

**RESEARCH ARTICLE ON REGULATORY REQUIREMENTS FOR THE APPROVAL
OF DIETARY SUPPLEMENTS UNDER FOOD SAFETY AND STANDARDS
AUTHORITY OF INDIA [FSSAI] IN COMPARISON WITH SWEEDEN****Dr. P. Ashok Kumar*, Ullas M. R.¹, Vikas H. N.², Sumanth Shettar³, Bhavana A. R.⁴, Manohari A. S.⁵**Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy. 1st Left Cross, 3rd Block, Mahalakshmi Nagar, Near Railway Gate, 80 Feet Road, Batwadi, Tumkur-572103. Karnataka (India).***Corresponding Author: Dr. P. Ashok Kumar P.**Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy. 1st Left Cross, 3rd Block, Mahalakshmi Nagar, Near Railway Gate, 80 Feet Road, Batwadi, Tumkur-572103. Karnataka (India).**DOI:** <https://doi.org/10.5281/zenodo.23032571>**How to cite this Article:** Dr. P. Ashok Kumar*, Ullas M. R.¹, Vikas H. N.², Sumanth Shettar³, Bhavana A. R.⁴, Manohari A. S.⁵. (2026). Research Article on Regulatory Requirements For The Approval of Dietary Supplements Under Food Safety And Standards Authority of India [Fssai] In Comparison With Sweeden. European Journal of Pharmaceuticaland Medical Research, 13(10), 270–279.This work is licensed under [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by-nc/4.0/).

Article Received on 02/09/2026

Article Revised on 22/09/2026

Article Published on 01/10/2026

ABSTRACT

This project aims to analyse and compare the regulatory requirements related to dietary supplements in pharmaceutical products in India and Sweden. In India, these regulations are governed by the food safety and standards authority of India (FSSAI), whereas in Sweden, they fall under the jurisdiction of the medical Products Agency (MPA), in line with both the national legislation and European Medicines Agency (EMA) directives. The study categorizes the type of pharmaceutical products intended to supplement the normal diet by providing nutrients or other substances that have a nutritional or physiological effect. They are commonly available in forms such as tablets, capsules, powders, liquids, and gummies. The findings may be useful for manufacturers, researchers, and policymakers involved in the dietary supplement industry and may contribute to improving regulatory compliance and international trade. The global dietary supplement market has expanded rapidly, increasing the need for robust regulatory frameworks to ensure product safety, quality, and consumer protection. This study evaluates the regulatory requirements governing dietary supplements in India under the Food Safety and Standards Authority of India (FSSAI) and compares them with the regulatory framework in Sweden. In India, dietary supplements are regulated as health supplements and nutraceuticals under the Food Safety and Standards Act, 2006, and related regulations that specify requirements for product composition, manufacturing practices, licensing, labelling, safety assessment, and health claims. This comparative study provides insights for pharmaceutical companies looking to market their products in both regions, guiding them to navigate regulatory expectations efficiently. The project also highlights potential challenges and opportunities in harmonizing global regulatory Practices.

KEYWORDS: Dietary supplements, FSSAI, India, Sweden, nutraceuticals, food, supplements, regulatory requirements, EU, health claims.**INTRODUCTION**

Dietary supplements are products meant to supply nutrients or other components that can help maintain good health. Examples of such components include vitamins, minerals, amino acids, proteins, fatty acids, enzymes, probiotics, herbs, and many other plant-based substances. These supplements are produced in different forms like tablets, capsules, powder, liquid, and gummies.

The history of dietary supplements is old, starting with the ancient times when plants, herbs, and natural materials were used to keep good health. However, once there was the emergence of nutritional science, individual components like vitamins and minerals were identified, which led to the formation of modern supplements.

The rise in the importance of nutrition, preventive care, diseases associated with lifestyle, exercise and fitness, and healthy ageing have influenced the development of the dietary supplements market. This group of products

is now frequently used by a variety of people like athletes, the elderly, pregnant women, and those with nutritional deficiencies.^[1]



Figure no. 01: Dietary supplements product.

