



**DIETARY SUPPLEMENTS; PRESENT SCENARIO AND FUTURE PERSPECTIVE**

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**Abstract**

In recent few years, the use of dietary supplements has escalated, the trend being almost equivalent throughout the world this is evident from an exponential increase in their market investment before covid pandemic period. After corona pandemic period, the combination of different herbs with a claim to augment immunity against infection is contributing to a major investment in the market share of dietary supplements. Dietary supplements are used by athletes and sportsmen to increase their physical performance while in the general population, multimineral, multivitamin, and omega-3 fatty acids are consumed to supplement the daily intake of these vital nutrients. Some herbal extracts have been used by people to revert weight gain while some antioxidants have been used to delay the aging process. The present study succinctly describes dietary supplements in health and diseases, boosting immunity, sports, their side effect, and regulations in India, EU (European Union), and the US (United States), and a survey about people's perception of dietary supplements.

**Keywords-** Dietary supplements, Regulations, Survey, Multivitamin, Nutrients.

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**Dietary Supplements**

Food is an indispensable part of human life to maintain sustainable growth. Food with health benefit and the ability to alter the biological function of the human body or helps in disease risk reduction are known as functional foods, nutritional or dietary supplements. Dietary supplements are designed to deliver or supplement the nutrition that may have deficit quantities in the food (Eufic, 2022). As per DSHEA (Dietary Supplement Health and Education Act), Dietary supplements can be a mineral, herbs, vitamins, amino acids, fatty acids, extracts, and a combination of these ingredients. Dietary supplements are usually delivered to consumers in the form of tablets, capsules, powders, pills, liquids, etc. The human body requires only a definite amount of nutrients to function properly and exceeding this amount may lead to harmful effects. Thus, to ensure the safety of consumers, supplements should only be sold with a recommended daily dose and should contain a warning statement on the label not to exceed that dose (Eufic, 2022), (Vector Consumer, n.d.).

### **Dietary supplements in Health and Diseases**

Insufficient quantities of nutrition in diet and micronutrient deficiencies are the most frequent causes that affect health. However, a number of dietary supplements are available in the market to address these issues. Dietary supplements could prominently help to make up for the deficiencies of nutrition and thus, help in health benefits and prevention of diseases (Shahidi, 2012).

### **Supplements for bone health and prevention of osteoporosis**

Osteoporosis is a condition in which bones become brittle and weak and thus, affects bone density. It generally results when the osteoclastic activity overtakes the osteoblastic activity i.e., bone resorption exceeds bone formation. The cycle of bone being broken and reformed is known as bone remodelling and this process requires a sufficient supply of nutrients (McGrane, 2021). Dietary supplements contain a broad range of products that have ingredients (certain nutrients) to prevent osteoporosis or to improve bone health. Their ingredient includes 1) **Major vitamin and minerals:** Vitamin D, Calcium, Magnesium, Vitamin C, and Vitamin K. 2) **Other nutrients in bone health:** Fluoride, Boron, Copper, Manganese, Zinc, and Strontium (Garriguet, 2011).

### **Vitamin D**

Vitamin D is vital for bone health and plays an important role in calcium absorption. Food sources of vitamin D are limited in number which includes fortified dairy products, cereals, and fatty fish. Most people rely on sunlight exposure for their vitamin D requirement however, this is not practically possible because the formation of vitamin D requires direct exposure of sunlight to the human skin as most of the human body is covered by clothes, people are usually deficient in vitamin D. It has been found in a study that people suffering from osteoporosis are more likely to be a deficit in vitamin D. Thus, taking vitamin D supplements can help an individual in lowering the incidence of osteoporosis by 8 weeks (McGrane, 2021).

**Table 1-** Briefly describes the amount of vital minerals on daily basis for healthy well-being.

<b>RDI (Reference daily intake)</b>	<b>Age group</b>
600 IU	Children and adults (1-70 years)
800 IU	Pregnant or breast-feeding adults and people of 71 years or older.
400- 800 IU	To reduce the risk of bone fracture in adults.

### **Calcium**

Calcium plays a major role in bone formation and is vital for bone structure and strength. Calcium along with vitamin D is used as first-line therapy for the prevention and treatment of osteoporosis (Garriguet, 2011). Intake of an adequate amount of calcium in young adult years is linked with better bone mass and bone density in children and teens. A number of researches have been carried out and it has been found that postmenopausal women who do not take supplements lose 2% bone/year while the supplemented (1000-1600 mg calcium/day) woman lose only 0.25%-1% bone/year (Garriguet, 2011). Calcium carbonate, calcium citrate, calcium citrate maleate, calcium phosphate, calcium lactate, and calcium gluconate are different forms of calcium supplements that are available in the market (Rautiainen et al., 2016). Consuming large doses of calcium can have possible concerns i.e., calcium supplements linked with symptoms like kidney stones, constipation, and increased risk of heart attacks.

**Table 2-** Summarizes the RDI (Reference Daily Intake) of calcium for different age groups (McGrane, 2021), (Garriguet, 2011), (Rautiainen et al., 2016).

