# NSF International Standard for Dietary Supplements — Dietary supplements

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## 3 Definitions

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

**3.1 active ingredient:** The principal ingredient identified in a product's name or on its principal display panel.

**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 of plant species or form.~~ An ingredient consisting of, or derived from a plant or microorganism (i.e. 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.~~8~~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.~~9~~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 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.~~10~~8 finished product:** A product requiring no further processing prior to sale to the consumer.

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

| Ingredient | Aerobic | Yeast/Mold | Enterobacteriaceae |
|---|---|---|---|
| Vitamin and/or mineral ingredient | $1 \times 10^3$ CFU/g | $1 \times 10^2$ CFU/g | $1 \times 10^2$ CFU/g |
| Botanical ingredient – extract / Other dietary supplement ingredient | $1 \times 10^4$ CFU/g | $1 \times 10^3$ CFU/g g | $1 \times 10^2$ CFU/g |
| Botanical ingredient – non-extract | $1 \times 10^7$ CFU/g | $1 \times 10^5$ CFU/ | $1 \times 10^4$ 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 – extract / Other dietary supplement ingredient | ND(2) | ND(2) | ND(2) |
| Botanical ingredient – non-extract(1) | ND(2) | $1 \times 10^2$ CFU/g | 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 | $1 \times 10^3$ CFU/g | $1 \times 10^2$ CFU/g | $1 \times 10^2$ CFU/g |
| Category 2 | ~~Finished products containing botanical ingredients – non-extract~~ Finished products containing Botanical ingredient – extract / Other dietary supplement ingredient | $1 \times$ ~~$10^7$~~ $10^4$ CFU/g | $1 \times$ ~~$10^5$~~ $10^3$ CFU/g | $1 \times$ ~~$10^4$~~ $10^2$ CFU/g |
| Category 3 | ~~Finished products containing Botanical extract / Other dietary supplement ingredient.~~ Finished products containing botanical ingredients – non-extract | $1 \times$ ~~$10^4$~~ $10^7$ CFU/g | $1 \times$ ~~$10^3$~~ $10^5$ CFU/g | $1 \times$ ~~$10^2$~~ $10^4$ 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 | | Salmonella sp. | Escherichia Coli ~~1~~(2) | Staphylococcus aureus |
|---|---|---|---|---|
| Category 1 | Finished products containing only vitamin and minerals | ND ~~2~~(3) | ND ~~2~~(3) | ND ~~2~~(3) |
| Category 2 | ~~Finished products containing botanical ingredients – non-extract~~. Finished products containing Botanical ingredient – extract / Other dietary supplement ingredient | ND ~~2~~(3) | ~~$1 \times 10^2$ CFU/g~~ ND(3) | ND(3) |
| Category 3 | ~~Finished products containing Botanical ingredient – extract / Other dietary supplement ingredient~~ Finished products containing botanical ingredients – non-extract | ND ~~2~~(3) | ~~ND~~ $1 \times 10^2$ CFU/g | ND ~~2~~(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.

~~1~~(2) 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~~(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.

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