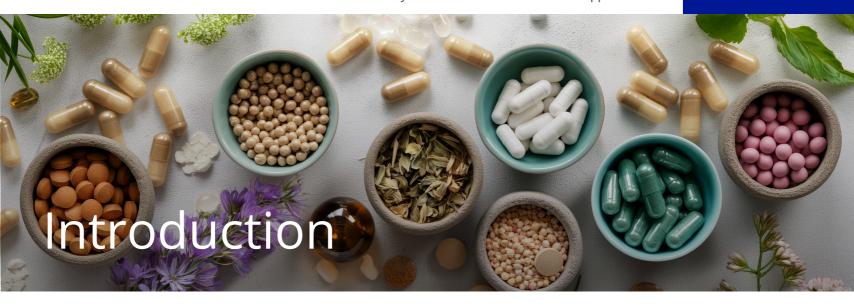




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Although the term "nutraceutical" is relatively new, the benefits of these products and ingredients have been understood for hundreds, even thousands of years. The use of wheatgrass, for example, traces back more than 5,000 years when ancient Egyptians discovered the natural juice's benefits to health and energy. Another example is the use of echinacea, which dates back more than 300 years when Plains Indians used the medicinal plant for ailments including toothaches, snakebites, coughs and colds, and rabies.

Naturally occurring remedies and health enhancements have long been in use, but it wasn't until 1989 when the category was given an official name. That's when Dr. Stephen DeFelice coined the term "nutraceutical" which, according to the Annals of Pharmacology and Pharmaceutics, brings together two defining characteristics: Nutrition indicating a food component and Pharmaceutical – with references to a drug. As defined by Dr. DeFelice, <u>nutraceuticals include</u> "any substance that is a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease." Products that fall under the nutraceutical heading, according to DeFelice, "may range from isolated nutrients, dietary supplements and specific diets to genetically engineered designer foods, herbal products, and processed foods such as cereals, soups, and beverages."

Today the nutraceutical industry includes hundreds of thousands of products used throughout the world. Overall, the global nutraceutical market was valued at \$591.1 billion during 2024, with North America (Canada and the United States) leading the world with a 35.9% share of market. The size of the global market is expected to grow at an annual rate of 7.6% through 2030. Businesses engaged in nutraceutical production range from global corporations such as Amway and ADM to smaller businesses such as Canada's Novotrend and Promino.

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during 2024, with North America (Canada and the United States) leading the world with a 35.9% share of market.



The size of the global market is expected to grow at an <u>annual</u> rate of 7.6% through 2030.

The industry has benefited from trends including an aging global population, interest in pursuing healthy lifestyles, increasing middle-class incomes, enhanced access to information through the internet, and easy purchasing options available through e-commerce and other buying platforms.

For U.S. and Canadian nutraceutical businesses, this has meant increased opportunities to tap into global enthusiasm for health-related products. Any cross-border expansion though, will require an understanding of local market conditions and regulatory requirements, along with full compliance with all customs requirements.

And of course, a business will need a comprehensive cross-border logistics strategy to ensure the safe, timely, and efficient delivery of products into international markets.

The following discussion provides an overview of the nutraceutical and dietary supplement industry, including information about top-selling products and regulatory requirements. The discussion also sheds light on key trends and challenges, including the need for logistics efficiency.





The "nutraceutical" term is often used interchangeably with other categories such as dietary supplements and functional foods. However, there are important distinctions, especially with regard to regulatory requirements. In addition, certain products may fall under multiple category headings. Two examples include probiotics and echinacea which, depending on its form, may be either a nutraceutical or a dietary supplement.

The differences can be subtle. A good distinction provided by Dietary Supplements and Nutraceuticals journal explains: "Both dietary supplements and nutraceuticals serve to improve the health and wellness of individuals; however, dietary supplements are generally consumed in the form of pills and contain singular components like vitamins to treat a form of deficiency, whereas nutraceuticals are normally given in a food, herbal, or extract form in order to treat diseases and disorders." The two categories can be complementary, but also confusing. Following is a brief overview of each:





What are Nutraceuticals?

In an interview with <u>The New York Times</u>, Dr. DeFelice cited his mid-1960's work with <u>carnitine</u>, a naturally occurring substance produced in the liver, as his first foray into what we now call nutraceuticals. At the time Dr. DeFelice was working as an endocrinologist in a New York City hospital when, "on a hunch from a colleague," he decided to use <u>carnitine</u> as a treatment for

hyperthyroidism. That hunch proved to be correct since, the article noted, the treatment "reversed he symptoms in a week – much faster than the traditional thyroid medication, and just as effectively." DeFelice went on to discover, "by accident," that carnitine was also an effective treatment for angina pectoris, a heart ailment that causes chest pain and shortness of breath. "The more I did, the more I saw it working, the more excited I became," he said.

What began as a "hunch" and an "accident" has evolved into today's nutraceutical industry.

As Dr. DeFelice made clear in his pioneering definition, a nutraceutical is essentially any substance that is a food, or derived from food sources, that provides medical or health benefits including the prevention and treatment of disease. In arriving at this definition, DeFelice cited increased evidence supporting "the potential benefits of a growing range of products on a rapidly expanding array of specific disease processes."

A few **examples** include:

- The use of **B-carotene** to prevent certain types of lung cancer.
- Niacin to prevent recurrent heart attacks.
- **Pyridoxine** to treat and prevent depression.
- · Vitamin A to treat measles.
- Magnesium to treat hypertension.
- Garlic to reduce atherosclerosis.
- Fish oil for hypertension.
- **Cranberry juice** to prevent urinary infections.
- Antioxidants to reduce damage from heart attacks.
- Omega-3 in reducing inflammation, and treating depression and Alzheimer's disease.
- Glucosamine which can play a role in cartilage formation and repair, and help protect joints and tendons from injury.

This list continues to evolve, according to Functional Foods and Nutraceuticals in Metabolic and Non-Communicable Diseases, due to ongoing market development, research, and consumer interest. "The low cost and easy availability compared to prescription drugs" the authors note, "are factors that are expected to increase demand...."

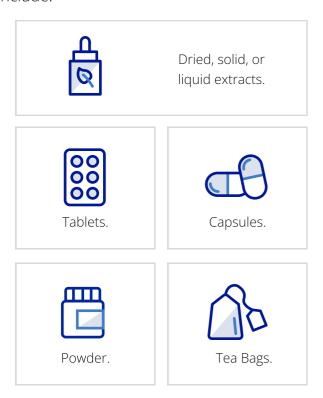
Top Nutraceutical Products

This list continues to evolve, according to Probiotics account for more than 25% of total nutraceutical sales, according to <u>Tilley Distribution</u>, and represent the fastest growing nutraceutical category. Other top products and their primary uses, according to <u>BioThrive Sciences</u> include:

- Probiotics maintain or improve "good" bacteria in the body.
- Liquid Prenatal Vitamins prenatal health.
- **Vitamin D3** promotes development and maintenance of healthy bones and teeth.
- Garcinia Cambogia weight loss.
- Raspberry Ketones weight loss.
- Green Tea supports energy and alertness.
- **Echinacea** fights infection including urinary tract infections; used for skin problems including eczema and psoriasis.
- Omega 3 Fatty Acids Reduce inflammation and may help lower the risk of chronic disease such as heart disease, cancer, and arthritis.
- Alpha-Lipoic Acid Weight loss, wound treatment, rheumatoid arthritis, and diabetic nerve pain.
- Vitamin B12 Aids with metabolism.

Nutraceuticals come in many forms

Products are offered in a variety of forms that include:



Nutraceutical Regulation

As a relatively new category, a "globally accepted" definition of nutraceuticals has yet to be developed. This has resulted in a lack of harmonized regulations between countries, or mutual agreement about how to classify nutraceutical products.

According to the <u>British Journal of Clinical</u> <u>Pharmacology (BJCP)</u>, nutraceuticals fall "in the grey area between pharmaceuticals and food," but the lack of common regulatory standards is causing confusion among consumers, and "challenges with safety and health claim substantiation," since manufacturers are often not held accountable for claimed health benefits.

Efforts to establish international standards for nutraceuticals have been under discussion for many years. In the early 2000's Dr. Stephen DeFelice, the "founding father of nutraceuticals," proposed a worldwide <u>Nutraceutical Commission</u> for the purpose of setting global standards for clinical research associated with substantiating nutraceutical health claims. Absent a global regulatory framework, the <u>BJCP</u> notes that many countries rely on "rules for producing and marketing foodstuffs and their derivatives," put in place by both the United Nations Food and Agricultural Organization (FAO) and the World Health Organization (WHO).