<b>Age group (years)</b>	<b>RDI (milligrams)</b>
1-3	500
4-8	800
9-18	1200
19-50	1000
51 and above	1200
Pregnant or lactating- below 19	1300
Pregnant or lactating- 19- 50	1000

### **Vitamin C And Vitamin K**

Vitamin C and Vitamin K are also vital for bone health and are involved in the synthesis of bone protein. Various studies have established a correlation between bone mineral density and vitamin C intake. Vitamin K is available in 3 forms i.e., Vitamin K<sub>1</sub>, Vitamin K<sub>2</sub>, and Vitamin K<sub>3</sub>. Vitamin K is responsible for the carboxylation of bone proteins (osteocalcin, matrix Gla protein, and anticoagulant protein S) and thus, enables these bone proteins in the binding of calcium to increase bone mineralization (Garriguet, 2011). It has been observed that in elderly women, intake of low levels of Vitamin K is linked with an increased chance of hip fractures. Adequate intake of Vitamin K is 90 mcg per day for women (age 18 and older) and 120 mcg per day for men (age 18 and older). It is important to consult with a healthcare professional prior to taking Vitamin K supplements owing to the interaction of Vitamin K with various medications, including drugs like warfarin (McGrane, 2021), (Garriguet, 2011), (Rautiainen et al., 2016).

**Trace minerals in bone health**

These include boron, copper, manganese, zinc, strontium, etc. pre-clinical studies concluded that boron increases the metabolism of calcium and vitamin D or enhances the useful effect of estrogen on bone. From a clinical study on 12 menopausal women, who were initially put on a boron deficit diet i.e., 0.25 mg boron/2000 kcals for 119 days after 119 days the boron intake was increased to 3 mg for 48 days it was concluded that the increased amount of boron in supplemented diet led to an increase of 17β-estradiol and testosterone in serum that prevents calcium loss and bone demineralization. Based on research 1-3 mg of boron per day is considered beneficial (Garriguet, 2011), (Rautiainen et al., 2016).

Studies have shown that copper works by inhibiting osteoclastic and osteoblastic activity and thus, slowing bone turnover. Calcium if taken with other supplements like manganese and zinc is found to prevent spinal bone loss. In women, a low level of zinc is associated with low bone density and osteoporosis. An adequate level of zinc and manganese is linked with better bone density (McGrane, 2021), (Garriguet, 2011).

**Dietary supplements in boosting immunity**

Immunity is the ability of multicellular organisms to fight against or not be affected by diseases. Nutrients like vitamins, minerals, fatty acids, polysaccharides, and polyphenols (non-nutrient) have been shown to increase the immunity of people. In today’s fast-paced and hectic lifestyle, it becomes very difficult for people to have food containing balanced nutrients. As a result, dietary supplements become the need of the hour to fulfil the requirement of nutrition and thus, help individuals to boost their immunity.

**Table 3-** Summarizes some of the nutrients and minerals that are used as supplements to increase immunity (Thirumdas et al., 2021).

Nutrient and mineral	RDA (Recommended dietary allowance)	Function
Vitamin-A (Retinol, retinal and retinoic acid)	RDA values for age group 4-8, 9-13 and 14-15 years is 1200, 1800 and 2700 IU respectively.	<ul style="list-style-type: none"> <li>• It is useful in the growth and development of eye vision.</li> <li>• Boost immunity.</li> <li>• Boost anti-inflammatory cytokines and antibodies (IgA) to provide immunity</li> </ul>

		<p>against viral infection like measles.</p> <ul style="list-style-type: none"> <li>• Vitamin target the T-cells and B-cells to increase immunity in virus infected people.</li> </ul>
Vitamin-D	RDA value for age group 4-5 years is 15 mg.	<ul style="list-style-type: none"> <li>• Vitamin D boost the immunity by boosting the natural killer cells, cytotoxic cells, and macrophages.</li> <li>• It acts as a physical barrier and boost cellular innate immunity to protect against the viruses.</li> </ul>
Vitamin-C	RDA values for age groups 4-8, 9-13, 14-13 and 19-50 years is 25, 45, 75 and 95 mg respectively.	<ul style="list-style-type: none"> <li>• It is a potent antioxidant-free radical scavenging that boost immunity of human body.</li> <li>• Supplementation with vitamin C can decrease up to 85% symptoms of flu and cold.</li> </ul>
Vitamin-E	RDA values for age groups 4-8, 9-13 and 14-50 years is 7, 11 and 15 mg respectively.	<ul style="list-style-type: none"> <li>• Potent antioxidants.</li> <li>• Increase immunity.</li> </ul>
Zinc	RDA values for age groups 4-8, 9-13 and 14-50 years is 5,8 and 11 mg respectively.	<ul style="list-style-type: none"> <li>• Antibodies production.</li> <li>• Increase the natural killer cell activity.</li> </ul>
Selenium	RDA values for age groups 1-3, 4-13, 14-50 and 51 years is 15, 40, 70 and 100 µg respectively.	<ul style="list-style-type: none"> <li>• Increase immunity</li> <li>• Boost free radical scavenging and protect from oxidative stress.</li> </ul>

