3.8 *Staphylococcus aureus*

Testing shall be performed based on the USP Test for Absence of *S. aureus* (USP <2022>).

7.3.9 *Pseudomonas aeruginosa*

For semisolid or liquid products containing less than 25% alcohol v/v, testing shall be performed based on the USP <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.

7.3.10 Aflatoxins

Testing shall be performed based on the methods described in Chapter 49, Natural Toxins, pp 49-1 to 49-49 of the AOAC *Official Methods of Analysis*.

7.4 Test methods for chemical contaminants

Testing shall be performed based on USFDA's Method for Determination of Aristolochic Acid in Traditional Chinese Medicines and Dietary Supplements.

The most appropriate method shall be used to confirm claims for the product under evaluation. The source of these methods may include AOAC International, USP, EPA, FDA, AHP, European, German, Japanese monographs, INA, industry standards, etc. The use of any new method shall require that a validation be performed which includes an evaluation of specificity, linearity, reproducibility, spike recovery, and method detection limit. More rigorous validation could follow according to the guidelines of ICH²², USFDA⁶, GLP⁶, CEN²³, and/or AOAC⁷, as appropriate.

Unless a manufacturer has controls in place to assess the rancidity of oil ingredients, the following testing shall be performed. The Peroxide Value of the oil shall be tested according to AOAC Method 965.33 (which is equivalent to AOCS 8-53). The p-Anisidine Value of the oil shall be tested by AOCS Cd 18-90.⁷ The Totox Number shall be calculated as the sum of the p-Anisidine Value and two times the Peroxide Value.

7.5 Test methods for industrial contaminants

7.5.1 Test methods for Fish Oil

Testing of fish oil samples for PCBs and dioxin-like PCBs shall be performed utilizing a high resolution gas chromatography-high resolution mass spectrometry (HRGC-HRMS) method, EPA Method 1668, Revision A: Chlorinated Biphenyl Congeners in Water, Soil Sediment and Tissue by HRGC-HRMS. Testing of fish oil samples for dioxins and furans shall be performed utilizing a high resolution gas chromatography-high resolution mass spectrometry (HRGC-HRMS) method, EPA Method 1613, Revision B: Tetra- through Octa-Chlorinated Dioxins and Furans by Isotope Dilution HRGC-HRMS. The preparation steps for these methods are applicable to water, soil, fish tissue and other environmental samples. For the analysis of fish oil, for both methods, the preparation of the sample involves dissolution in hexane followed by column based sample clean-up steps prior to the described instrumental analysis.

Manufacturers shall meet this testing requirement by one of the following routes:

- through the use of compliant ingredients as demonstrated by third party testing; or
- performing testing utilizing a laboratory accredited for PCBs, Dioxin and Furans under ISO 17025 and providing the sample results, data, and quality control results, for review to support compliance

7.5.2 Test methods for Glycerin

Testing for diethylene glycol in the glycerin raw material shall be performed utilizing identity tests, including the gas chromatographic limit test for DEG, which appear in the USP Glycerin monograph or other method that is scientifically valid and demonstrated as fit for purpose.

Manufacturers shall meet this testing requirement by providing testing documentation which can be reviewed and clearly shows the association of the test results with the lot of finished product material being certified.

Manufacturers shall meet this test requirement by either providing their own data, providing data from their qualified supplier(s) or acquiring third party test data.

8 Good Manufacturing Practices

The manufacture and handling of dietary supplements and dietary supplement ingredients shall meet all applicable regulatory requirements set forth by 21 CFR § 111, with the following additional requirements.

8.1 Written recall procedures

Procedures shall be established and followed that define the recall of a product(s) should it become necessary.

Written procedures shall be established and followed.

8.2 Compliance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Manufacturers of Dietary Supplements shall submit application to USFDA for registration, receive a Registration Number, and provide the Registration Number upon request.