Closer to home, following is a brief overview of regulatory requirements in the United States and Canada.

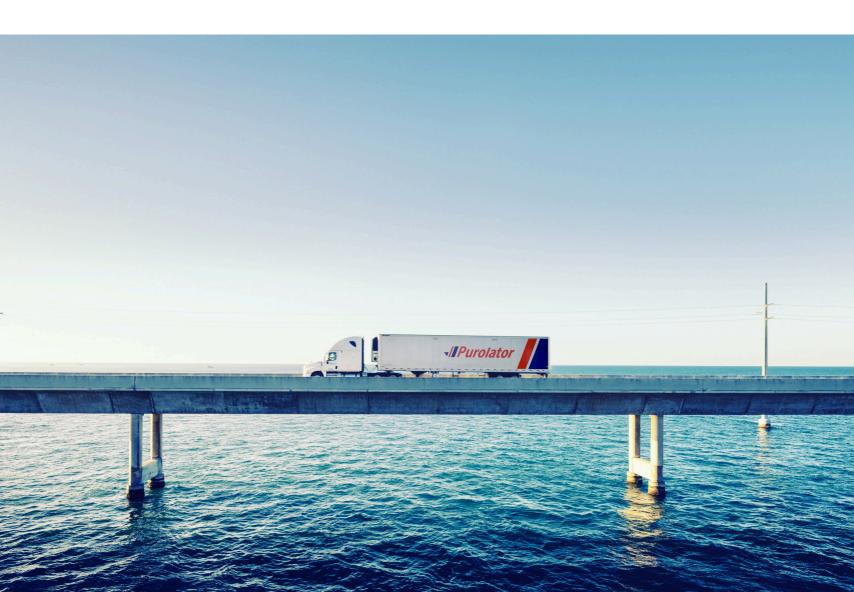




Nutraceuticals are widely available in the U.S. and fall under the regulatory umbrella of the U.S. Food and Drug Administration (FDA). However, since nutraceuticals are not considered "drugs," they are not subject to the same rigorous pre-market testing and review processes as medications. Instead, notes the BJCP, the FDA "acknowledges the term nutraceutical" and applies a <u>regulatory approach</u> that falls somewhere between its handling of drugs and foods.

Specifically, the onus for safety is left to manufacturers. Manufacturers are responsible for ensuring that a nutraceutical is safe before it is marketed, but the FDA has authority to take action against any product found to be unsafe, "after it reaches the market."

This means, explains Men's Health, that "manufacturers do not have to prove [nutraceuticals] work before selling them." The lack of nutraceutical regulation, according to Tilley Distribution, is a source of concern for many consumers. "Without regulatory analysis, manufacturers and distributors are responsible for putting safe, ethical products in the marketplace," the report explained. Absent official standards, manufacturers rely on "high-quality assurance, storage and formulation standards," while distributors depend on suppliers to ensure the integrity of all materials used to create various nutraceutical products.





Canada

In Canada, nutraceuticals are classified as dietary supplements and fall under the regulatory authority of Health Canada. Products do not need a prescription and are widely available in retail outlets.

As <u>"natural health products"</u> (NHPs), nutraceuticals are subject to the <u>Natural Health Products</u> Regulations which, according to Health Canada, are intended to give Canadians confidence "that the products they use are safe, effective, and of high quality." Unlike in the United States, nutraceuticals must be approved for sale by <u>Health Canada</u>. Once approved, products are subject to ongoing review and adherence with applicable regulations.

Regulations applicable to nutraceutical products include:

- Products are required to undergo a premarket approval process and obtain a product license prior to entering the market.
- · Commercial importers must obtain a Natural Product Number (NPN).
- Manufacturers must obtain a site license to produce a NHP.
 - License holders are required to monitor all adverse reactions and report serious reactions to Health Canada.
- Manufacturers are subject to the post-approval <u>Marketed and Health Products Directorate</u>
 (<u>MHPD</u>) which, among other functions, maintains a "licensed natural health products database"
 which allows consumers to determine if a product has been properly licensed for sale and use.
- Labeling: Because nutraceuticals do not require a prescription, Health Canada notes the
 important role labels can have in affecting a consumer's purchasing decision. "NHP consumers
 generally select a product that best suits their personal health needs by comparing products and
 gathering information from labels, thus making the information provided on the label of an NHP
 and its legibility very important for consumer health and safety." As such, Health Canada imposes
 strict labeling requirements including a precise "product facts" table that lists all ingredients,
 dosage information, and uses.





What are Functional Foods?

Functional foods are a subcategory of nutraceuticals, <u>defined</u> as foods "consumed as part of a usual diet" that have "demonstrated physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions."

According to the <u>Canadian Medical Association</u> <u>Journal</u>, a product is considered a functional food when a bioactive ingredient is contained within the food, and can be easily incorporated into an individual's everyday diet. This differs from a nutraceutical, in which the bioactive ingredients are "independent" of a food and usually found in pill or capsule form.

Examples of functional foods include vitaminfortified juices and dairy products, tomatoes that are rich in lycopene, and eggs enriched in omega-3-fatty acids.



What are Dietary Supplements?

Dietary supplements are used by millions of consumers worldwide, either to help meet nutritional needs or address specific health-related concerns. In the United States nearly 50% of adults take at least one supplement, a rate that jumps to more than 65% among women. In Canada, Health Canada reports nearly 75% of adults use natural health products (NHPs), with 57% reporting daily use.

Why do people use supplements?

Most people who take a supplement do so on their own volition, rather than at a doctor's behest. Research reported in <u>Nutrients</u>, the open-source journal for research professionals, found primary reasons for taking a supplement include:



Most popular dietary supplements

Research reported in February 2025 by ConsumerLab.com found that for the tenth year in a row, vitamin D was the most popular supplement. According to the National Institutes for Health, although vitamin D has an important role in promoting bone strength and preventing osteoporosis, it is found naturally in very few foods. Instead, consumers look to fortified foods, namely milk and dairy products, along with oral supplements to satisfy their vitamin D needs.





The "top 10" supplements, according to ConsumerLab.com include:

- 1. Vitamin D.
- 2. Magnesium.
- 3. Fish Oil/Krill Oil/Algae Oil/Omega-3.
- 4. Multivitamins/Multiminerals (including prenatal).
- 5. CoQ10/Ubiquinol/MitoQ.
- 6. Probiotics.
- 7. Vitamin C.
- 8. B-Complex.
- 9. Zinc.
- 10. Vitamin K.



Many types of supplements

According to the FDA, supplements are ingested and come in forms that include:

- Tablets.
- · Capsules.
- Soft gels.
- Gel caps.
- · Powders.
- Bars (but only if the product is not represented as a food).
- Gummies.
- · Liquids.

Regulation of Dietary Supplements

Most people who take a supplement do so on their own volition, rather than at a doctor's behest. Research reported in <u>Nutrients</u>, the open-source journal for research professionals, found primary reasons for taking a supplement include:



United States

Unlike nutraceuticals, for which there is no government definition, dietary supplements are accounted for in U.S. law. The <u>Dietary Supplement Health and Education Act of 1994</u> established a definition for dietary supplements that remains in use today: "A product (other than tobacco) that is not represented as a conventional food and

- is intended to supplement the diet;
- contains a vitamin, mineral, herb or botanical, dietary substance, or a concentrate, metabolite, constituent, extract, or combination of the above ingredients;
- is intended to be taken by mouth as a pill, capsule, powder, tablet, or liquid; and
- is labeled on the front panel as being a dietary supplement."

The FDA's authority over dietary supplements has evolved over the years. Today products are regulated as food under the Federal Food, Drug, and Cosmetic Act. As such, and similar to its oversight of nutraceuticals, the FDA generally does not take regulatory action "until something goes wrong with a product that is on the market." That said, the FDA does have authority to act when supplements are labeled incorrectly (misbranded) or contain unsafe ingredients (adulterated).

An overview of the federal regulatory process, provided by the <u>National Institutes of Health (NIH)</u> includes:

"FDA is the federal agency that oversees both supplements and medicines, but FDA regulations for dietary supplements are different from those for prescription or over-the-counter medicines.

Medicines must be approved by the FDA before they can be sold or marketed. Supplements do not require this approval.

Supplement companies are responsible for having evidence that their products are safe, and the label claims are truthful and not misleading. However, as long as the product does not contain a new dietary ingredient (one introduced since October 15, 1994), the company does not have to provide this safety evidence to FDA before the product is marketed.