Iron	RDA values for age groups 4-8, 9-13 and 14-50 years is 10, 8 and 11 µg respectively.	<ul style="list-style-type: none"> <li>• Protein synthesis</li> <li>• DNA synthesis</li> <li>• Immunity</li> </ul>
Copper	RDA values for age groups 4-8, 9-13, 14-18 and 19-50 years is 400, 700, 890 and 900 µg.	<ul style="list-style-type: none"> <li>• Vital role in macrophages, neutrophils, and monocyte and hence increases the natural killer cell activity.</li> </ul>

### Supplements for weight loss

As per WHO (World Health Organization), more than one billion people are obese and this number is still rising. It is estimated that by the year 2025, around 167 million people (adults and children) will become less healthy due to obesity (World Health Organization, n.d.). The medical and psychosocial impact of being overweight, as well as lacking in physical activity and making improvement in diet usually turn the obese population towards the OTC dietary supplements who desires a “magic bullet” for weight loss. Dietary supplements in weight loss fulfil two purposes 1) supply an adequate quantity of nutrients that may be absent in a calorie deficit diet. 2) their function of stimulating weight loss through mechanisms such as increasing resting metabolism and decreasing hunger (Dwyer, Allison, & Coates, 2005), (Batsis et al., 2021).

**Table 4-** Briefly describes the common dietary supplements used in weight loss along with their mechanism (Saper et al., 2004):

Function	Dietary supplement
Increase energy expenditure	Country mallow, ephedra, caffeine, yerba mate, guarana, bitter orange.
Increase satiety	Psyllium, glucomannan, guar gum.
Modulate carbohydrate metabolism	Chromium, ginseng.
Reduce fat synthesis or increase fat oxidation	Liquorice, green tea, vitamin B <sub>5</sub> , pyruvate.
Increase water elimination	Cascara, dandelion.
Block dietary fat absorption	chitosan
Mood enhancer	St. john’s wort

### Miscellaneous dietary supplements in health and diseases:

**Iron in pregnancy:** Supplementation with iron during pregnancy is considered to be a benefit for both mother and child as iron plays an important role in the transport of oxygen by RBC, energy production, and meeting the high demand for haematopoiesis, and growth and development during the pregnancy. Pregnant women are more prone to conditions like iron deficiency and iron deficient anaemia and thus,

an adequate amount of iron must be provided during this vulnerable stage of life but the question of concern has been arising about the effects of iron supplementation when individuals are iron-replete. The iron need is especially high during pregnancy estimated at 1000-1200 mg, about 2/3 of this iron is for maternal needs and the rest is for placental and foetal tissue needs (Brannon & Taylor, 2017).

**Milk thistle:** milk thistle is an herb used as an herbal dietary supplement. The seed extract of the milk thistle plant has been used for the treatment of liver and biliary disorders. The botanical name of the milk thistle is **Silybum marianum**. The chemical constituent silymarin of milk thistle is responsible for its liver-protecting activities. Silymarin has antioxidant and chemoprotective effects on the liver. Within the recommended dose range there is no reported side effect of milk thistle (Post-White et al., 2007).

**Omega-3 fatty acids as a supplement:** Omega-3 fatty acids are essential and must be provided through diet as they cannot be synthesized in the human body by de novo synthesis. The relationship between fish oil and low cardiovascular disease among Greenlanders was first reported in the late 1970s. The major fish and omega-3 fatty acids present in marine life are EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) (Hassan et al., 2020).

A study demonstrated that Greenlanders who stick to their traditional meat and fish diet rich in polyunsaturated omega-3 fatty acids had significantly lower levels of plasma total lipids, plasma triglyceride, plasma cholesterol, and pre- $\beta$ -lipoprotein. Since then, polyunsaturated omega-3 fatty acids taken in the supplement form of fish oil, krill oil, or a mixture of DHA and EPA. Omega-3 fatty acids have metabolites with anti-inflammatory effects that electrically stabilize the ion channel in cardiac myocytes and have been linked to cardi-protective effects (Balk & Lichtenstein, 2017).

Fish oil and omega-3 fatty acids are well tolerated at doses of 1000-2000mg/day, there is not much evidence of toxicity. However, fish oil supplements with vitamin A taken along with multivitamins could possibly result in hypervitaminosis A. These supplements can interact with anticoagulant medications such as warfarin and may exacerbate anticoagulation and promote bleeding in patients that put on such medication (Hassan et al., 2020).

### **Dietary supplements in sports**

Supplements are becoming popular among athletes and sports persons. As a result, the global market for sports supplements is increasing exponentially. In a survey conducted in 2021, the global sports nutrition market was valued at 40.0 billion USD and is expected to grow at a growth rate of 8.5% from 2022-2030 ("Sports Nutrition Market Size & Trends Analysis Report, 2030," n.d.), (Transparency Market Research, n.d.). Sports persons use dietary supplements for the following reason: Recovery from

training, health benefits, to compensate poor diet, and treatment and prevention of illness (Naderi et al., 2016). There are numerous sports supplements (amino acids, herbals, metabolites, constituents, extracts, and minerals) used by athletes.