8.3 Compliance with the Dietary Supplement and Non Prescription Drug Consumer Protection Act

Written procedures shall be established and followed for reporting serious adverse events to the USFDA in accordance with the Dietary Supplement and Non Prescription Drug Consumer Protection Act.⁶

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Table 3 – Test methods for dietary ingredients

| Dietary ingredient Latin binomial (standardized common name) | Plant part | Chemical identification method | Source of methods | Validation of Method ⁽¹⁾ |
|--------------------------------------------------------------------------------------------------------|-------------------|--------------------------------------|-------------------------|-------------------------------------------|
| <i>Actaea racemosa</i> (Black Cohosh) | root/rhizome | TLC ⁽²⁾ | BHP | mutual recognition |
| <i>Aesculus hippocastanum</i> (Horse Chestnut) | Fruit | TLC ⁽²⁾ | BHP | mutual recognition |
| <i>Allium sativum</i> (Garlic) | Cloves | TLC ⁽²⁾ | USP | mutual recognition |
| <i>Astragalus membranaceus</i> (Astragalus Root) | Root | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Capsicum annuum</i> (Cayenne) | Fruit | TLC ⁽²⁾ | BHP | mutual recognition |
| <i>Crataegus monogyna</i> , <i>Crataegus laevigata</i> (Hawthorn) | berry/leaf/flower | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Echinacea angustifolia</i> , <i>Echinacea pallida</i> <i>Echinacea purpurea</i> , (Echinacea) | root/aerial parts | TLC ⁽²⁾ | BHP | mutual recognition |
| <i>Eleutherococcus senticosus</i> | root/rhizomes | TLC ⁽²⁾ | BHP | mutual recognition |

Table 3 – Test methods for dietary ingredients

| | | | | |
|----------------------------------------------------------------------------------------------------------------|--------------|----------------------|-----|--------------------|
| (Eleuthero) | | | | |
| <i>Ganoderma lucidum</i> (Reishi Mushroom) | Whole | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Ginkgo biloba</i> (Ginkgo) | Leaf | TLC ⁽²⁾ | USP | mutual recognition |
| <i>Hydrastis Canadensis</i> L. (Goldenseal) | Root | TLC ⁽²⁾ | BHP | mutual recognition |
| <i>Hypericum perforatum</i> (St. John's Wort) | aerial parts | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Matricaria recutita</i> (Chamomile) | aerial parts | TLC ⁽²⁾ | USP | mutual recognition |
| <i>Panax ginseng</i> (Asian Ginseng) (Chinese Ginseng) (Korean Ginseng) | Root | TLC ⁽²⁾ | USP | mutual recognition |
| <i>Piper methysticum</i> (Kava) | Rhizome | TLC ⁽²⁾ | BHP | mutual recognition |
| <i>Serenoa repens</i> (Saw Palmetto) | Berry | TLC ⁽²⁾ | USP | mutual recognition |
| <i>Salix daphnoides</i> , <i>Salix fragilis</i> , <i>Salix pentandra</i> , <i>Salix purpurea</i> (Willow Bark) | Bark | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Silybum marianum</i> (Milk Thistle) | Seed | TLC ⁽²⁾ | USP | mutual recognition |
| <i>Schisandra chinensis</i> (Schisandra Berry) | Berry | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Tanacetum parthenium</i> (Feverfew) | aerial parts | TLC ⁽²⁾ | USP | mutual recognition |
| <i>Uncaria tomentosa</i> (Cat's Claw) | Bark | TLC ⁽²⁾ | BHP | mutual recognition |
| <i>Vaccinium macrocarpon</i> , <i>Vaccinium oxycoccos</i> (Cranberry Fruit) | Fruit | HPLC ⁽³⁾ | USP | mutual recognition |
| <i>Valeriana officinalis</i> (valerian) | Root | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Viburnum opulus</i> (Cramp Bark) | stem/root | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Viburnum prunifolium</i> (Black Haw Bark) | stem/root | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Vitex agnus-castus</i> (Chaste tree) | Fruit | HPTLC ⁽⁴⁾ | AHP | mutual recognition |
| <i>Withania somnifera</i> (Ashwagandha Root) | Root | TLC ⁽²⁾ | AHP | mutual recognition |
| <i>Zingiber officinale</i> (Ginger) | root/rhizome | TLC ⁽²⁾ | USP | mutual recognition |

⁽¹⁾ Methods Validation Levels (AOAC draft document dated 12/13/00)

- | | |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Collaborative Method Validation | 8-10 laboratory validation study |
| 2. Mutual Recognition Method Validation | 3-4 laboratory validation study |
| 3. Peer-Verified Method Validation | Single independent laboratory validation study in addition to in-house validation |
| 4. In-House Method Validation | In-house validation study with but not limited to accuracy, precision, linearity, ruggedness, robustness, specificity, sensitivity, limit of detection, and limit of quantitation. |
| 5. Emergency Method Validation | Validation study with two different positive and negative controls. |