Dietary supplement labels may include certain types of health-related claims. Manufacturers are permitted to say, for example, that a supplement promotes health or supports a body part or function (i.e., 'Calcium builds strong bones'). These claims must be followed by the words, 'This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Manufacturers must also follow good manufacturing practices (GMPs) which establish "minimum standards" for manufacturing, ingredient control, packaging, labeling, and distribution. With regard to labeling, dietary supplements are required to have a "supplement facts panel," as opposed to a "nutrition facts panel" that is used for foods.

According to NIH, a product can be removed from the market if the FDA determines it to be unsafe. FDA also monitors the marketplace for potential illegal products that may make false or misleading claims.

Supplement manufacturers are subject to <u>Federal Trade Commission (FTC)</u> oversight with regard to advertising and direct marketing.

Important to note, the purpose of the 1994 law was to facilitate consumer access to dietary supplements, rather than infringe on manufacturers' ability to bring products to market. Dietary supplements are "presumed to be safe," notes the Congressional Research Service (CRS), which is decidedly different from procedures in place for food additives and drugs, which must undergo a strenuous review process and document their safety and efficacy.





Canada

As noted in the prior discussion of nutraceutical regulation, <u>Health Canada</u> oversees regulation of natural health products (NHPs), which include dietary supplements.

According to the <u>Canadian Medical Association</u>
<u>Journal (CMAJ)</u>, this includes setting conditions "for licensures to produce and sell NHPs, uphold good manufacturing practices and labelling requirements, including name, dose, medicinal and non-medicinal ingredients, potential allergens, and a requirement for a natural product number (NPN)."

Dietary supplement regulation falls to the <u>Natural</u> and <u>Non-prescription Health Products Directorate</u> (<u>NNHPD</u>), which is a division of Health Canada. NNHPD regulatory protocols include:

- Premarket Assessment: NHPs are required to undergo a <u>premarket assessment</u> to demonstrate safety, quality, and efficacy.
- Product license: Every natural health product sold in or imported into Canada must have a product license from Health Canada. A manufacturer must apply for a license and, once approved, Health Canada will issue a unique 8-digit Natural Product Number (NPN) which must be displayed on the product's label. All NPNs are listed in a Licensed Natural Health Products Database, which allows consumers to review product details that include:
- Medicinal ingredients.
- Non-medicinal ingredients.
- Dosage.
- Recommended use or purpose.
- Risk information associated with the product's use.

Product license holders must ensure that it enlists a manufacturer that holds a site license (see below).

- Site license: A business wishing to manufacture natural health products in Canada must apply for a site license for its manufacturing facility.
 Once Health Canada's requirements have been satisfied, a site license will be issued, clearing the way for production to begin.
- Labelling requirements: <u>Labels</u> must feature specific details that include:
 - Product name and license number.
 - · Quantity of product in the container.
 - A complete list of medicinal and nonmedicinal ingredients.
 - · Recommended use.
 - · Dosage.
 - Any cautionary statements, warnings or possible adverse reactions.
 - Priority allergen information.
 - *Standardized product facts table.
 - *Specific font requirements.
 - *Manufacturer contact information such as a website.
 - Bilingual Information must be listed in both English and French, which are recognized as Canada's two official languages.
 - · Special storage requirements.

*New requirements that are being <u>phased in</u>. Products have until June 2028 to comply with new labelling requirements.

Good Manufacturing Practices (GMPs): In 2024, Health Canada revised its guidance for natural health product manufacturers with regard to manufacturing, packaging, labeling, and product storage. Those changes to the country's existing Good Manufacturing Practices (GMP) include new requirements for quality management, recordkeeping and traceability, testing protocols, and mandatory supplier verification.





Nutraceuticals and dietary supplements have experienced explosive growth in recent decades. Manufacturers can be found across the globe, ranging from multi-billion dollar multinational corporations, to third-party contractors, to small start-ups.





Snapshot: Nutraceutical and Dietary Supplement Companies in the United States

The United States leads the world with regard to nutraceutical and dietary supplement production, accounting for 28% of nutraceutical market revenue, and 39% of the dietary supplement market.

U.S. nutraceutical market

The nutraceutical market was valued at US\$163.7 billion in 2024, according to <u>Grand View Research</u>, and is projected to grow at an annual rate of 6.2% through 2030, when market value is forecast to exceed US\$235 billion.

Probiotics account for 33.3% of total nutraceutical revenue, as consumers seek the benefits of "good bacteria" including improved gastrointestinal health and women's health. Other leading nutraceutical categories include weight management and satiety products, along with functional beverages and products presumed to address men's health issues.

U.S. dietary supplements market

The U.S. dietary supplement industry, according to Grand View Research, was valued at US\$53.5 billion during 2023, and is expected to grow at an annual rate of 5.7% through 2030. The industry's projected 2030 value is US\$78.9 billion.

The Grand View Research analysis lists "energy and weight management supplements" as the leading category within the supplement industry, with a 67.5% market share. The use of these products, the analysis notes, "is driven by the busy, hectic lifestyles of many Americans," with consumers attracted by potential benefits that include increased metabolism, appetite suppression, and enhanced energy levels. Other leading categories include multivitamins, prenatal vitamins, and probiotics.

In terms of manufacturing, many of the world's largest nutraceutical and supplement companies are based in the United States. The market also includes many leading international companies, along with a vibrant network of innovative smaller companies. The industry is highly competitive, notes the analysis, with manufacturers "continually launching new and innovative" products that address specific consumer needs and preferences.

To put the explosive growth of the U.S. industry in context, consider that in 1994, when the Dietary Supplement and Health Education Act (DSHEA) was passed, an <u>estimated 600 manufacturers</u> marketed about 4,000 products. Today almost 200,000 products are listed in the National Institutes of Health's <u>Dietary Supplement Label Database</u>.



Snapshot: Nutraceutical and Dietary Supplement Companies in Canada

Natural health products, which include both nutraceuticals and dietary supplements, are quite popular among Canadians, with an estimated 75% of the population using at least one product on a regular basis.

Canada's nutraceutical industry

Canada's nutraceutical industry accounts for 2.5% of global production and in 2023 was valued at US\$7.8 billion. The industry is projected to grow at an annual rate of 8.7% over the next several years, with a forecast value of US\$14.03 billion by 2030.

According to <u>Grand View Research</u>, functional foods account for 37.6% of the country's nutraceutical industry, with several companies actively engaged in research and new product development. Other important sectors include weight management & satiety products, which account for 20.5% of nutraceutical revenue, along with "men's health nutraceuticals," which are projected to grow at an annual rate of 15.6% through 2030.