**Table 5-** Summarizes all these supplements used in sports (Williams, 2005), (Williams, 2006).

<b>Amino Acids</b>	<b>Herbal</b>	<b>Metabolite, Extracts</b>	<b>Minerals</b>
Tryptophan	Ginseng	Creatine	Calcium
BCCA	Gingko Biloba	HMB ( $\beta$ -hydroxy- $\beta$ -methyl butyrate)	Phosphate
Glutamine	Kava Kava		Iron
Whey protein			Zinc

Athletes use dietary supplements regularly to increase their performance but there is always risk associated with the benefits of these supplements. As a result, athletes must have the proper knowledge to pick good supplements from thousands of supplements available in the market but the evidence of safety and efficacy is available for only a few supplements (Maughan et al., 2007), (Burke & Read, 1993). The timing of consuming sports supplements plays an important role i.e., whether the supplement is to be consumed prior to exercise, during the exercise, or after the exercise.

**Table 6-** Summarizes the timing of some supplements (Naderi et al., 2016), (Maughan et al., 2007).

<b>Supplements</b>	<b>Timing</b>
B-Alanine	With meals rich in carbohydrates and protein
Nitrate	Before exercise (2-2.5 hours)
Caffeine	Before exercise (1-1.5 hours)
Creatine	After exercise
Sodium bicarbonate	Before exercise (1-3 hours)
Carbohydrates	Prior to exercise or after exercise depends upon the other ingredient
Protein	After exercise

### **Side effects of dietary supplements**

There are a wide variety of supplements available in the market that are used by people from birth starting from infant formulas to fulfil their supplementation needs. People believe these OTC supplements are completely safe, however dietary supplements carry some risks. Some of the measures that help people to ensure product quality and safety include tracking down supplement performance in the market, users' feedback, complaints, and adverse event reporting (Resu et al., 2019).



There is a proverb saying “EXCESS OF EVERYTHING IS BAD” and the same applies to dietary supplements means that high doses of dietary supplements can potentially have adverse effects. The active ingredient of dietary supplements can potentially have a strong effect on the body. Thus, it is always advisable for the consumer to be cautious while consuming such supplements. Supplements consumed prior to surgery can alter your response to anaesthesia, some supplements even increase the risk of bleeding (Shao, 2017). Thus, the following actions must be avoided, otherwise may have fatal effects:

- Consuming a combination of supplements without expert guidance.
- Consuming supplements along with medication.
- Consuming excessive amounts of supplements like Vitamins and Iron supplements.

Post-market surveillance is very crucial, it involves gathering information from users about adverse events, documenting the reported adverse events on databases, and notifying the adverse events to regulators and consumers. In addition, it involves gathering and examination of consumer feedback and complaints to acknowledge consumer problems and further improvement of products.

**Table 7-** Describes the adverse effects of some of the dietary supplements (NIH Office of Dietary Supplements, n.d.), (Ronis et al., 2018), (Deldicque & Francaux, 2016).

<b>Supplements</b>	<b>Associated side effect</b>
Vitamin K	Can interfere with blood thinner drugs like warfarin
Hypericum perforatum	Can speed up the breakdown and effectiveness of various medicines including anti-HIV drugs, antidepressants, birth control pills, and heart medication
Antioxidant	Vitamin c and e are found to reduce the effectiveness of some types of cancer chemotherapy.
Vitamin A	High doses can lead to headaches and liver damage.
Milk thistle	Mild laxative and gastrointestinal upset. Mild allergic reaction at dose > 1500 mg/d
Vitamin B6 (Pyridoxin)	Doses higher than 500 mg/d have been associated with reports of photosensitivity and neurotoxicity.

### **Banned list of supplements by WADA**

Certain chemicals which are used in the formulation of dietary supplements for a specific purpose like increasing the Vigor and stamina of athletes and weight loss by suppression of appetite have shown serious health hazards in the subjects, especially after chronic use for a long time. The WADA has published a list of such hazardous chemicals which are recommended to be banned by it. Nevertheless, the laws and regulations of dietary supplements are still very feeble to take notice of the presence of such banned chemicals in dietary supplements and the scenario is more or less the same in every country.

**Table 8-** Enlist substances banned by WADA (World Anti-Doping Agency, 2023).

<b>Category</b>	<b>Example</b>
S0 (Non approved substances)	Pharmacological substance which is not approved by regulatory bodies.
S1 (Anabolic agents)	1-Androstenediol, Mestanolone, Clostebol etc.
S2 (Peptide Hormones, Growth Factors, and Mimetics)	Erythropoietin, Chorionic Gonadotrophin, Fibroblast Growth Factors, etc.
S3 (Beta-2- Agonist)	Formoterol, Salmeterol, Terbutaline, etc.
S4 (Metabolic modulators and Hormones)	Clomifene, Testolactone, Formestane etc.
S5 (Diuretics and masking agent)	Desmopressin, Acetazolamide, amiloride, etc.