⁽²⁾ TLC = thin layer chromatography

⁽³⁾ HPLC = high-performance liquid chromatography

⁽⁴⁾ HPTLC = high-performance thin layer chromatography

Table 4 – Test methods for marker constituent compounds

| Dietary ingredient Latin binomial (Standardized common name) | Marker constituent compound | Test method | Validation of method |
|-------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|---------------------------------|
| <i>Actaea racemosa</i> (Black cohosh) | Actein, 26-deoxycimifigoside, Cimiracemoside A, 27-deoxyactein, Acetyl shengmanol xyloside, Cimicifugoside, Cimiracemoside F, Cimiracemoside C, and Cimiracemoside E. | INA, Black Cohosh Assay by ELSD | mutual recognition method |
| <i>Allium sativum</i> (Garlic) | Allicin | INA, Allicin by High- Performance Liquid Chromatography | in-house method |
| <i>Astragalus membranaceus</i> (Astragalus Root) | Calycosin, Formononetin, Ononin | AHP, Astragalus Flavonoids by HPLC | mutual recognition method |
| <i>Camellia sinensis</i> (Green tea) | Epigallocatechin, catechin, Epicatechin, Epigallocatechin gallate, Catechin Gallate, Gallocatechin gallate, Epicatechin Gallate and Gallic acid | INA, Catechins and Gallic Acid in Green Tea by HPLC | in-house method |
| <i>Crataegus monogyna, Crataegus laevigata</i> (Hawthorn Leaf and Flower) | Vitexin | AHP, Flavonoids in Hawthorn Leaf and Flower by HPLC | mutual recognition method |
| <i>Echinacea angustifolia Echinacea pallida Echinacea purpurea</i> (Echinacea) | Caftaric acid, Cichoric acid, Chlorogenic acid, Echinacoside | INA, Phenolics in Echinacea by HPLC | in-house method |
| <i>Ginkgo biloba</i> (Ginkgo) | Ginkgolide A, Ginkgolide B, Bilobalide | INA, Ginkoterpenoid Assay by HPLC | in-house method |
| <i>Ginkgo biloba</i> (Ginkgo) | Kaempferol, Quercetin, Isorhamnetin | INA, Ginkgo Flavonol Glycoside Assay by HPLC | in-house method |
| <i>Hypericum perforatum</i> (St. John's Wort) | Rutin trihydrate, Hyperoside, Hypericin, Quercitrin, Chlorogenic Acid, Hyperforin, Isoquercitrin, Quercetin, Pseudohypericin | INA, St. John's Wort Assay by HPLC | in-house method |
| <i>Piper methysticum</i> (Kava) | Desmethoxyyangonin, Dihydromethysticin, Dihydrokavain, Methysticin, Yangonin, Kavain | INA, Kavalactone Assay by HPLC | in-house method |
| <i>Salix daphnoides, Salix fragilis, Salix pentandra, Salix purpurea</i> (Willow Bark) | Salicin, L-Picein | AHP, Willow Bark Assay by HPLC | in-house method |
| <i>Schisandra chinensis</i> (Schisandra Berry) | Schisandrin A, Schisandrin B | AHP, Schisandra berry Assay by HPLC | mutual recognition method |

Table 4 – Test methods for marker constituent compounds

| Dietary ingredient Latin binomial (Standardized common name) | Marker constituent compound | Test method | Validation of method |
|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|---------------------------------|
| <i>Serenoa repens</i> (Saw palmetto) | Hexanoic, Hexanoic, Nonanoic Decanoic, Dodecanoic, Tetradecanoic, Hexadecanoic, Heptadecanoic, Octadecanoic, 9-Octadecenoic, 9,12- Octadecadienoic, 9,12,15- Octadecatrienoic acids | INA, Fatty Acid Content in Saw Palmetto by Gas Chromatography | in-house method |
| <i>Serenoa repens</i> (Saw palmetto) | Stigmasterol, campesterol, brassicasterol, and β -sitosterol | INA, Sterols Content in Saw Palmetto by Gas Chromatography | in-house method |
| <i>Valeriana officinalis</i> (Valerian) | Valerenic acid, acetoxyvalerenic acid, hydroxyvalerenic acid | AHP, Valerenic Acids in Valerian by HPLC | mutual recognition method |
| <i>Vitex agnus-castus</i> (Chaste tree) | Casticin | AHP, Casticin Assay in Chaste Tree Fruits by HPLC | mutual recognition method |