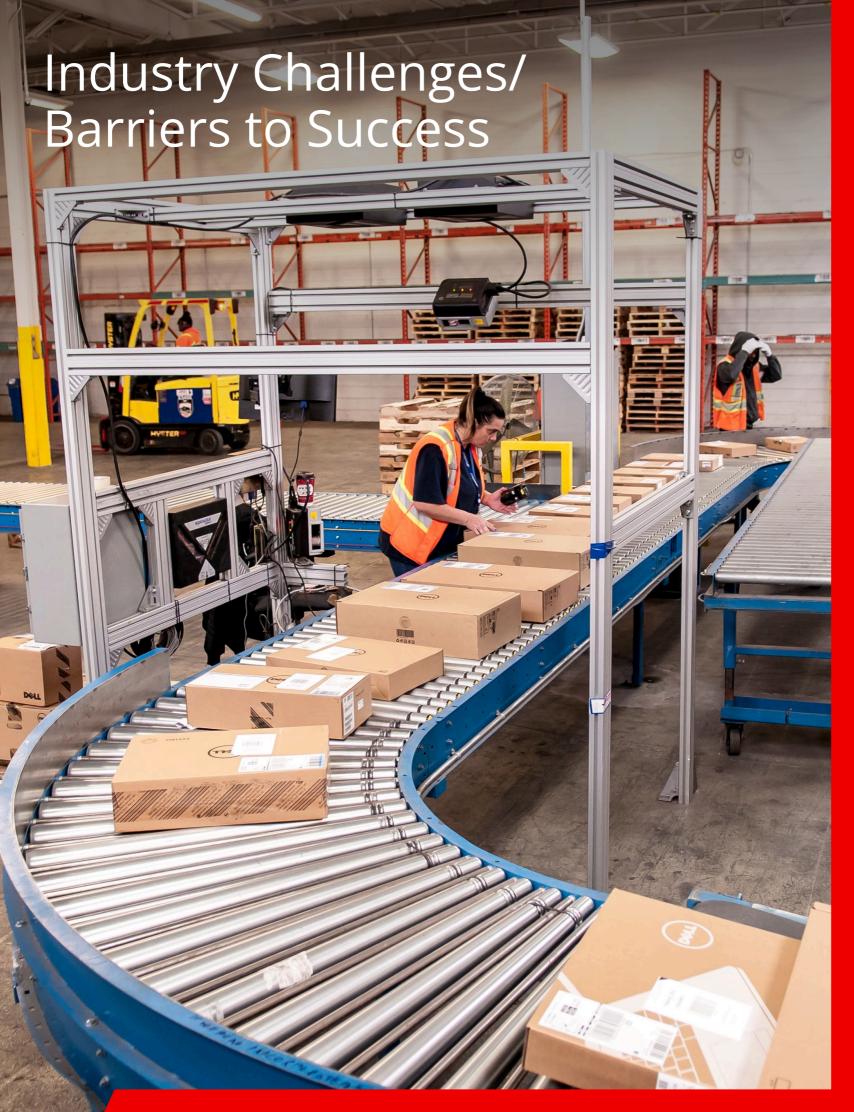
Canada's dietary supplement industry

Canada's dietary supplement industry accounts for 1.8% of global production, with a 2024 market value of US\$3.4 billion. Grand View Research forecasts an annual growth rate of 6.9% through 2030, with a projected value of US\$5.04 billion.

Vitamins are the largest category within the dietary supplement industry, accounting for 29.4% of 2024 revenue. Other important categories include botanicals, minerals, proteins & amino acids, fibers & specialty carbohydrates, and probiotics.

Canada's growing manufacturing industry services not only domestic demand, but can be found in consumer homes around the world. Certain geographic regions, Edmonton, for example, have embraced the surge in natural health product popularity, and actively encourage investments in nutraceutical and dietary supplement manufacturing. "The Edmonton Metropolitan Region," notes the local government's website, "has all the ingredients needed to attract international investment into the growing nutraceutical industry." Overall, the federal government's Inspector General notes that more than 91,000 licenses for natural health products have been issued since 2004.





Although nutraceuticals and dietary supplements have been embraced by consumers worldwide, several factors potentially pose a risk to their continued success. A few of those factors include:



Changing Public Perceptions

Because nutraceuticals and supplements are made from foods and naturally occurring products, consumers generally believe they are safe options for diet and health purposes. 2023 research by the Council for Responsible Nutrition (CRN), a trade association for the dietary supplement industry, found that 92% of consumers who use supplements consider them "essential to maintaining their health," with 84% saying they had "trust" in the dietary supplement industry. In fact though, notes the FDA: "Many supplements contain ingredients that can have strong effects in the body." This includes certain products that may interact with medications or other supplements, interfere with lab tests or have dangerous effects during surgery. The National Institutes of Health notes that vitamin K, for example, may reduce the ability of blood thinner warfarin to prevent blood from clotting, while antioxidant supplements such as vitamins C and E, could reduce the effectiveness of certain cancer medications. Any significant uptick in harmful effects could affect the public's otherwise strong embrace of the natural health products market.



Adverse Reactions

Research by the <u>Centers for Disease Control (CDC)</u> found over 23,000 emergency department visits were related to dietary supplements. Of that amount, more than 2,100 resulted in hospitalizations. These findings, the <u>study's</u> authors said, demonstrate the need for increased

consumer awareness about potential dangers, and for heightened regulation of the industry. This lack of regulation has left consumers susceptible and manufacturers at risk of litigation. Reporting by SupplySide Supplement Journal noted that dietary supplement companies were the focus of 58 class action lawsuits filed in 2024, and 62 filed during 2023. "Nearly half (45%) of the dietary supplement lawsuits in 2024 were tied to so-called 'false fact claims,' such as claims pertaining to statements like 'clinically proven' or claims contending the purported benefit of the product is false," the report explained. In December 2024, for example, Quincy Bioscience, manufacturer of dietary supplement Prevagen was ordered by a federal court to stop claiming the product improved memory or cognitive function.



Consumer Distrust

Analysis by <u>PricewaterhouseCoopers</u> cites an increase in consumer distrust that has resulted from "the use of deceptive advertising and communication strategies by some companies. The dishonest practices of some companies, the analysis notes, threatens to tarnish the reputation of the entire industry and could open the door to additional regulation.



Counterfeit Products

The <u>PricewaterhouseCoopers</u> analysis cites an increase in counterfeit and fake products that have found their way onto the consumer market. Illicit products, the analysis notes, use "low-cost non-standard materials and are not tested or approved by regulatory authorities," and represent a major challenge for legitimate manufacturers.



Global Trade Factors

Nutraceutical and dietary supplement manufacturers increasingly export products to consumers throughout the world. Manufacturers also rely on international suppliers for ingredients including proteins, minerals, vitamins, and other materials. As such, the industry is vulnerable to any changes in global trade practices. This includes a series of import tariffs implemented by the United States in April 2025. In a survey conducted shortly before the tariffs were announced, Nutraceuticals World found that 44% of manufacturers expected to adapt to the increases by "implementing price adjustment strategies," while 23% said they expected to diversify their supplier bases, and 18% said they would look for domestic manufacturing alternatives.