Types of Dietary Supplements

Supplements can be put into groups based on what is in them and what they are used for

1. Vitamin Supplements
2. Mineral Supplements
3. Herbal or Botanical Supplements
4. Protein Supplements
5. Amino Acid Supplements
6. Fatty Acid Supplements
7. Supplements
8. Fiber Supplement
9. Specialty Supplements
10. Combination or Multi-nutrient Supplement

Functions

- Supporting Growth and Development
- Enhancing Overall Health
- Preventing Nutrient Deficiencies
- Supporting Immune Function
- Promoting Bone and Joint Health
- Providing Antioxidant Protection^[2]

Scope of dietary supplements in India

Dietary supplements in India are really big. Getting bigger all the time. People in India are becoming more aware of their health. This is driving the demand for dietary supplements. The government is also making it easier for companies to make and sell supplements. More and more people want to stay healthy and prevent illnesses so they are looking for supplements. This means that the dietary supplement industry in India is very important and is growing fast. The dietary supplement industry is also a place for new ideas and, for selling products to other countries.

Scope of dietary supplements in Sweden

The dietary supplement market in Sweden is really big. It's getting bigger. This is because people in Sweden care more about their health they want to prevent illnesses. There are more old people. They also want different products that help them feel good. The government makes sure these products are safe and follow rules. Sweden is also part of a market in Europe, which helps the industry grow. The dietary supplements are popular, in Sweden.

FSSAI (Food Safety and Standards Authority of India)^[3]

In India the Food Safety and Standards Authority of India also known as the FSSAI is in charge of supplements. The FSSAI is a part of the **Ministry of Health and Family Welfare Government of India.**

The Food Safety and Standards Authority of India (FSSAI) is the principal regulatory body responsible for ensuring the safety, quality, and availability of food products in India. Established under the Food Safety and Standards Act, 2006, FSSAI operates under the Ministry of Health and Family Welfare, Government of India. The authority was created to consolidate various food-related laws and establish a single reference point for all matters relating to food safety and standards in the country. The FSSAI makes sure dietary supplements are safe under the Food Safety and Standards Act, 2006. The Food Safety and Standards Authority of India has its rules for dietary supplements, these rules were made in 2022 to cover things like health supplements and special foods.

The Food Safety and Standards Authority of India is very important for supplements, in India. These regulations specify:

- The government says what vitamins and minerals are okay to use in food.
- They also say how much of each thing you can have in your food like the most and the least amount.
- When you buy something to eat the label has to tell you what is inside and what it can do for you.
- The people who make food have to follow rules to make sure what they make is safe for you to eat and good quality this is also true, for supplements.

An ounce of prevention is worth a pound of cure

FSSAI angle: Supplements are meant to supplement diet, not replace medicine. "NOT FOR MEDICINAL USE" is literally on the label.

Food safety and standards regulations

Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011
 (Food Products Standards and Food Additives) Regulation, 2011
 (Prohibition and Restriction of Sales) Regulation, 2011
 (Contaminants, Toxins and Residues) Regulation, 2011
 (Laboratory and Sampling Analysis) Regulation, 2011
 (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016
 (Food Recall Procedure) Regulation, 2017
 (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017
 (Recognition and Notification of Laboratories) Regulation, 2018
 (Safe food and balanced diets for children in school) Regulations^[4], 2020



Figure no. 02: Major FSSAI Regulations.

Food Business Registration and Licensing in India Introduction^[5]

The food industry is one of the fastest-growing sectors in India and plays an important role in the country's economy. To ensure that food sold to consumers is safe

and hygienic, the Government of India regulates food businesses through the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006. Every food business involved in manufacturing, processing, packaging, storage, transportation, distribution, or sale of food must obtain the appropriate FSSAI registration or license before starting operations.

Types of FSSAI Licenses

1. Basic Registration

For small food businesses with annual turnover up to ₹12 lakh.

Applicable to street vendors, home-based businesses, and petty retailers.