### **Regulations of Dietary supplements**

The marketplace of dietary supplements is increasing globally and thus, the challenges in the area of regulation and scientific evaluation of the safety, quality, and efficacy of these supplements are common to all countries and need to be addressed. The primary challenge in the regulation of dietary supplements is that different countries have their own set parameters for defining dietary supplements, NHP (natural health products), and food supplements. For example, a product considers to be a supplement in India can be considered to be a therapeutic good or prescription medicine in another jurisdiction. The situation become more complex in countries like China and India where a regulatory framework for traditional medicines already exists. Another challenge associated with the regulation of dietary supplements is that regulators want that customers to have informed choices about the products they use. Dietary supplement is a polarizing topic and different expert has their own diversified opinions on the regulation of these products (Dwyer et al., 2018).

### **Regulations in India**

In recent times, awareness among people has been observed in India toward healthy and stress-free life. This leads to a shift of people towards OTC (Over-The-Counter) purchases of health supplements (Verma, 2009). The health supplement market is expected to have a CAGR of 14% during 2022-202 (Market Research Company, n.d.). The OTC health supplement segment allows companies to freely

play in the marketing and brand building, but still, the health supplement market is blurred and proper control and regulations must be implemented by the regulatory bodies (Verma, 2009).

In India, supplements fall under the umbrella term that is Functional foods defining Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purposes, Functional Food, and Novel Food. The Indian parliament passed the food safety standard act in 2006 with the main intention is to integrate all the existing food laws and establishing a single regulatory body i.e., FSSAI (Food Safety Standard Authority of India) acts as a single contact point for all food and supplements related regulation in India (Bhupathiraju et al., 2019). Health supplements fall under subcategory 13.6 of category 13.0; category 13.0 group of foodstuffs that are required for particular nutrition, as per the codex food category system (Boindala & Lewis, 2019).

**Table 9-** Summarizes the dietary supplement regulations in India (FSSAI, n.d.), (Rechan, n.d.).

<b>Regulations</b>	<b>Purpose/description and Laws/Act</b>
FSSA 2006	<ul style="list-style-type: none"> <li>✓ Unified the existing food safety laws.</li> <li>✓ Chapter IV, Article 22 of the act addresses nutraceutical, functional food, and dietary supplements.</li> <li>✓ Articles 23 and 24 address the packaging and labeling of food and the restriction of advertisements regarding foods.</li> </ul>
FSS Regulation 2022	<ul style="list-style-type: none"> <li>✓ Supersede the FSS regulation 2016.</li> <li>✓ Categorize ingredients into various schedules and the product shall contain an ingredient from this list as per the different categories of functional food.</li> <li>✓ Provide RDA (Recommended Dietary Allowance) for the vitamins and minerals.</li> <li>✓ Maximum and minimum permitted range of various ingredients used in the supplements.</li> </ul>

<p>Information on the label</p>	<p>Health supplements in India must comply with the following regulations.</p> <ul style="list-style-type: none"> <li>✓ FSS Regulation 2022 provide the specific requirement of packing for functional foods (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food)</li> <li>✓ Compliance with the FSS (Packaging and labelling) Regulation 2011.</li> <li>✓ Compliance with general labelling requirements for pre-packaged foods FSS (PL) 2011.</li> </ul>
<p>Licensing and import</p>	<p>Every FBO must possess a licence (manufacturing, import, storage, distribution, sale, marketing).</p> <ul style="list-style-type: none"> <li>✓ The import of health supplements is according to the FSS (Import) Regulations 2017.</li> <li>✓ Must comply with-                     <ul style="list-style-type: none"> <li>○ FSS (Licensing and Registration of Food Businesses) Regulations 2011.</li> <li>○ FSS (Import) Regulations 2017.</li> </ul> </li> </ul>

### Regulations in the USA

Dietary supplements are commonly used among American people to fulfil their nutritional needs and to improve their quality of life. In US dietary supplements are regulated as a food by FDA (Food and Drug Administration). The federal government is continuously making efforts to ensure that the people of America have access to high-quality, safe, and contaminant-free dietary supplements (Larsen & Berry, 2003).

**Table 10-** Summarizes the dietary supplement regulation in the US supplements (Larsen & Berry, 2003), (Talbot, 2003), (Swann, 2016), (McNamara, 2005).