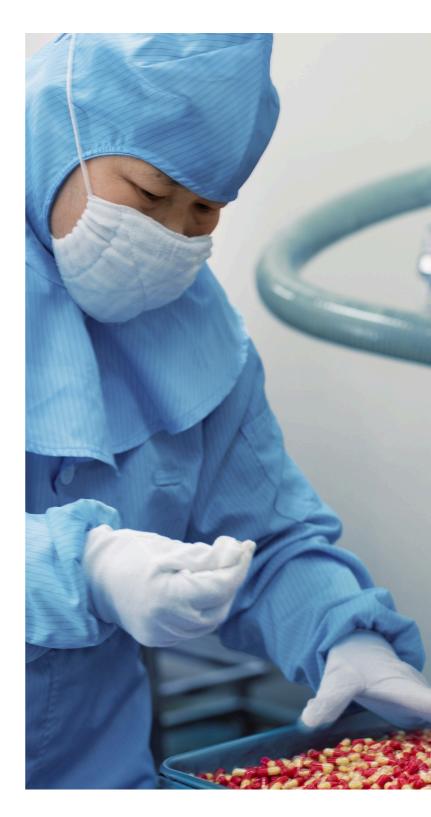


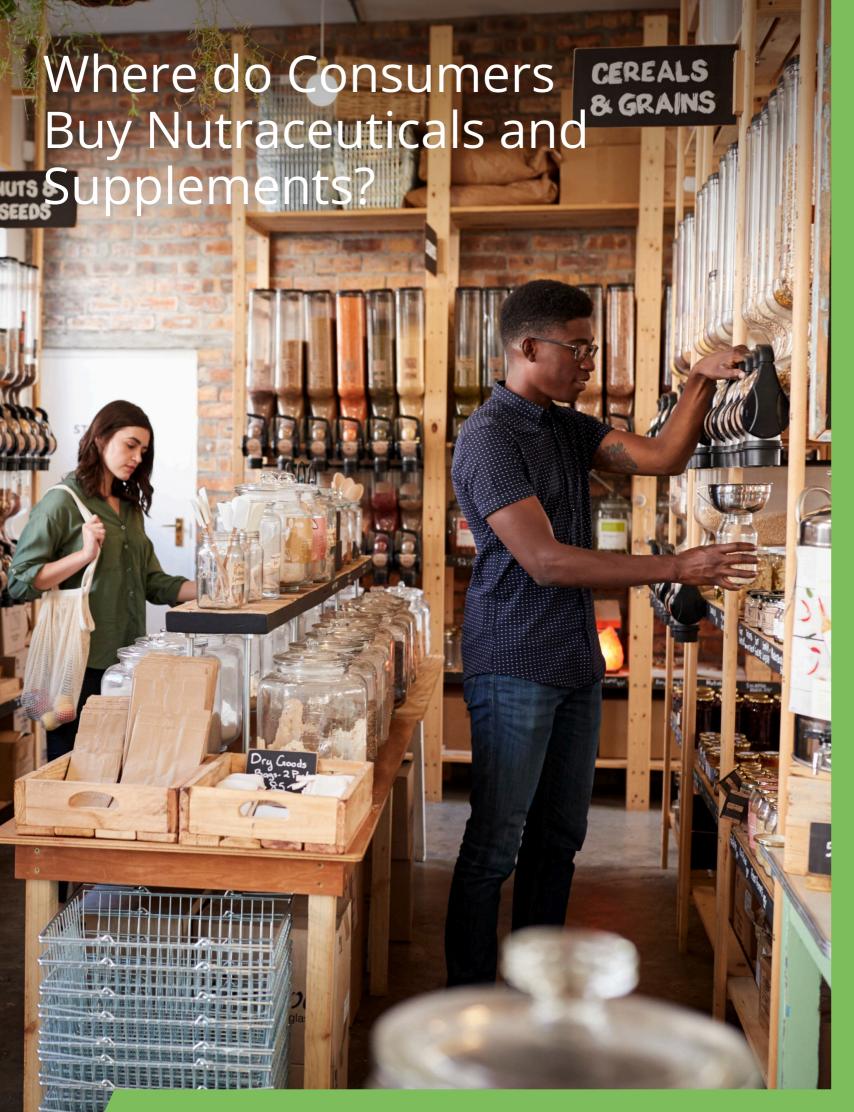
Supply Chain Integrity

As the industry expands, and manufacturer supply chains become more complex, the risk of quality-related issues may increase. According to the American Medical Association, "the supply chain link between manufacture and distribution of dietary supplements can involve multiple ingredient suppliers, brokers, and domestic and international contract manufacturers. Supply chain complexity can obscure tracking of ingredients' lineages and identities of parties involved in producing a single supplement."

In the United States, the FDA inspects, on average, just <u>five percent</u> of supplement manufacturing facilities each year. Of that amount, the FDA reported that in 2022, <u>40% were found to be in violation</u> of current good manufacturing processes.

Similarly, an <u>audit by Canada's Inspector General</u> found that Health Canada "did not always verify that manufacturing facilities followed good manufacturing practices." Among areas in need of improvement, the audit found high levels of noncompliance with manufacturing practices, and "product quality problems" at sites visited.





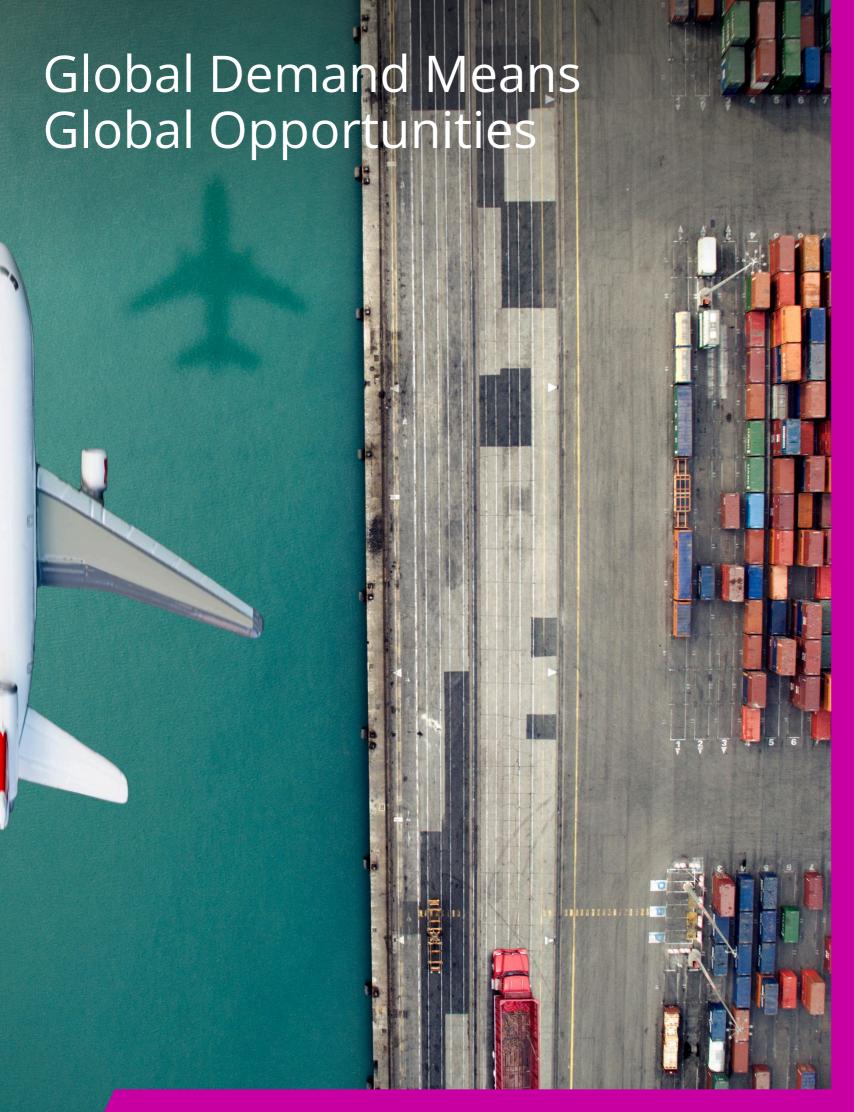
Unlike pharmaceuticals, nutraceuticals and dietary supplements do not require a prescription and are generally available in supermarkets, pharmacies, convenience stores, and through e-commerce retailers. According to the Council for Responsible Nutrition (CRN), consumers take advantage of convenient buying options, with purchasing preferences that include:

- Mass merchandisers (i.e., Walmart, Target) 46%.
- Drugstore or Pharmacy 39%.
- Supermarket 24%.
- · Warehouse club 21%.
- Specialty Vitamin Retailer (i.e., health stores) 18%.

Specific to e-commerce, CRN reports that almost 80% of supplement users have purchased supplements from Amazon during the past year.

Other online options include 22% of consumers who make purchases directly from a supplement manufacturer's website, and 23% who have purchased from "other online retailers."





U.S. and Canadian manufacturers are responding to worldwide demand for nutraceuticals and dietary supplements by seeking out customers located beyond North America. Quebec-based <u>Fruit d'Or</u>, for example, boasts a 60% share of the world organic cranberry market, and cites Europe, followed by China, as its largest markets. "Three years ago, we weren't there at all, but the market is rapidly evolving," the company's sales director explained on the <u>Fruit d'Or website</u>.

The market, it seems, is evolving everywhere. <u>Grand View Research</u> provides a snapshot overview of significant international activity that includes:

Country	Nutraceuticals % Share of Global Market/CAGR (through 2030)	Nutraceuticals 2023 Market Revenue (USD)	Dietary Supplements % Share of Global Market/CAGR (through 2030)	Dietary Supplements 2023 Market Revenue (USD)	Largest segments
United States	27.9% 7.5% CAGR	\$88.3 billion	<u>29.3%</u> 5.9% CAGR	\$54.8 billion	-Probiotics -Vitamins
Canada	2.5% 8.6% CAGR	\$7.8 billion	<u>1.8%</u> 6.9% CAGR	\$5.0 billion	-Probiotics -Vitamins
Mexico	<u>4.5%</u> 9.1% CAGR	\$14.4 billion	<u>0.9%</u> 6.3% CAGR	\$1.7 billion	-Probiotics -Vitamins
Brazil	<u>2.7%</u> 11.2% CAGR	\$8 .6 billion	<u>3.4%</u> 9.8% CAGR	\$6.4 billion	-Probiotics -Vitamins
India	<u>8.5%</u> 13.4% CAGR	\$26 billion	<u>3.6%</u> 14.4% CAGR	\$6.7 billion	-Probiotics -Vitamins
Japan	3.5% 14.2% CAGR	\$11.1 billion	<u>10.8%</u> 13.2% CAGR	\$20 billion	-Probiotics -Vitamins
China	<u>11%</u> 10.5% CAGR	\$34.7 billion	<u>14.7%</u> 12.5% CAGR	\$27.4 billion	-Probiotics -Vitamins
France	2.5% 9.3% CAGR	\$7.8 billion	<u>2.2%</u> 6.7% CAGR	\$4.1 billion	-Probiotics -Vitamins
Germany	<u>5.0%</u> 7.7% CAGR	\$15.8 billion	<u>3.6%</u> 7.4% CAGR	\$6.7 billion	-Probiotics -Vitamins
United Kingdom	<u>4.3%</u> 8.4% CAGR	\$13.7 billion	<u>2.2%</u> 7.9% CAGR	\$4.1 billion	-Probiotics -Vitamins

The global appeal of nutraceuticals and dietary supplements means manufacturers have vast opportunities to expand to new markets. For U.S. and Canadian companies, this can mean taking advantage of the two countries' proximity and established trade relationship to pursue crossborder opportunities. Increasingly though, businesses are looking beyond North America to tap into global trade opportunities either through e-commerce or by forging relationships with retailers and suppliers in those markets.