2. State License

For medium-sized businesses with turnover between ₹12 lakh and ₹20 crore.

Required for restaurants, hotels, dairies, warehouses, and distributors.

3. Central License

Required for large manufacturers, importers, exporters, and businesses operating in multiple states or with turnover above ₹20 crore.

Registration Process

- Determine the appropriate license category.
- Submit an online application through the Fusco's portal.
- Verification of documents.
- Inspection of the premises, if required.
- Issue of the FSSAI license with a unique 14-digit number.



Figure no. 03: Food business registration process.

Food Business Registration and Licensing in Sweden Introduction

Sweden has a highly developed food safety system that follows European Union (EU) food laws. Food businesses must register with the local municipal

authority before starting operations. The system focuses on preventive food safety and regular inspections to protect consumers.^[6]

Regulatory Authorities

The Swedish Food Agency (Livsmedelsverket) is responsible for developing food regulations, coordinating inspections, and ensuring compliance with EU legislation. Local municipalities register food businesses and conduct inspections.

Registration Process

- Register the business with the local municipality.

- Prepare a food safety plan based on HACCP principles.
- Premises are inspected for hygiene and food safety.
- The business is allowed to operate and is monitored through regular inspections.

Advantages

- High consumer confidence.
- Strong food traceability.
- Risk-based inspection system.
- Transparent regulations.
- Compliance with EU food standards.

Comparison of Food Business Registration and Licensing in India and Sweden

Table no 01: Comparison of Food Business Registration and Licensing in India and Sweden.

Feature	India	Sweden
Regulatory Authority	FSSAI	Swedish Food Agency
Governing Law	Food Safety and Standards Act, 2006	EU Food Law
Registration	Basic, State and Central Licenses	Municipal Registration
Inspection	Periodic	Risk-based

Food Quality Requirements and Regulations in India

Introduction: Food quality regulations in India are governed by the Food Safety and Standards Act, 2006 and implemented by FSSAI. These regulations ensure that food products are safe, hygienic, nutritious, and correctly labelled.^[7]



Figure no. 04: Food quality management process.

Food Quality Standards

Food quality is assessed through

- Physical quality (appearance, freshness, texture).
- Chemical quality (safe levels of additives and pesticide residues).
- Microbiological quality (absence of harmful bacteria).
- Nutritional quality (accurate nutritional information).
- Good Manufacturing Practices (GMP)

GMP ensures food is produced under hygienic conditions through

- Clean equipment and facilities.
- Safe water supply.
- Pest control.
- Employee hygiene.
- Proper waste management.
- Good Hygienic Practices (GHP)

Food Quality Requirements and Regulations in Sweden^[13]

Introduction

Sweden follows strict food safety regulations based on European Union legislation. The Swedish Food Agency and local municipalities ensure that food businesses maintain high standards of hygiene and quality throughout the food supply chain.

Main Requirements

- Compliance with EU Food Law.
- HACCP-based food safety management.
- Proper hygiene practices.
- Complete food traceability.
- Accurate food labelling.
- Regular inspections.

Food Traceability

Food businesses must be able to trace every food product from supplier to consumer. This enables quick product recalls when safety issues arise.

Food Labelling

Labels must clearly display

- Product name.
- Ingredients.
- Allergen information.
- Nutritional values.

- Storage instructions.
- Best-before or use-by date

Advantages

- High food safety standards.

- Excellent traceability.
- Strong consumer confidence.
- Effective inspection system.

Table no 02: Comparison of Food Safety Systems.

Feature	India	Sweden
Main Authority	FSSAI	Swedish Food Agency
Food Safety System	GMP, GHP, HACCP	HACCP-based
Inspection	Periodic	Risk-based
Traceability	Required	Highly developed
Food Labelling	FSSAI Regulations	EU Regulations

GMP COMPLIANCE FOR DIETARY SUPPLEMENTS IN INDIA AND SWEDAN

Introduction

This project focuses on **Good Manufacturing Practices (GMP) compliance for dietary supplements in India and Sweden** and the **production registration process under the Food Safety and Standards Authority of India (FSSAI)**. The study compares the regulatory systems followed in both countries to ensure the safety, quality, and effectiveness of dietary supplements. In India, dietary supplements are regulated by FSSAI under the Food Safety and Standards Act, 2006, while in Sweden they are regulated under European Union food laws and supervised by the Swedish Food Agency.