Regulations/Act	Purpose/description
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FFDCA 1938 (Federal Food, Drug and Cosmetic act).	<ul style="list-style-type: none"> <li>✓ Regulated dietary supplements as food under FFDCA.</li> </ul>
DSHEA 1994 (Dietary Supplement Health and Education Act).	<ul style="list-style-type: none"> <li>✓ Authorizes FDA to form new regulations of dietary supplements that include-                             <ul style="list-style-type: none"> <li>○ Dietary supplements specific cGMP guidelines.</li> <li>○ Requirements for NDI (New Dietary Ingredient) (75 days premarket notification to FDA)</li> <li>○ Labeling</li> <li>○ Certain types of Health Claims.</li> </ul> </li> <li>✓ Authorizes FDA to take mandatory action against adulterated and unsafe products.</li> <li>✓ Rule out the dietary supplement's ingredients from the food additives.</li> </ul>
Dietary supplements and Non-Prescription Drug Consumer Protection Act.	<ul style="list-style-type: none"> <li>✓ Mandatory reporting of the adverse event of dietary supplements.</li> </ul>
Public Health Security and Bioterrorism Preparedness and Response Act.	<ul style="list-style-type: none"> <li>✓ Registration of food including dietary supplements packers, processors, and manufacturers with FDA.</li> </ul>
FSMA (Food Safety Modernization Act).	<ul style="list-style-type: none"> <li>✓ Mandatory recall of adulterated dietary supplements and foods and those containing unknown ingredients.</li> </ul>
FTC (Federal Trade Commission).	<ul style="list-style-type: none"> <li>✓ Regulate advertisement of dietary supplements with FDA coordination.</li> </ul>
NLEA 1990 (Nutrition Labelling Education Act).	<ul style="list-style-type: none"> <li>✓ Requirement of nutritional labeling for dietary supplements.</li> <li>✓ General principles for health claims.</li> </ul>
FDA ONDLS (Office of Nutrition, Labeling, and Dietary Supplements)	<ul style="list-style-type: none"> <li>✓ Responsible for labeling regulations of dietary supplements.</li> <li>✓ ONDLS team is responsible for review of dietary supplement products involve                             <ul style="list-style-type: none"> <li>○ Review of health claims</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ Nutrient content claim</li> <li>○ Review of labeling</li> <li>○ Review of NDI</li> </ul>
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### Regulations in EU

In the EU dietary supplements are known as food supplements. European Union has a unique multi-level governance system. There are two types of laws in the EU i.e., 1) Primary law – Based on the treaties and agreements between member states. 2) Secondary law – Includes Directives, regulations, recommendations, and opinions.

**Table 11-** Summarizes the Dietary supplement regulations in the EU (Zayets, 2019), (Gulati, Ottaway, & Coppens, 2014), (Coppens & Pettman, 2014).

Regulations/Directives	Description
Regulation 178/2002	✓ General Food law
Directive 2002/46/EC	<ul style="list-style-type: none"> <li>✓ Laws relating to dietary supplements from all member states.</li> <li>✓ Defines dietary supplements.</li> <li>✓ Harmonize EU regulations on dietary supplements.</li> <li>✓ Provide positive list</li> <li>✓ Recommendation on maximum and minimum levels of dietary supplements for daily consumption.</li> <li>✓</li> </ul>
Directive 2000/13/EC	<ul style="list-style-type: none"> <li>✓ Laws relating to –                             <ul style="list-style-type: none"> <li>○ Labeling</li> <li>○ Presentation</li> <li>○ advertisement</li> </ul> </li> </ul>
Regulation 1924/2006	✓ Nutrition and health claims.
Regulation (EU) No. 1169/2011	✓ provision for information on food to consumers
EFSA	<ul style="list-style-type: none"> <li>✓ Responsible for risk assessments and sharing information on dietary supplements with the public.</li> <li>✓ DRV tool gave make calculations about dietary reference values.</li> </ul>

## **Survey**

A survey was conducted among the general population to study people's perceptions of dietary supplements.

## **Methodology**

The study was an online questionnaire with the main **Aim** - To study people's perception of dietary supplements. The questionnaire was designed using google forms and circulated among the general population across Rohtak city of Haryana with the help of social media (WhatsApp and Facebook). The questionnaire consists of multiple-choice option-based questions that were designed to collect data to assess their knowledge, use, frequency, and purchasing decision of dietary supplements.

## **Data collection:**

For the collection of data, a questionnaire was designed. The questionnaire was consisting questions from the following backgrounds;

1. Sociodemographic questions
2. Questions about knowledge of dietary supplements
3. Question about knowledge on dietary supplement interaction and adverse effects.
4. Question about the frequency of purchasing and consuming dietary supplements.

## **Outcomes of survey**

A total of 164 responses is recorded to date. The survey involved Participants from medical (46.3%), paramedical (27.4%), and other professions (26.2%). Among 164 respondents 74.4% were male and 25.6% were female. When participants are asked about where did they get information about dietary supplements, the majority of participants answered with Internet, Television, and Print media (81 responses i.e.,49.4%).

The majority of factors that contribute to the consumption of dietary supplements without expert guidance/consultation were found to be the previous experience of use (34.1%) and safe to use (28.7%) as shown in table 12.