As the above chart makes clear, consumers can be found throughout the world, along with manufacturers, suppliers and partners.

Success in the worldwide market though, requires careful planning that takes into account market nuances and customs requirements. And critically important, success requires a comprehensive logistics strategy that accommodates specific nutraceutical and dietary shipment needs.







Both the U.S. and Canadian governments offer extensive resources for businesses interested in pursuing international trade opportunities.

Free Trade Agreements

A good place to start is by reviewing each country's free trade agreements (FTAs). These are the agreements entered into with other countries that reduce or eliminate trade barriers as a way to promote trade activity. U.S. and Canadian businesses are undoubtedly familiar with the United States-Mexico-Canada Agreement (USMCA) which sets the terms for trade between the three countries, including duty-free status for qualified products. That agreement, which took effect in 2020, replaced the North American Free Trade Agreement, which was in place from 1994-2020.

Beyond the USMCA, free trade agreements give U.S. and Canadian businesses access to dozens of other markets. Canada currently has <u>15 FTAs</u> in effect that provide access to <u>1.5 billion consumers</u> worldwide, and more than 60% of the world's GDP. This includes the <u>Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)</u> which facilitates trade between Canada and more than 500 million consumers located throughout 11 other countries including Australia, Japan, Singapore and, most recently, the <u>United Kingdom</u>. The United States has <u>14 FTAs</u> in force that affect trade with 20 countries.

United States Import and Export Resources

U.S. manufacturers can access materials that include:

Basic Information: The U.S. Customs and Border Protection (CBP) agency offers extensive information about importing to and exporting from the United States. Nutraceutical and dietary supplement manufacturers can use this information to familiarize themselves with customs mandates, including the types of required information and documentation. In general, required documentation will include a commercial invoice and shipment specific information including a tariff classification code, product valuation, and accurate country of origin.

• Partner Government Agencies: In addition to CBP, nutraceuticals and dietary supplement shipments will require review by the Food and Drug Administration and possibly other government agencies. Such agencies are referred to as "partner government agencies," and include the dozens of entities that have authority over imports and exports of products under their jurisdiction. Specific to nutraceuticals and dietary supplements, FDA requirements ensure proper labeling, use of approved ingredients, and adherence with Good Manufacturing Practice Standards, among other factors.

• Centers of Excellence and Expertise:

Businesses can ensure compliance with all customs requirements by consulting the appropriate Center of Excellence and Expertise. CBP maintains 10 different centers, with each focused on specific industries. Each center is staffed by industry experts who offer guidance and direction for importing and exporting products that fall under their jurisdiction. Depending on a product's ingredients and characteristics, nutraceuticals and dietary supplements may fall under the scope of the New York center, which specializes in "pharmaceuticals, health & chemicals," or the Miami center, which oversees shipments of "agriculture & prepared products."

Country Commercial Guides: The U.S.

International Trade Administration offers detailed "country commercial guides" for more than 125 countries. Each guide provides insight about market conditions, industry opportunities, leading sectors, regulatory environment, and business customs.

International Market Research: Businesses can access international market intelligence reports, also produced by the International Trade Association, to keep apprised of market data and potential opportunities in dozens of countries.

National Trade Estimate Report: The Office of the U.S. Trade Representative (USTR) publishes the National Trade Estimate Report (NTER) which is "an annual report detailing foreign trade barriers faced by U.S. exporters," along with USTR actions to counter those barriers. The most recent NTER was released in March 2025.

U.S. Export Assistance Centers: The Small Business Administration maintains a network of Export Assistance Centers throughout the United States that support small businesses interested in pursuing export opportunities.

This partial listing is in addition to import and export resources offered by each state and often, through business organizations including the <u>U.S.</u>

<u>Chamber of Commerce</u>, the <u>Consumer Healthcare</u>

<u>Products Association</u>, and the <u>Council for</u>

<u>Responsible Nutrition</u>.

Canada Import and Export Resources

Canadian businesses can learn about import/ export requirements and identify potential international opportunities through resources that include:

Basic Information: Canada Border Services
Agency (CBSA) publishes detailed information
about Canada's commercial goods import and
export processes. That information is available
online, but the following is a brief overview.





For imports, required steps include:

- 1. Obtain a business number from the <u>Canada</u> <u>Revenue Agency</u>.
- 2. Set up an account with <u>CBSA's Assessment and</u> <u>Revenue Management (CARM) system</u> which is the official system for the collection of duties and taxes.
- 3. Identify the goods to be imported and gather as much information about those products as possible.
- 4. Determine if a licensed customs broker will be used. Customs brokers facilitate the import process with services that include:
- · Overseeing the release of goods from CBSA;
- · Payment of duties;
- Preparation and transmission of required documentation;
- Record keeping; and
- Responding to any CBSA concerns.
- 5. Determine the country of origin for the goods to be imported.
- 6. Identify the correct tariff classification code as located in the <u>Canadian Customs Tariff</u> listing.
- 7. Determine if goods are subject to additional oversight. Similar to the US process, Canadian goods may be subject to oversight by government agencies which are referred to as "other government departments (OGDs).

 Specific to nutraceuticals and dietary supplements, this may require compliance with protocols from Health Canada and the Canadian Food Inspection Agency, and possibly other entities with regulatory authority.



For exports, required steps include:

- Identify the goods to be exported. This
 includes determining if the goods are eligible
 for export, and eligible for entry into the
 intended country.
- 2. Determine if an "export declaration" and/or permit is required based on whether a product meets the definition of a <u>restricted</u> good, <u>special good</u>, or <u>regular good</u>. According to CBSA, most products will require an export declaration. Two common exceptions include:
- Goods exported for consumption in the United States; and
- Non-restricted goods valued at less than C\$2,000.
- 3. Submit the export declaration with accurate information that includes:
- Valid business number as issued by the <u>Canada Revenue Agency</u>;
- Tariff classification number from the <u>Canadian</u> <u>Customs Tariff</u> listing.
- 4. Determine which of CBSA's two reporting methods will be used to submit the export declaration. Options include:
- · Canadian Export Reporting System (CERS).
- <u>G7 Electronic Data Interchange Export</u> <u>Reporting (G7-EDI)</u>.
- 5. Once a submission is made, the CERS and G7-EDI system will issue a "proof of report number." That number must be provided to a shipment's carrier.

Country Specific Overviews. The Trade

Commissioner Service produces <u>detailed market</u> <u>overviews</u> for several dozen countries. Each overview includes a market summary along with information about key industries/sectors, and updates about Canada's trade relationship with that country.

Export Guides. The Trade Commissioner Service also publishes online a <u>series of guides</u> that a business can use to develop its export strategy. Featured topics include:

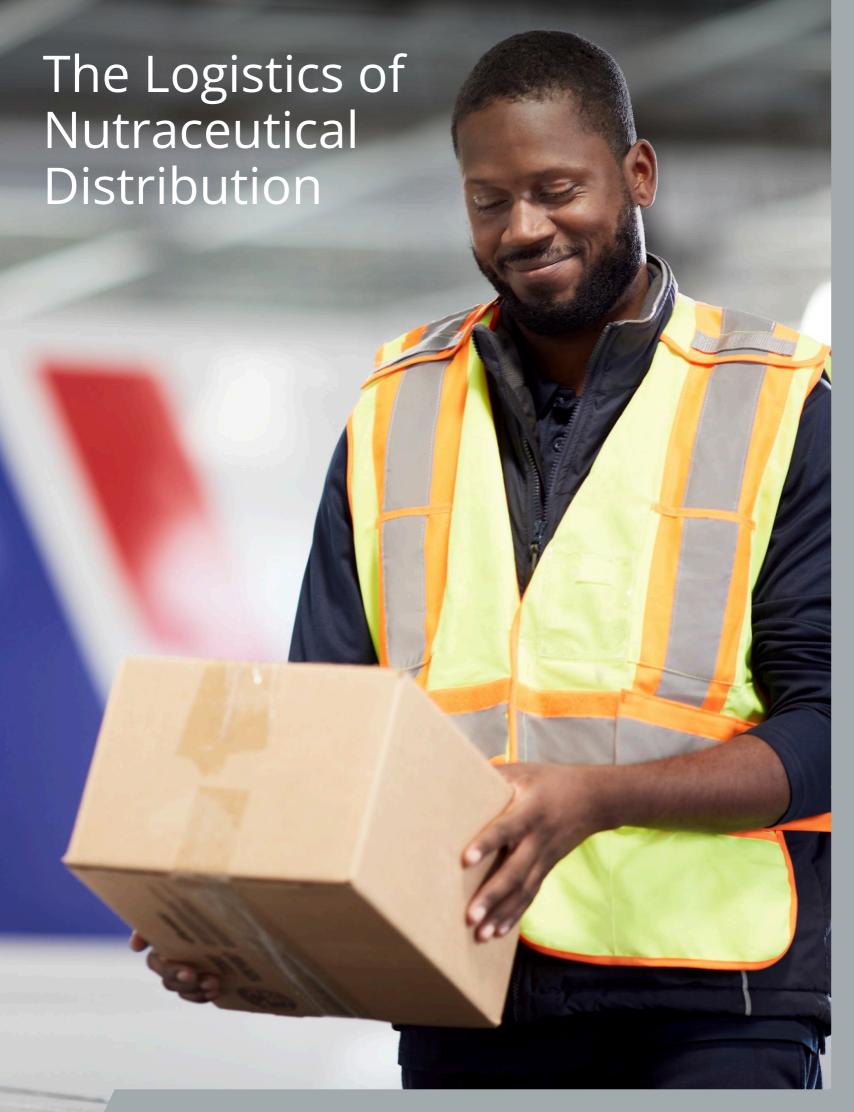
- F-commerce.
- Canada's free trade agreements Regional overviews.
- International finance opportunities.