The project explains the importance of GMP in maintaining hygienic manufacturing conditions, quality control, proper documentation, and safe production practices. It also describes the process of obtaining FSSAI registration, including licensing requirements,

manufacturing standards, packaging, labelling, and regulatory compliance for dietary supplement manufacturers.

With the increasing demand for dietary supplements across the world, maintaining quality standards has become essential for protecting consumer health. This study highlights the similarities and differences between the Indian and Swedish regulatory frameworks and emphasizes the importance of following GMP guidelines to produce safe and high-quality products. The findings of this project will be useful for students, manufacturers, researchers, and regulatory professionals who wish to understand international standards for dietary supplement manufacturing. The study also provides valuable knowledge about FSSAI production registration and demonstrates how proper regulatory compliance supports consumer safety, product quality, and global market acceptance.



Figure no. 05: Key GMP Requirements in Sweden.

GMP in Dietary Supplement Manufacturing^[8]

This image explains the main steps involved in manufacturing dietary supplements by following **Good Manufacturing Practices (GMP)**. The process starts with selecting high-quality raw materials from approved

suppliers. These materials are then tested to confirm their identity, purity, potency, and safety. After successful testing, the ingredients are processed in a clean and controlled manufacturing environment. Quality control

checks are carried out during and after production to ensure that every product meets the required standards. The finished products are properly packaged and labelled with accurate information before they are stored and distributed. Following GMP helps reduce contamination and manufacturing errors while ensuring consistent product quality. It also builds consumer trust by providing safe and reliable dietary supplements.

Key GMP Requirements in Sweden

- Compliance with EU food regulations.

Product registration for FSSAI



Figure no. 06: Product Registration for FSSAI.

FSSAI plays a vital role in ensuring the safety and quality of dietary supplements in India. By following GMP guidelines and obtaining FSSAI registration, manufacturers can produce safe, reliable, and high-quality products. Compliance with FSSAI regulations not only protects consumers but also improves business credibility and supports growth in domestic and international markets.

Regulatory requirements for sale, import and Marketing of dietary^[9] supplements in India

Sale of supplements

- **To sell supplements sellers must get an FSSAI license or registration first**

This is a step that sellers have to take before they can start marketing supplements. The sale of supplements is very important. Sellers have to do this.

- Registration with the Swedish Food Agency.
- Hygienic manufacturing environment.
- Approved ingredients and suppliers.
- Quality testing during production.
- Accurate product labelling.
- Complete documentation and traceability.
- Safe storage and distribution.

- **Dietary supplements have to follow the rules set by FSSAI**

The Food Safety and Standards Regulation from 2016 is what dietary supplements have to comply with. This regulation is important for the sale of supplements.

- **Only ingredients that FSSAI says are okay can be used in supplements**

Dietary supplements must be safe. Meet certain quality standards.

The quality of supplements is very important.

- **Labels on supplements have to have some important information**

This includes the name of the supplement product what is in its information about the product the FSSAI license number, when it expires, how to take the dietary

supplement and a statement that says dietary supplements are "**NOT FOR MEDICINAL USE**".

Import of supplements^[14]

- To import supplements into India the importer needs to get a valid FSSAI license first. The importer must have this FSSAI license before they can import supplements.
- The dietary supplements have to follow the rules set by FSSAI. This means the dietary supplements must have ingredients that are allowed and they have to be safe for people to use. The dietary supplements have to meet the food safety and standards regulation.
- When it comes to labeling the imported dietary supplements have to have labels that follow rules. These labels need to have the name of the product a list of ingredients, nutritional information and details about the importer. The labels also need to have the batch number, expiry date and a statement that says the dietary supplements are "NOT FOR MEDICINAL USE".
- The importer has to make sure the dietary supplements are made in a facility that follows manufacturing practices. The dietary supplements

have to meet quality standards. This is all part of quality control for supplements.