<b>Factor</b>	<b>Percentage</b>
Previous experience of use	34.1%
Convenience	22.6%

**Table 12-**  
factors  
consumption

Safe to use	28.7%
No cost of consultation	14.6%

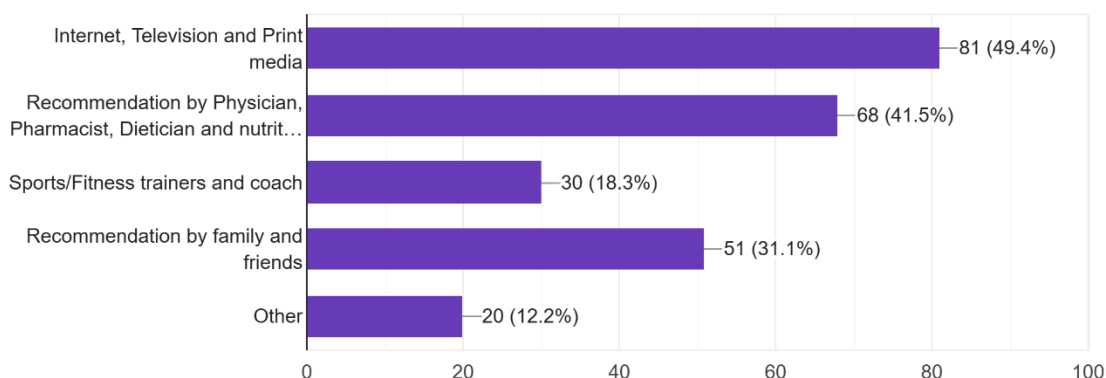
Describing  
contributing to  
of

supplements without expert guidance.

Most of the participants consider available scientific data and nutritional facts while purchasing dietary supplements, around 81 responses recorded this option. Figure 1,2,3,4,5,6,7,8 shows the responses obtained through the survey.

Where do you get information about dietary supplements? Please check all that apply.

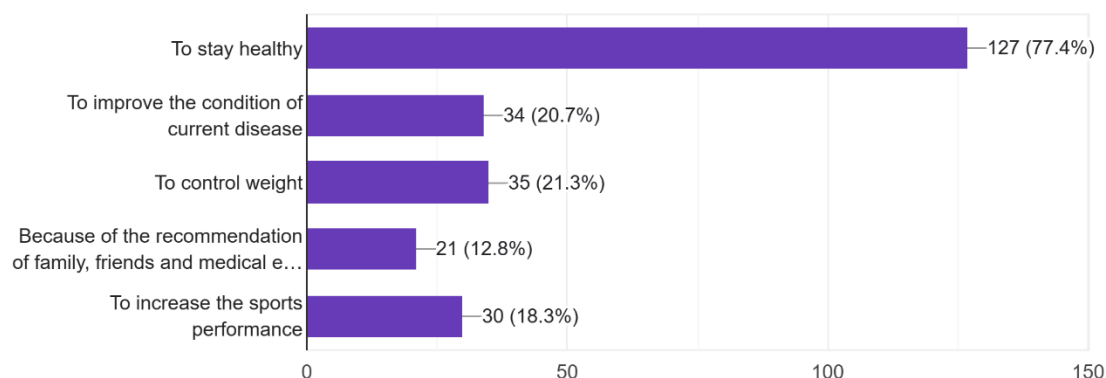
164 responses



**Figure 1**

What is the reason for the consumption of dietary supplements? Please check all that apply.

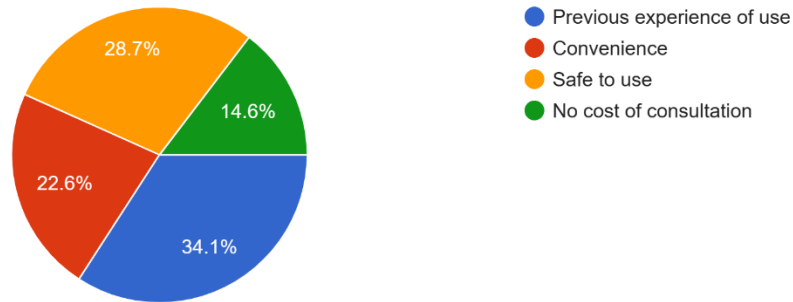
164 responses



**Figure 2**

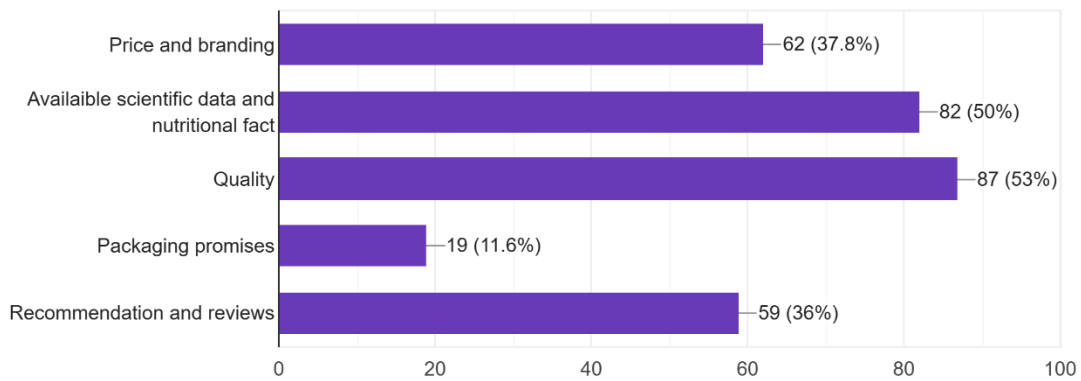


Why do you think people consume dietary supplements without expert guidance/consultation?  
164 responses