Trade Offices. Businesses can visit one of the more than 160 Trade Commission offices located throughout the country. Offices are staffed by experienced trade professionals who offer guidance and insight about international opportunities for a particular business or industry.

Export and Import Controls. Global Affairs
Canada provides an updated listing of all products
subject to import and export controls. Should a
product be subject to control, information is
provided about the additional authorizations and
requirements that need to be satisfied in order to
obtain necessary permits and/or licenses.

This partial listing of federal government resources is in addition to trade-related assistance offered through each province. In addition, nutraceutical and dietary supplement manufacturers can consult business organizations such as the <u>Canadian Health Food Association</u> (CHFA) and the <u>Canadian Chamber of Commerce</u>.





As U.S. and Canadian businesses consider expanding to international markets, a comprehensive logistics strategy must be integral to the planning process. Afterall, without a solid plan to ensure on-time, quality deliveries to customers – regardless of where in the world they are located -- a business essentially enters an international market at a disadvantage. It's essential then, to select a logistics provider that not only services the required geographic regions, but does so with innovative solutions that support the unique needs of the nutraceutical industry.



What exactly are those unique needs? A few considerations include:



Omnichannel fulfillment.

Consumers have demonstrated their preference for an "all of the above" strategy when it comes to where and how nutraceuticals and dietary supplements are purchased.

This includes traditional in-store venues along with e-commerce options, including online purchases from international retailers.

Overall global e-commerce is surging, with expectations that cross-border sales will reach <u>US\$3.3 trillion</u> by 2028. This, as more of the world's population gains online access and retailers expand their international footprints.

While nutraceuticals will certainly benefit from e-commerce opportunities, including online subscription services, consumers still favor instore purchases. For businesses expanding to international markets, this means a carefully-managed inventory strategy, along with flexible logistics solutions that can accommodate a wide range of service needs – throughout the world.



Regulatory considerations.

Nutraceutical and dietary shipments are subject to extensive regulations with regard to ingredients, product safety, health claims, manufacturing practices, labeling, and recordkeeping, among other requirements.

And regulations will vary every time a product crosses an international border. Businesses must have fail-proof processes in place to identify all regulatory obligations, ensure full compliance, and oversee reporting of required documentation and proper recordkeeping.



Inventory management.

Nutraceuticals and dietary supplements often include ingredients with strict "sell by" dates, which means businesses need full visibility into their inventories, including real-time access to expiration dates and the ability to segment products based on consumer demand.



Proper packaging.

Products come in a variety of containers and forms, including everything from liquid juices and smoothies to pills/capsules to packaged cereals and powders. All products must be shipped in appropriate packaging that ensures safety, minimizes the risk of product damage, and satisfies regulatory requirements.



E-Commerce/Fulfillment accuracy.

As e-commerce becomes an increasingly popular purchasing option, nutraceutical and dietary supplement companies must take steps to ensure fulfillment accuracy. In addition, since consumers often purchase multiple products during a single online visit, businesses should ensure inventory is available to complete an order in a single package. This avoids the additional costs of multiple shipments, reduces packaging, and better meets consumer expectations.



Returns Management/Safe disposal.

Businesses must also plan for an unavoidable volume of product returns. For nutraceutical and dietary supplement businesses, a returns management plan must accommodate products that have been opened, partially consumed, or that have exceeded their expiration date and cannot be resold. Such products require a safe disposal process that meets all regulatory requirements, including accurate recordkeeping.



Shipment Security.

Cargo theft reached <u>"unprecedented levels"</u> during 2024, with thieves utilizing increasingly sophisticated methods to steal products at various points in the distribution process.

Consumer products including nutraceuticals and dietary supplements are especially vulnerable since they are highly popular and can quickly be sold on a secondary market. Shipment theft is a worldwide problem, which means security must be a priority for any business engaged in cross-border sales.





Logistics Solutions that Deliver Innovation and Efficiency

Logistics providers have responded to the needs of nutraceutical and dietary supplement businesses with <u>increasingly sophisticated solutions</u>. This includes, for example, the ability to ensure on-time deliveries to consumers and businesses located just about anywhere in the world.

However, not all companies are the same, so a business will need to carefully review a logistics provider's capabilities to ensure it is a "match" with its service needs. For many nutraceutical and dietary supplement businesses, Purolator is the logical choice for their international shipping needs. This includes shipments moving between the United States, Mexico, and Canada as well as products destined for overseas markets. As these businesses have come to appreciate, Purolator offers extensive capabilities throughout the world, with the highest levels of efficiency, accountability, and dependability. A few "Purolator advantages" include:

Customized solutions. Every Purolator
customer undergoes an extensive consultation
in which detailed information is exchanged
about a business's operations and priorities.
That information is used as the basis for a
customized solution that addresses specific
needs and nuances. Plan components might
include, for example, evening pickups, or a
hybrid solution that combines air and ground
services for time-sensitive deliveries.

Another option could enable U.S. businesses to fulfill Canadian market orders from a U.S. distribution center. No two solutions are ever the same. Instead, businesses are assured of innovative solutions that meet their precise needs, regardless of where in the world a delivery needs to be made.

• Extensive Service Portfolio. Purolator has long prioritized the unique shipping needs of healthcare products including nutraceuticals and dietary supplements. This commitment to extra care begins with a "H+" label that flags each shipment and ensures priority processing. Each package also includes a barcode that is embedded with identifying information and enables real-time visibility and accountability throughout the distribution process. The H+ identifier is especially helpful during the last mile of service, when shipments are assured of extra care that may include inside deliveries, chain of custody, or special handling, among other services.

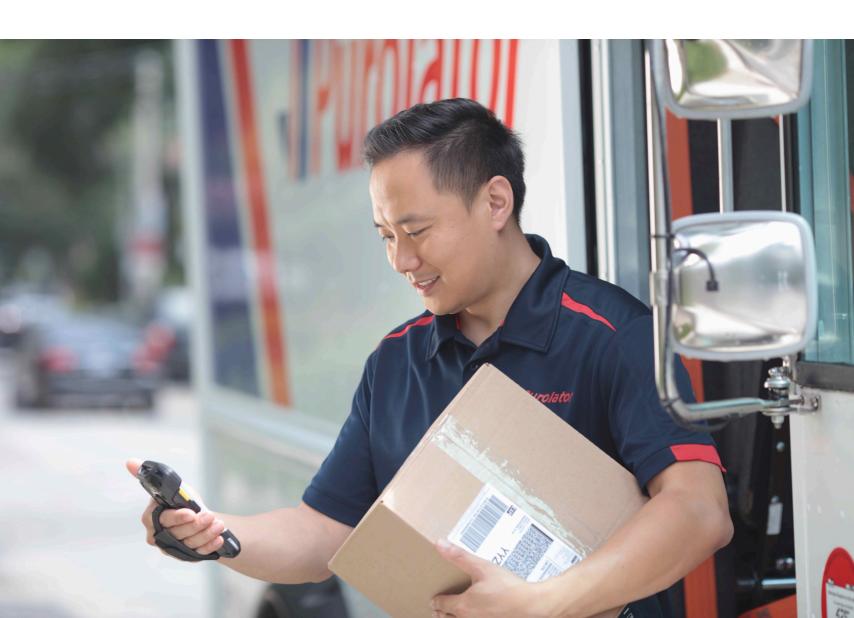
Businesses can access Purolator's extensive service portfolio to select the ideal solution for their shipments. This includes, for example, access to "mission critical" air services for time-sensitive, high value, or fragile shipments; courier services that can accommodate e-commerce deliveries to consumers' homes along with just-in-time deliveries to manufacturing facilities, health centers, or retail locations; freight services; last mile services that prioritize special handling, or any combination of these services.