- To get certification the importer needs to get it from a trusted organization like the National Sanitation Foundation or NSF International. This certification is important, for supplements.

Fees

FSSAI Basic Registration ₹100 per year
 FSSAI State License ₹2,000–₹5,000 per year
 FSSAI Central License ₹7,500 per year
 Product approval for nutraceutical supplement approximately ₹10,000 per product
 Non-specified food product approval application Up to ₹5,00,000 per application

Time

FSSAI license application and approval 3–10 days*
 Product formulation and label compliance review 1–2 weeks
 Import Export Code (IEC) registration 1–7 days
 Import clearance by Customs and FSSAI 7–30 days
 Product testing and sampling 7–15 days
 Market launch and distribution 1–2 weeks after approval

Marketing of dietary supplements^[10]

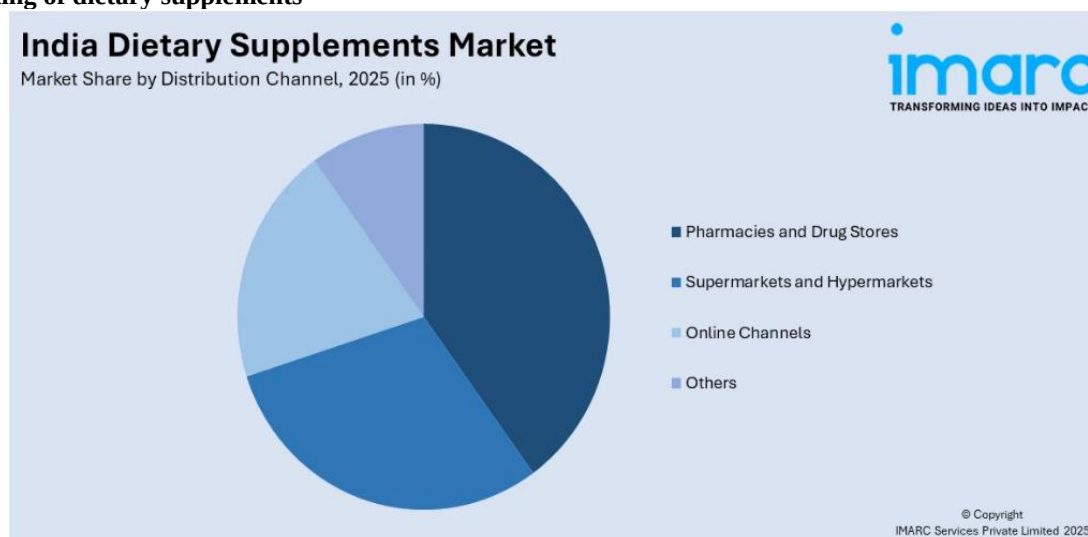


Figure no. 07: India dietary supplements market.

The dietary supplement market in India is growing fast. This is because people are becoming more aware of their health and fitness is becoming a part of their lives. They are also taking steps to prevent illnesses. They have more money to spend.

The market for supplements in India was worth about **INR 201 billion in 2025**. It is expected to increase by **than 12% every year**. The dietary supplements market is really picking up in India. People are taking supplements to stay healthy and fit. The market is growing rapidly due, to dietary supplements.

Regulatory Requirements for Sale, Import and Marketing of Dietary Supplements in Sweden^[6]

Sale Requirements in Sweden

We can sell botanicals and other substances in Sweden. Sometimes the European Food Safety Authority checks if they are safe. Sweden does not have limits for how much of a substance can be in a supplement. The European Food Safety Authority can set limits. If a product has a lot of a substance, it might be considered a medicine.

A. Product Composition: Vitamins and minerals listed in Annex I and II of Directive 2002/46/EC can be used in Sweden may trigger medicine classification.

