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The Real Definition of a Dietary Supplement

The legislation that governs dietary supplements is called DSHEA, and it enumerates nine different categories. This guide explains what they are and what they mean.

Illustration by Gabriel Silveira for Endpoints

Highlights:

→ There are an estimated 77,000 dietary supplements on the market, with more than 5,000 new products introduced each year.

→ According to the FDA, a dietary supplement is a "product (other than tobacco) intended to supplement the diet that 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 people to supplement the diet by increasing the total dietary intake, a concentrate, metabolite, constituent, extract" or a combination of any of these.

→ If a supplement maker introduces a new ingredient to the market, it's supposed to notify the FDA. The FDA has had some trouble with compliance.

The dietary supplement market in the U.S. is estimated at more than $30 billion (based on industry group stats and projections from McKinsey), with more than 50 percent of U.S. adults taking one of the more than 77,000 estimated supplements on the market. That means you're probably taking one—and likely educating yourself about its role in health, too. But how does the government, which regulates dietary supplements, describe them? And what do those words mean?

The legal definition of a dietary supplement, codified in the Dietary Supplement Health and Education Act of 1994 (DHSEA), describes a "product (other than tobacco) intended to supplement the diet that 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 people to supplement the diet by increasing the total dietary intake, a concentrate, metabolite, constituent, extract" or a combination of any of these.

The Food and Drug Administration (FDA), which supervises dietary supplements, offers some insight as to how one should think about these categories when it issues "guidance" to the industry, which it did most recently in 2016, but there remain large gaps, which we aim to clear up here with some straightforward definitions and examples in each category. These are our interpretations, not definitions from a regulatory body, and they're meant to help better understand what you're seeing on a supplement label—not to recommend any particular supplement.

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Before You Start: What Are Essential Nutrients?

A handful of nutrients are considered "essential," meaning that humans can't synthesize them in sufficient quantities endogenously, but we need them for normal biological function. These numbers have changed over time (and may well again), but currently the list of essential nutrients includes nine amino acids, two fatty acids, 13 vitamins, and 15 minerals.

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Vitamins

What They Are: Vitamins are organic compounds required by the body for biological functions, but which aren't created in sufficient quantities endogenously. That means we need to get them through diet. There are 13 vitamins—actually, most of them are families of vitamins with different chemical structures but similar biological activity—which play a variety of roles, most commonly as precursors or cofactors in enzymatic reactions, which means they help move along the chemical reactions that make up our metabolism. The prevalence of multivitamins notwithstanding, humans get most of their essential vitamins through diet, either through whole foods or through fortified processed foods.

Common vitamins: The families of vitamins are A, B1, B2, B3, B5, B6, B7, B9, B12, C, D, E, and K. The vitamin B3 family, for example, includes niacin, nicotinamide, and nicotinamide riboside, which are precursors of varying degrees of efficacy for the coenzyme NAD+, and are also involved in other processes like lipid metabolism.

Minerals

What They Are: Like vitamins, minerals are fairly straightforward: They're chemical elements (that is, from the periodic table) from the earth required for biological processes, which make their way up the food chain from the soil. Humans get them from eating plants or animals. Minerals act similarly to vitamins, primarily as cofactors in enzymatic reactions. Magnesium, for instance, is required for hundreds of enzymatic activities, including ATP synthesis and the synthesis of DNA and RNA. Sodium is another classic example of an essential mineral, and it's used for signaling pathways in the central nervous system. Again, like vitamins, minerals are usually available in the diet with whole foods or in fortified foods.

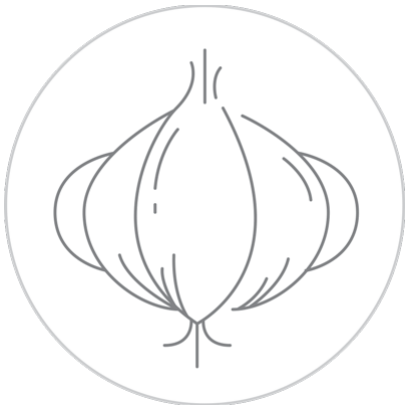
Common Minerals: Calcium, potassium, sodium, magnesium, chlorine, phosphorus, iron, zinc, manganese, copper, iodine, chromium, molybdenum, selenium, cobalt.

Amino Acids

What They Are: Like vitamins and minerals, some amino acids are considered essential to life-sustaining biological activity in humans. Amino acids are typically described as the chemical building blocks, or substrates, of protein synthesis; they're the primary ingredient (behind water) in muscles and tissues. Research over the past few decades has revealed that they have other important roles, acting as regulators of metabolic pathways in gene expression, cell signaling, antioxidative responses, and immunity. While there's a great deal of research on amino acids, there remains debate about how much of each amino acid

humans need in their diets, at which stage in life, and even which amino acids are considered necessary to proper biological function.