– concluded –

Table 5A – Acceptable limits for microbiological contaminants in raw materials

| Ingredient | Aerobic | Yeast/Mold | Enterobacteriaceae |
|-------------------------------------------------------------------------|--------------------------|--------------------------|-----------------------|
| Vitamin and/or mineral ingredient | 1×10^5 CFU/g | 1×10^2 CFU/g | 1×10^2 CFU/g |
| Botanical ingredient – extract / Other dietary supplement ingredient | 1×10^7 CFU/g | 1×10^5 CFU/g | 1×10^4 CFU/g |
| Botanical extract / Other dietary supplement ingredient | 1×10^4 CFU/g | 1×10^3 CFU/g | 1×10^2 CFU/g |

Table 5B – Acceptable limits for pathogenic microbiological contaminants in raw materials

| Ingredient | Salmonella sp. | Escherichia Coli ⁽¹⁾ | Staphylococcus aureus |
|-------------------------------------------------------------------------|-------------------|------------------------------------|--------------------------|
| Vitamin and/or mineral ingredient | ND ⁽²⁾ | ND ⁽²⁾ | ND ⁽²⁾ |
| Botanical ingredient – non-extract ⁽¹⁾ | ND ⁽²⁾ | 1×10^2 CFU/g | ND ⁽²⁾ |
| Botanical ingredient – extract / Other dietary supplement ingredient | ND ⁽²⁾ | ND ⁽²⁾ | ND ⁽²⁾ |

⁽¹⁾ Upon the presence of *Escherichia coli*, 7.3.6.2 is to be followed to determine whether the colonies are enterovirulent. There is a zero tolerance for the presence of enterovirulent *Escherichia coli*.

⁽²⁾ ND = Not Detected. Not Detected requires that no colonies shall be present in 10 g of sample when tested under the conditions of the USP method cited in 7.3. The detection level for this testing is 10 CFU/g for the period of time tested.

Table 6A – Acceptable limits for microbiological contaminants in finished products⁽¹⁾

| Finished Products | | Aerobic | Yeast/Mold | Enterobacteriaceae |
|-------------------|---------------------------------------------------------------------------------------------------|---------------------------|---------------------------|---------------------------|
| Category 1 | Finished products containing only vitamin and minerals | 1 x 10 ³ CFU/g | 1 x 10 ² CFU/g | 1 x 10 ² CFU/g |
| Category 2 | Finished products containing Botanical ingredient – extract / Other dietary supplement ingredient | 1 x 10 ⁴ CFU/g | 1 x 10 ³ CFU/g | 1 x 10 ² CFU/g |
| Category 3 | Finished products containing botanical ingredients – non-extract | 1 x 10 ⁷ CFU/g | 1 x 10 ⁵ CFU/g | 1 x 10 ⁴ CFU/g |

⁽¹⁾ The category designation shall be based on ingredients present at 1% or more by weight in the formula as provided in the full product formulation. For a product containing ingredients from more than one category, the finished product category will be assigned based on the ingredient with the highest category number.

Table 6B – Acceptable limits for pathogenic microbiological contaminants in finished products⁽¹⁾

| Finished Products | | <i>Salmonella</i> spp. | <i>Escherichia Coli</i> ⁽²⁾ | <i>Staphylococcus Aureus</i> |
|-------------------|---------------------------------------------------------------------------------------------------|------------------------|----------------------------------------|------------------------------|
| Category 1 | Finished products containing only vitamin and minerals | ND ⁽³⁾ | ND ⁽³⁾ | ND ⁽³⁾ |
| Category 2 | Finished products containing Botanical ingredient – extract / Other dietary supplement ingredient | ND ⁽³⁾ | ND ⁽³⁾ | ND ⁽³⁾ |
| Category 3 | Finished products containing botanical ingredients – non-extract | ND ⁽³⁾ | 1 x 10 ² CFU/g | ND ⁽³⁾ |

⁽¹⁾ The category designation shall be based on ingredients present at 1% or more by weight in the formula as provided in the full product formulation. For a product containing ingredients from more than one category, the finished product category will be assigned based on the ingredient with the highest category number.

Examples:

- a) A product containing only Vitamin C and Zinc shall be in category 1.
- b) A product containing Vitamin C, Zinc, and Green Tea Extract shall be in category 2.
- c) A product containing Vitamin C, Zinc and Echinacea shall be in category 3.

⁽²⁾ Upon the presence of *Escherichia Coli*, 7.3.7 is to be followed to determine whether the colonies are enterovirulent. There is a zero tolerance for the presence of enterovirulent *Escherichia Coli*.

⁽³⁾ ND = Not detected. Not Detected requires that no colonies shall be present in 10 g of sample when tested under the conditions of the USP method cited in 7.3. The detection level for this testing is 10 CFU/g for the period of time tested.