B. Labeling. Mandatory Elements: The category of nutrients or substances or their nature must be on the label. The recommended daily portion must be on the label. There must be a warning that says "Do not exceed the stated recommended dose". There must be a statement that says "Food supplements should not be used as a substitute for a diet". There must be a statement that says "Keep out of the reach of children". The name, ingredients list, net quantity, expiry date storage conditions and business name and address must be on the label.

C. Claims and Advertising: Claims that a product prevents treats or cures disease are prohibited. Nutrition and health claims are only allowed if they are authorized by the European Union and must be scientifically substantiated by EFSA. Marketing must comply with the Commercial Practices Directive and the Swedish Marketing Act.

D. Notification: Sweden does not have a pre-market notification system but you must be able to prove compliance if Livsmedelsverket inspects.

Import Requirements

A. From EU or EEA Countries: There is no customs duty, VAT or other taxes and free movement applies if the product complies with European Union rules.

B. From Non-EU Countries: Customs duties, VAT and other taxes may. Tullverket may stop goods if they are classified as medicines instead of supplements. There must be a food versus medicine check and the commodity description on goods or packaging must be inspected and if uncertain you must contact Läkemedelsverket before ordering. Special rules apply if a supplement contains animal or plant products and you must contact the Swedish Board of Agriculture and a phytosanitary certificate may be needed.

C. Commercial Import: You must register as a food business with your municipalities environmental department and contact Livsmedelsverket for import guidance.

Marketing and E-commerce Rule

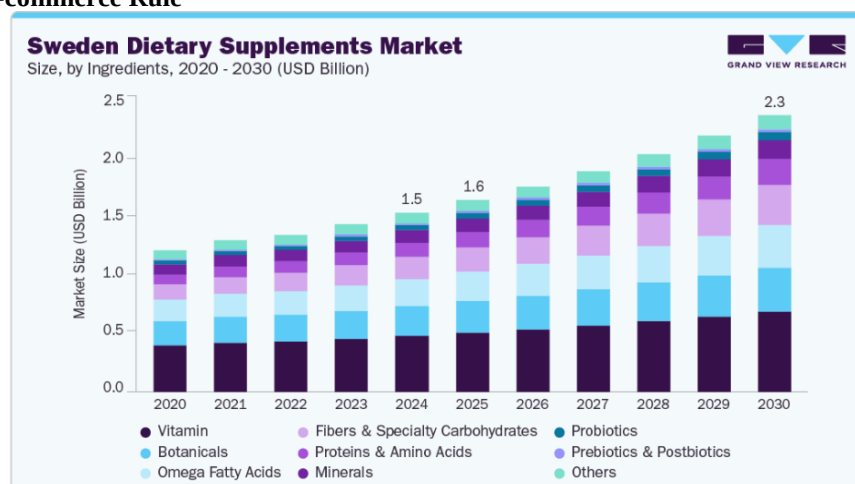


Figure no. 08: Sweden dietary supplements market.

Online sales must have all label information available before purchase in the web shop. Pricing, cancellation rights and information obligations must comply with European Union e-commerce rules. Subscription models must follow rules on auto-renewal, reminders and cancellation. Social media must comply with consumer protection law and the Unfair Commercial Practices Directive.

Product registration of dietary supplements in India and Sweden^[11]

India – Registration/Approval Process^[15]

Step 1 – Product classification: First determine whether the product is a health supplement, nutraceutical, FSDU, FSMP, probiotic/prebiotic food, specialty food or novel food. FSSAI's guidance places health supplements and nutraceuticals mainly under food category 13.6.

Step 2 – Ingredient assessment: Check every ingredient against the applicable FSSAI schedules, permitted levels

and other requirements. FSSAI specifically recommends checking permitted ingredients through its regulatory resources.

Step 3 – Determine whether prior approval is required: If an ingredient/product is non-specified or falls under novel-food requirements, additional approval may be necessary. FSSAI's regulations require prior approval for certain non-specified foods/ingredients.