**Figure 3**

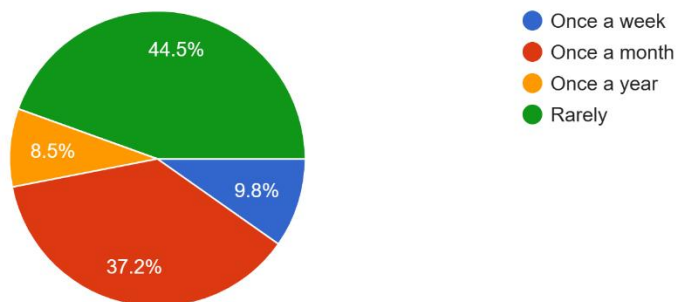
What do you usually consider the most while purchasing dietary supplements? Select all that apply.  
164 responses



**Figure 4**

How often do you purchase dietary supplements?

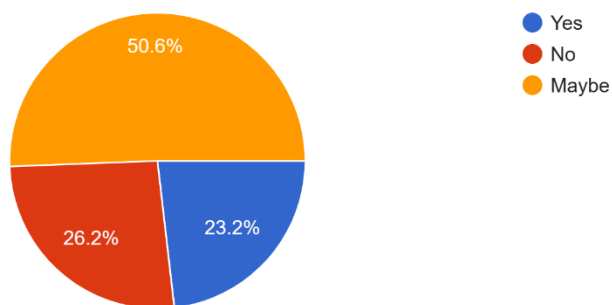
164 responses



**Figure 5**

Do dietary supplements have harmful side effects?

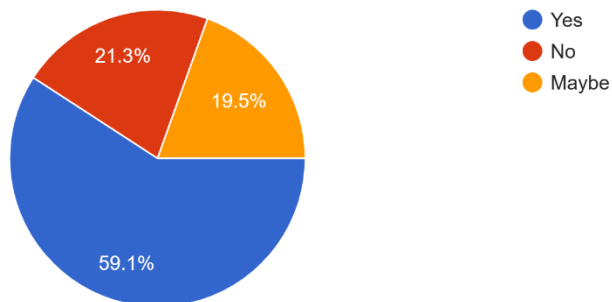
164 responses



**Figure 6**

Do you think pregnant women or breast-feeding female should not take dietary supplement without consulting the physician, dietician and nutritionist?

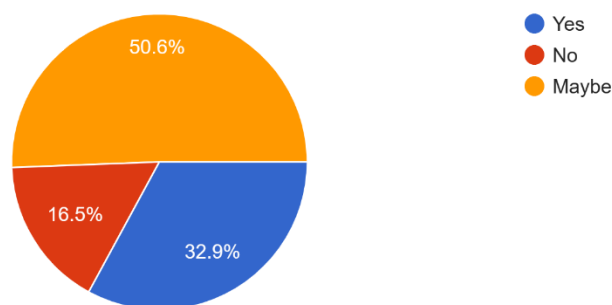
164 responses



**Figure 7**

Do you think dietary supplements can interact with other supplements or medication?

164 responses



**Figure 8**

### **Discussion**

The survey was conducted among the general population. Most people get information from an advertisement on social media, the internet, and print media. Thus, there should be proper control on the advertisement of dietary supplements as they affect the purchasing decisions of consumers. A large no of participants believed consuming dietary supplements without expert guidance is safe and many also indicated a lower level of concern regarding potential adverse effects and drug-supplement interaction. But dietary supplements can have harmful side effects and certain interactions with other medications and supplements. The most considerable factors while purchasing dietary supplements are 1) available scientific data and nutritional facts. 2) Quality 3) Price and branding. Efforts are needed to create more widespread awareness of dietary supplements' role in optimizing health. The proper measure should be taken by FSSAI to ensure the general public is made aware decisions about dietary supplements and have sound knowledge about their use, interaction, and harmful effects.

### **Conclusion**

Dietary supplements are being widely used by people and the trend is toward the increase in their market investments. Feeble regulations not only for the manufacturing and sale of dietary supplements but also in their advertisement are contributing to their increased use among the general public. Hence, A legal check is required for the judicious sale and use of dietary supplements. There is no global consensus on how to define and regulate dietary supplements. They are regulated differently around the globe as per their different set parameters.

Corona pandemic period has changed the mindset and it has been recognized that daily use of supplements like Vitamin C, and D and some herbal supplements like curcumin can boost immunity and prevent infectious diseases.

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