Annex A
(normative)

Table A1 – Botanicals known or suspected to contain aristolochic acid²⁴

| | |
|------------------------------------|----------------------------------|
| <i>Aristolochia</i> spp. | <i>Asarum splendens</i> |
| <i>Aristolochia acuminata</i> | <i>Asaum forbesii</i> |
| <i>Aristolochia argentina</i> | <i>Asarum heterotrroides</i> |
| <i>Aristolochia baetica</i> | <i>Asarum sieboldii</i> |
| <i>Aristolochia bracteata</i> | <i>Akebia</i> spp. |
| <i>Aristolochia chilensis</i> | <i>Akebia quinata</i> |
| <i>Aristolochia cinnabarina</i> | <i>Akebia trifoliata</i> |
| <i>Aristolochia clematidis</i> | <i>Bragantia wallichii</i> |
| <i>Aristolochia contorta</i> | <i>Clematis</i> spp. |
| <i>Aristolochia cymbifera</i> | <i>Clematis armandii</i> |
| <i>Aristolochia debilis</i> | <i>Clematis chinensis</i> |
| <i>Aristolochia elegans</i> | <i>Clematis hexapetala</i> |
| <i>Aristolochia esperanzae</i> | <i>Clematis Montana</i> |
| <i>Aristolochia fangchi</i> | <i>Clematis uncinata</i> |
| <i>Aristolochia fimbriata</i> | <i>Cocculus</i> spp. |
| <i>Aristolochia indica</i> | <i>Cocculus carolinus</i> |
| <i>Aristolochia kaempferi</i> | <i>Cocculus diversifolius</i> |
| <i>Aristolochia kwangsiensis</i> | <i>Cocculus hirsutus</i> |
| <i>Aristolochia macrophylla</i> | <i>Cocculus indicus</i> |
| <i>Aristolochia manschuriensis</i> | <i>Cocculus laurifolius</i> |
| <i>Aristolochia maurorum</i> | <i>Cocculus leaebe</i> |
| <i>Aristolochia maxima</i> | <i>Cocculus madagascariensis</i> |
| <i>Aristolochia mollissima</i> | <i>Cocculus orbiculatus</i> |
| <i>Aristolochia pistolochia</i> | <i>Cocculus palmatus</i> |
| <i>Aristolochia rigida</i> | <i>Cocculus pendulus</i> |
| <i>Aristolochia rotunda</i> | <i>Cocculus thunbergii</i> |
| <i>Aristolochia serpentaria</i> | <i>Diploclisia affinis</i> |
| <i>Aristolochia watsoni</i> | <i>Diploclisia chinensis</i> |
| <i>Aristolochia watsonii</i> | <i>Menispermum dauricum</i> |
| <i>Aristolochia westlandi</i> | <i>Saussurea lappa</i> |
| <i>Aristolochia westlandii</i> | <i>Sinomenium acutum</i> |
| <i>Aristolochia zollingeriana</i> | <i>Stephania</i> spp. |
| <i>Asarum canadense</i> | <i>Stephania tetrandra</i> |
| <i>Asarum himalacium</i> | <i>Vladimiria soulei</i> |
| <i>Asarum himalaycum</i> | |

²⁴ The source of this table is an April 19, 2001 US FDA correspondence from the Office of Nutritional Products, Labeling and Dietary Supplements <www.cfsan.fda.gov/~~/dms/ds-bot14.html>.

Annex B (informative)

Reference information for contaminant level acceptance criteria

This annex contains reference information regarding the sources of information used to establish acceptance criteria for contaminant levels.

B.1 Metals

Acceptance limits for cadmium and lead were obtained from the Joint FAO/WHO Expert Committee on Food Additives, World Health Organization,²⁰ International Programme on Chemical Safety, Safety Evaluation of Certain Food Additives and Contaminants.

The acceptance limit for chromium was obtained from the US Environmental Protection Agency¹⁸ (1998), Integrated Risk Information System (IRIS): Hexavalent Chromium.

The acceptance limit for mercury was obtained from the US Environmental Protection Agency¹⁸ (1989), Integrated Risk Information System (IRIS): Mercury (inorganic).

The acceptance limit for arsenic was obtained from the British Herbal Pharmacopoeia.⁹

B.2 Microbiological contaminants

The acceptance limits contained in tables 5A, 5B, 6A, and 6B for microbiological contaminants were established with consideration of limits allowed by WHO and USP and were agreed to by the Joint Committee on Dietary Supplements.