Step 4 – Obtain FSSAI license: Food business applies through FoSCoS. FSSAI states that food businesses must obtain the applicable license/registration, and the FoSCoS system is used for licensing and registration. For manufacturers of products covered by the nutraceutical/health-supplement regulations, FSSAI has directed that licensing is handled through the Central Licensing Authority.

Step 5 – Product documentation and compliance: The applicant should maintain the product formulation, ingredient specifications, manufacturing information,

quality specifications, testing records and other supporting information. FSSAI's guidance also refers to product information and quality confirmation for relevant products.

Step 6 – Labelling and marketing: The final label must comply with FSSAI labelling requirements, including product name/category, ingredients, quantity, nutrition information, directions/warnings where applicable, batch information, dates and FSSAI license details.

Sweden – Registration/Market Entry Process

Sweden does not generally operate like India with a separate FSSAI-style product license for every ordinary dietary supplement. Food supplements are food products and the food business operator is responsible for ensuring that the product is safe and compliant before placing it on the market. Swedish food businesses are subject to registration/approval and official control.

Step 1 – Classify the product as a food supplement: Confirm that the product is a food supplement and not a medicinal product. Products making medicinal-type claims can fall under medicinal-product legislation.

Step 2 – Check ingredients: Verify vitamins and minerals and their permitted forms. Swedish rules refer to the vitamins/minerals and chemical forms permitted under the EU food-supplement framework.

Step 3 – Novel food assessment: Determine whether any ingredient is a novel food. A food/ingredient without significant consumption in the EU before 15 May 1997 may be considered novel. Novel foods generally need EU authorization before marketing. If the status is uncertain, a consultation can be requested from the Swedish Food Agency. The dossier can include a cover letter, explanatory note, technical dossier and references.

Step 4 – Register the food business: The food business must be registered/approved with the appropriate competent authority before operating, according to the applicable Swedish food-control system.

Step 5 – Prepare compliant label: The label must comply with EU food-information requirements and Swedish requirements applicable to food supplements.

Table no. 03: Comparison of the following components between India and Sweden.

SL.NO	FEATURES	INDIA	SWEDEN
1	Regulatory Authority	Dietary Supplements are regulated by the Food Safety and Standard Authority of India (FSSAI) under the Food Safety and Standard Act 2006	Swedish Food Agency Regulations are based on European Union (EU) legislation.
2	Guidelines	Detailed guidelines for Dietary supplements as per FSSAI have specific guidelines for Dietary supplements (2006)	Governed by EU Food Supplements Directive 2002/46/EC, Regulation (EC) No. 178/2002, Regulation (EU) No. 1169/2011, and Swedish national food regulations.
3	Registration Process	Online Registration	Offline Registration
4	Registration Fees	Rs 1000/- to 5000/-	~Rs 8700/-
5	Inspection	Primarily managed by CDSCO Operates under Ministry of Health and Family Welfare	Municipal Food Control Authorities of EU
6	Labelling	FSSAI guidelines for Labelling	EU-compliant label with ingredients, dosage, warnings
7	Ingredients	FSSAI approved Ingredient List	EU approved Ingredient List
8	Import and Export	Requires Import and Export License from FSSAI	Requires Import and Export License from EU
9	Reference Product	More Stringent	Less stringent
10	Post Marketing Surveillance	More Comprehensive Framework	Limited Framework

CONCLUSION

The present comparative study underlines the need to improve and harmonize the regulatory requirements to ensure consumer safety and to promote the growth of the dietary supplement business in both the countries. Sweden should develop more detailed standards and India should strengthen its post-market surveillance and enforcement systems. Overall, this research contributes to the continued effort to establish more efficient and

standardized laws that regulate dietary supplements in the field. By understanding each other's strengths and weaknesses, India and Sweden can work together to create a more coherent and flexible regulatory regime that safeguards the safety and efficacy of dietary supplements for end users. Overall, effective regulatory control is essential for maintaining the safety, quality, and efficacy of dietary supplements while supporting innovation and market growth. Learning from each

other's regulatory approaches can help India and Sweden develop more consistent, transparent, science-based, and consumer-oriented regulatory practices. Such improvements can contribute to safer dietary supplements and greater consumer confidence in both markets.