Common Amino Acids: Essential: histidine, isoleucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine. Non-essential: alanine, asparagine, arginine, aspartic acid, cysteine, glutamic acid, glutamine, glycine, proline, serine, tyrosine.



Herbs or Botanicals

What They Are: An herb or botanical is a plant, alga, or fungus; a part of a plant, e.g., bark, leaves, stems, roots, flowers, fruits, seeds, berries; or their exudates like sap or resin. These are not endogenous and not traditionally considered essential to physiological function. Records from Mesopotamia and Egypt indicate that plant-based products have been used for health purposes for millennia, and from the pharmaceutical perspective, the compounds in plants are the foundation of discovery for new drugs meant to activate metabolic pathways or inhibit pathways—and that's because compounds from plants can be very active molecules.

A classic example is acetylsalicylic acid, or aspirin, which was derived from the bark of the willow tree *Salix alba* L. Herbs and botanicals can often be found in the produce aisle, or as supplements in a variety of forms—teas, extracts, and concentrates, for example. Because herbs and botanicals are natural, they're often thought to be safe, but the reality is that some are and some aren't, and in many cases the full extent of their relationship to biological processes isn't well studied and understood.

Interestingly, while vitamins, minerals, and amino acids can be synthetic under FDA guidelines, synthetic versions of herbs and botanicals (as well as constituents, extracts, or concentrates thereof) can't be sold as dietary supplements.

Common Herbs or Botanicals: garlic, curcumin (turmeric), ginko biloba.

Metabolites

What They Are: Metabolites, as the name suggests, can be intermediates along, and products at the end of, a metabolic pathway, the chain reactions inside cells that sustain life. This is quite a broad definition with overlap in other areas, for instance, with amino acids, which are intermediates of metabolism. The FDA considers metabolites to be eligible as dietary supplements only if they have been synthesized from other dietary ingredients, and when the production process mimics the human metabolic process for creating it.

A well-studied metabolite sold as a sports supplement is creatine, a nitrogenous organic acid derived from amino acids, which is essential to energy transfer in skeletal muscle and the brain. Many food additives are also technically metabolites, including sucrose, citric acid, and D-sorbitol.

Common Metabolites: creatine, melatonin, ubiquinone.

Concentrates, Constituents or Extracts

What They Are: A **concentrate** is a substance with most of its base component or solvent removed, e.g., water, such that the original material has just been reduced in volume (i.e., to fit into a smaller capsule or container) and what remains is a solid, semi-solid, or syrup. **Extracts** are also concentrated forms of the original substance, but usually they are the concentrated form of just the active ingredient, which has been extracted using a solvent (methanol and ethanol, for example) to separate a class of compounds. From an efficacy standpoint, the end goal with concentrates and extracts is similar to using an herb or botanical, or extract, which is to activating pathways or inhibiting pathways. A **constituent**, finally, might just be one molecule isolated for a specific use.

Common Examples: juice concentrates and herbal extracts.

Dietary Substances

What They Are: Characterized as "something that increases total dietary intake," this sounds like it could theoretically be anything, but "substance" here means something that's commonly used as food or drink—i.e., that it's in the food supply either as a food or as an approved food additive, which is another category of ingredients the FDA oversees. The most recognizable example of a dietary substance today is probiotics, live microorganisms found in foods like yogurt and kombucha, which are isolated and sold as supplements. As a dietary substance, probiotics should be recognized as safe by the FDA in food before they can be used in supplements.

Common Dietary Substances: probiotics.

What about everything else I see in health food stores?

A handful of products that you'll find in the supplement aisle don't fit neatly into the categories above, most glaringly **fatty acids**, two of which are essential nutrients (alpha-linolenic acid and linoleic acid) and play critical roles in multiple biological processes, including regulating the structure and function of cell membranes, intracellular signaling, and gene expression. Fatty acid supplements appear commonly as fish oil or flaxseed oil supplements, which could be filed under extracts, metabolites, or constituents.

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A Final Word on New Dietary Ingredients

DSHEA introduced the term "new dietary ingredient" (NDI) in 1994. An NDI is a dietary ingredient not marketed in the U.S. before October 15, 1994 (those ingredients, with some caveats, were grandfathered in), and something that isn't already in the food supply and which fits into one of the categories explained above. The FDA requires manufacturers of NDIs to notify the FDA of the ingredient or supplement containing the ingredient at least 75 days before bringing it to market.

When DSHEA was passed in 1994, there were roughly 4,000 products on the market; today there are more than 77,000, so needless to say there have also been many new ingredients introduced as well. Part of the reason the FDA issued its latest guidance in 2016, by its own admission, is that compliance with the NDI notification process has been inconsistent. The FDA hopes to get more notifications of NDIs submitted, thereby avoiding companies simply introducing new and potentially unsafe ingredients to the consumer market.

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