Annex C (informative)

Calculating acceptance criteria

This annex contains information for calculating acceptance criteria for metal contamination levels for finished products.

C.1 Normalization of laboratory data

Normalization is the mathematical adjustment of laboratory results to estimate actual human exposure levels based on the manufacturer's recommended daily dosage.

C.2 Sampling and reporting of laboratory data

The laboratory will test a quantity of sample sufficient to minimize sampling error and to reach the desired limit of detection that is required for each metal contaminant.

The laboratory results will be reported in milligrams of contaminant per gram of tested product (mg/g) for solid materials. If the product is a liquid, it will be reported as milligram contaminant per milliliter of tested product (mg/mL).

C.3 Normalization calculations

- Normalized concentration = mg contaminant / g finished product x Maximum Daily Dosage (MDD); and
- MDD = maximum dose recommended on the label by the manufacturer.

The normalized concentration is compared to the acceptance criteria for finished product.

Example:

- MDD = (2) 500mg tablets taken 3 times a day = 3g of product;
- per laboratory results, the mg contaminant/g finished product = 0.002mg lead/g finished product;
- normalized concentration = 0.006mg/d = 0.002mg lead/g finished product x 3g (MDD); and
- acceptance criteria for lead is 0.02mg/d, therefore product is acceptable.

Standards²⁵

The following standards established and adopted by NSF as minimum voluntary consensus standards are used internationally:

- 2 Food equipment
- 3 Commercial warewashing equipment
- 4 Commercial cooking, rethermalization, and powered hot food holding and transport equipment
- 5 Water heaters, hot water supply boilers, and heat recovery equipment
- 6 Dispensing freezers
- 7 Commercial refrigerators and freezers
- 8 Commercial powered food preparation equipment
- 12 Automatic ice making equipment
- 13 Refuse processors and processing systems
- 14 Plastics piping system components and related materials
- 18 Manual food and beverage dispensing equipment
- 20 Commercial bulk milk dispensing equipment
- 21 Thermoplastic refuse containers
- 24 Plumbing system components for recreational vehicles
- 25 Vending machines for food and beverages
- 29 Detergent and chemical feeders for commercial spray-type dishwashing machines
- 35 High pressure decorative laminates (HPDL) for surfacing food service equipment
- 36 Dinnerware
- 37 Air curtains for entranceways in food and food service establishments
- 40 Residential wastewater treatment systems
- 41 Non-liquid saturated treatment systems
- 42 Drinking water treatment units – Aesthetic effects
- 44 Residential cation exchange water softeners
- 46 Evaluation of components and devices used in wastewater treatment systems
- 49 Biosafety cabinetry: Design, construction, performance and field certification
- 50 Equipment for swimming pools, spas, hot tubs and other recreational water facilities
- 51 Food equipment materials
- 52 Supplemental flooring
- 53 Drinking water treatment units – Health effects
- 55 Ultraviolet microbiological water treatment systems
- 58 Reverse osmosis drinking water treatment systems
- 59 Mobile food carts
- 60 Drinking water treatment chemicals – Health effects
- 61 Drinking water system components – Health effects
- 62 Drinking water distillation systems
- 140 Sustainability assessment for carpet
- 143 Environmentally preferable products – Hard surface cleaners
- 169 Special purpose food equipment and devices
- 170 Glossary of food equipment terminology
- 173 Dietary supplements
- 177 Shower filtration systems – Aesthetic effects
- 184 Residential dishwashers
- 222 Ozone generators
- 245 Wastewater treatment systems – Nitrogen reduction
- 305 Personal care products containing organic ingredients
- 321 Goldenseal root (*Hydrastis canadensis*)
- 330 Glossary of drinking water treatment unit terminology
- 332 Sustainability assessment for resilient floor coverings
- 342 Sustainability assessment for wallcovering products
- 360 Wastewater treatment systems – Field performance verification
- 372 Drinking water system components – Lead content
- 14159-1 Hygiene requirements for the design of meat and poultry processing equipment
- 14159-2 Hygiene requirements for the design of hand held tools used in meat and poultry processing equipment
- 14159-3 Hygiene requirements for the design of mechanical belt conveyors used in meat and poultry processing equipment

²⁵ The information contained in this Standards page 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 Standards page 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.



THE HOPE OF MANKIND rests in the ability of man to define and seek out the environment which will permit him to live with fellow creatures of the earth, in health, in peace, and in mutual respect.