ACKNOWLEDGEMENT

We would like to express our sincere gratitude to all those who have supported us in completing this comparative study on the regulatory requirements for the approval of dietary supplements under the food safety and standards authority of India in comparison with Swedish regulatory framework. First and foremost, we thank our faculty **Sir Dr. Ashok Kumar P**, a professor in the pharmaceutical regulatory science department at Sree Siddaganga college of pharmacy in Tukur, for valuable guidance, encouragement, and constructive suggestions throughout the course of this work. We are grateful to our institution for providing us with the resources and a learning platform to carry out this project. We also extend our thanks to the food safety and standards authority of India (FSSAI) and the medical Products agency (Sweden) for making regulatory information accessible, which served as the foundation of this comparison. Finally, we express our heartfelt appreciation to our families and friends for their constant support and motivation, without which this work would not have been possible.....

REFERENCE

1. Grand View Research – Sweden Dietary Supplements Market.[cited 2026 Aug 15] Available from: <https://www.grandviewresearch.com/industry-analysis/sweden-dietary-supplements-market-report>
2. Food World Journal of Advanced Research and Reviews, 2024; 23(03): 2558–2571. from URL: Safety and Standard Authority of India. About FSSAI. Retrieved from:https://fssai.gov.in/upload/advisories/2022/03/6243ef28079ceDirection_Nutra_30_03_2022.pdf
3. Global Dietary Supplement Market, 2023. Available from: <https://images.app.goo.gl/Nek5hQzeVmeqiCHU8>
4. Food World Journal of Advanced Research and Reviews, 2024; 23(03): 2558–2571. from URL: Safety and Standard Authority of India. About FSSAI. Availablefrom: https://fssai.gov.in/upload/advisories/2022/03/6243ef28079ceDirection_Nutra_30_03_2022.pdf
5. Global Dietary Supplement Market, 2023. Available from: <https://images.app.goo.gl/Nek5hQzeVmeqiCHU8>
6. EU-European union (Swedish medical products agency) Available from: URL: <https://en.wikipedia.org/wiki/>
7. Gautam, S., & Gautam, S. FSSAI Health Supplements Regulations & licensing process in India. Artixio.[cited 2026 Aug 18]Available from:<https://www.artixio.com/post/fssai-health-supplements-regulations-india>
8. Food research lab. Non compliance consequences of health supplements registration in India. (n.d.).[cited 2026 Aug 18] Availablefrom: <https://www.foodresearchlab.com/insights/regulation-updates/dietary-supplement-regulations-india-fssai/>
9. Livsmedelsverket. Swedish food agency. Health supplements registration in Sweden. (n.d.).[cited 2026 Aug 18] Available from: https://www.livsmedelsverket.se/en/business-legislation-and-control/legislation-food-business/food-supplements/#Registration,_approval_and_notification_of_food_supplements
10. Livsmedelsverket. Swedish Regulations on Food Supplements, LIVSFS 2003:9. [cited 2026 Aug 15] Availablefrom: <https://www.livsmedelsverket.se/>
11. Livemedelsverket. Swedish Medical Products Agency – Classification of Medicines and Food Supplements. [cited 2026 Aug 15] Available from:<https://www.lakemedelsverket.se/>
12. [IMARC Group – India Dietary Supplements Market] [cited 2026 Aug 15] Available from: (https://www.imarcgroup.com/india-dietary-supplements-market?utm_source=chatgpt.com)herbal medicine regulations. Int J Pharm Sci Res., 2021; 12(4): 2012-.[cited 2026 Aug 12]
13. Kaur R, Choudhary T, Kaur R, Garg M, Chauhan NS, Jain A, Baldi A. Adulteration in Herbal Medicines: A Comprehensive Review on Types, Detection, and Health Impacts. Pharmacognosy Research, 2025; 17(4). [cited 2026 Aug 12]