Businesses can count on Purolator for end-to-end services to just about anywhere in the world. One logistics company, multiple service options, global coverage, full visibility and guaranteed service.

- Omni-Channel Platforms. Omni-channel services require special logistics capabilities including warehousing, fulfillment services, and inventory allocation and management.
 Purolator manages the "alphabet soup" of omni-channel needs that can include:
- BOPIS Buy online, pickup in store.
- BOSS Buy online, ship from store.
- BORIS Buy online, return in store.
- STS Store-to-store transfers.

Extensive Customer Pickup Options. Flexibility and convenience consistently top consumer "wish lists" with regard to where and when packages are received. In Canada, Purolator meets those expectations with an extensive network of more than 3,000 access points that include:

- Purolator retail centers.
- Authorized shipping agents.
- Drop boxes, lockers, and kiosks.
- Partnerships with retail stores and third-party dropoff/pickup providers.
- Extensive tracking and delivery options.
 Enterprise shippers have the option to develop a profile within <u>Purolator Vision</u> to take advantage of end-to-end visibility for tracking shipments. This includes real-time dashboard access to critical delivery information and status updates, along with proactive shipment notifications.



Key feature of Purolator Vision for large enterprise shipping



Near "real-time" package tracking



Visibility for all Purolator Registered packages



Tracking and exception reposting for shipments



Enhanced customer satisfaction and reduced support queries



Customize & save user views and report format



Proactive notifications on your shipments



Learn more about Purolator Vision and how it can serve you and your business with streamlined shipping and delivery reporting.



Another solution is <u>Purolator Your Way™</u>, which allows shippers and receivers to customize delivery preferences, thus ensuring deliveries are never missed. Key capabilities include:

- · Remote signature release.
- Options for adding delivery location information such as buzzer codes.
- The ability to choose a preferred delivery dropoff location (e.g. front door, garage).
- Capacity to provide specific instructions, even when a delivery is on its way.

"Hold for Pickup" options, which allow endreceivers to select a preferred pick-up location from one of over <u>3000 access points</u> across Canada.

Key feature of Purolator Your Way™ for home deliveries and businesses



Total visibility of shipment journet



Clear next steps for missed delivery



Customizable delivery preferences



Remote signature release*



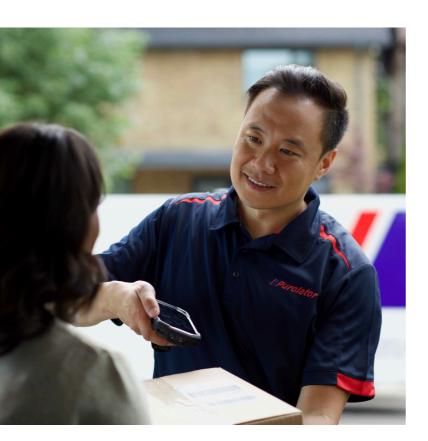
No app download required



Photo proof of delivery



- Inventory Segmentation. Nutraceutical and dietary supplement businesses must carefully monitor inventory with regard to product expiration dates, replenishment of top-selling products, and reliable access to slower-moving products. Purolator assists businesses with technology-based forecasting, which tracks onhand products, allocates products based on expiration, and helps project demand.
- Consolidation. Although this is not necessarily a "new solution," consolidation is more important than ever in adding efficiency to shipments moving from the United States into Canada. In a traditional consolidation model, smaller shipments are combined to form a single, larger unit with benefits that generally include improved transit time and reduced freight costs. Purolator improves on that model with capabilities that allow a business to load all Canada-bound shipments courier as well as freight onto a single truck. This is a gamechanger with benefits that include:



Reduced costs. Businesses no longer need to arrange separate trucks for courier and freight pickups. Instead, all shipments are picked up at the same time via a single truck, with the larger consolidated shipment qualifying for a lower freight rate.

Improved transit time. The consolidated shipment moves directly to the border with no additional stops or pickups. It's not unusual for a shipment to arrive in Canada on the same day as its U.S. pickup.

Customs efficiency. Consolidation is especially beneficial during the customs process.

Consolidated shipments are listed on a single-entry form, clear customs as a single unit, and are assessed a single fee. Alternatively, for non-consolidated shipments, paperwork must be completed and filed for each individual unit. Each unit must then be evaluated by customs personnel, pay duties and fees, and wait for final clearance.

Fast, direct deliveries throughout Canada. Once in Canada shipments enter Purolator's extensive distribution network which ensures direct, innetwork service to all provinces and territories. Shipments remain within the Purolator network which ensures visibility, accountability, and the highest levels of service.

Clearly, when it comes to <u>cross-border shipping</u> <u>into Canada</u>, consolidation can be a real gamechanger. Not every logistics company has the resources to offer the service, but given the potential benefits, it's worth investing the time to enlist a provider that does.



<u>Learn more</u> about consolidation efficiency.

• Geographic Reach. Many businesses have been surprised to do the hard work of enlisting new international customers only to experience difficulty finding a suitable logistics provider. This includes U.S. businesses that expand to the Canadian market but quickly learn that most carriers limit service to certain geographic regions. With regard to Canada, these service limitations are largely due to the relatively small size of the population – 40 million people – spread across a geographic area that is second in the world only to Russia. Maintaining a distribution network is expensive, and requires vast networks of vehicles, facilities, and personnel. Purolator is an exception in that it services the entire country. The Purolator distribution network includes all 10 provinces and 3 territories with guaranteed service to 100% of the country's postal codes. Shipments remain "in network," which means U.S. businesses never have to worry about losing track of a package or having to juggle multiple regional carriers.

On a global basis, Purolator partners with local companies that offer similarly high levels of service throughout the geographic regions they service. Through this global network, Purolator fills a critical need for U.S. and Canadian businesses with customers and suppliers located throughout the world.

• Customs Efficiency. Customs is an unavoidable part of international trade, but there are ways to facilitate compliance and reduce, sometimes even eliminate costs. This is especially applicable in 2025, as the U.S. and Canada trade relationship has come under review, and businesses face a period of uncertainty with regard to tariff rates and trade obstacles.



Purolator offers extensive capabilities that include:

- Internal trade specialists. A team of experienced trade experts ensure accuracy of shipment information and identify opportunities for customs-related efficiencies and cost savings.
- Livingston International Trade Services. In early 2025 Purolator expanded its global expertise with the acquisition of Livingston International. Livingston is a leader in the trade services and customs brokerage industry with unmatched regulatory and customs expertise for markets including Canada, the United States, Mexico, Europe and Asia. Businesses can rely on Livingston's decades of experience to help identify international opportunities, and ensure products meet all international regulatory and customs requirements.
- Tariff Classification Lookup Tool. Tariff classification codes determine a product's rate of tariff, including eligibility for duty free status under free trade agreements. But identifying the correct code can be quite difficult, which often results in improper duty assessments. Purolator provides customers with a "quick fix" through its online Trade Assistant tool. Customers can access the online tool to determine a product's correct classification code, which can then be used on customs documentation.





Every year since 1997, thousands of representatives of the nutraceutical industry have participated in an industry trade show called <u>Vitafoods™ Europe</u>. Billed as "the world's nutraceutical event," the gathering draws participants from more than 160 countries and offers an opportunity to network, tap into industry trends, and potentially build new partnerships for business growth.

Perhaps not surprisingly, the Vitafoods Europe event is promoted on the <u>U.S. International Trade</u>

<u>Association</u> website. "Unlock new business opportunities," a notification reads, adding that "this is where you need to be" if you're interested in new partnerships, products and solutions.

As the size and scope of this trade show – and the endorsement of the U.S. government make clear – the nutraceutical industry is booming, and opportunities are there for motivated U.S. and Canadian businesses. As businesses consider their international strategies, they can be assured that Purolator, the industry's trusted choice for logistics innovation, stands ready to help.





Learn how Purolator can optimize your healthcare strategy.

Speak to an expert

