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(REVIEW ARTICLE)

Regulatory requirements for dietary supplements under food safety and standards authority of India (FSSAI) in comparison with Cambodia

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Abstract

The Food Safety and Standards Authority of India (FSSAI) regulates dietary supplements in India; this study looks at such regulations and compares them with those in Cambodia. Regulations regarding production, labelling, licensing, and advertising are compared and contrasted. Although both nations have set up regulatory systems, the FSSAI guidelines in India are more extensive and have more stringent licensing and labelling requirements. The laws in Cambodia, on the other hand, are more focused on post-market surveillance and are less specific. The present study underscores the necessity of achieving regulatory requirements harmonization and improvement in order to safeguard consumer safety and foster the expansion of the dietary supplement business in both nations. The results will provide insight into the regulatory environment around dietary supplements in India and Cambodia for consumers, industry stakeholders, and policymakers1.

Keywords: Dietary supplements; Regulatory requirements; Regulatory framework; Harmonization; FSSAI

1. Introduction

Globally, the dietary supplement market has grown quickly due to rising consumer demand for wellness and health-related products. But this expansion has also sparked questions about the drugs' efficacy and safety. In response, governing bodies have set rules to guarantee the safety and quality of dietary supplements. The Ministry of Health in Cambodia is in charge of regulating the dietary supplement business, whereas the Food Safety and Standards Authority of India (FSSAI) is in charge in India. The legal specifications for nutritional supplements in India and Cambodia diverge greatly, even if their objectives are identical. This study attempts to identify similarities, differences, and opportunities for improvement between the regulatory frameworks for dietary supplements in Cambodia and India under the FSSAI recommendations. Through an analysis of the regulatory frameworks in both nations, this study aims to support the creation of more efficient and unified rules, ultimately guaranteeing consumer safety and encouraging the expansion of the dietary supplement market in the area.

Objective

- Nutritional Supplementation: To support general health and well-being by offering vital vitamins, minerals, and nutrients.
- Health Promotion: To use dietary supplements to prevent illness and promote health.
- Disease Prevention: Using dietary supplements to manage or prevent disease.
- Quality of Life: To enhance general health and correct dietary inadequacies in order to increase quality of life.

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Scope

- Regulation: Dietary supplements are governed by government agencies such as the MOH in Cambodia and the FSSAI in India.
- Manufacturing: Companies use natural ingredients and conventional methods to create dietary supplements.
- Industry Size: The global dietary supplement market is expected to be valued billions of dollars, with demand growing in developing countries.
- Research: Ongoing studies are being carried out to expand our understanding of dietary supplements and their effects on human health.

1.1. In India, dietary supplements are regulated by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006. Here are some key regulatory requirements

- License and Registration: Manufacturers and sellers of dietary supplements must obtain a license from the FSSAI.
- Product Approval: Products must be approved by the FSSAI before they can be sold.
- Labelling and Packaging: Labels must include details like ingredients, nutritional information, and instructions for use.
- Safety Standards: Products must comply with safety standards set by the FSSAI.
- Good Manufacturing Practices (GMPs): Manufacturers must follow GMPs to ensure product quality and safety.
- Advertising and Claims: Advertisements and claims made about products must be truthful and not misleading.
- Ingredients: Only approved ingredients can be used, and their sources must be declared.
- Quantity and Quality: Products must meet specified quantity and quality standards.
- Import and Export: Import and export of dietary supplements are regulated by the FSSAI and other authorities.
- Compliance with Ayurvedic, Unani, Siddha, and Homoeopathy (AUSH) regulations: If products are labelled as AUSH, they must comply with specific regulations2.

1.2. In Cambodia, dietary supplements are regulated by the Ministry of Health (MoH) and the Food and Drug Department (FDD) under the Law on Food Safety (2019) and the Sub-Decree on Dietary Supplements (2020). Here are some key regulatory requirements

- Registration: Dietary supplements must be registered with the FDD before sale.
- License: Manufacturers and importers must obtain a license from the FDD.
- Product Labelling: Labels must be in Khmer (Cambodian language) and include details like ingredients, nutritional information, and instructions for use.
- Safety Standards: Products must comply with safety standards set by the MoH.
- Good Manufacturing Practices (GMPs): Manufacturers must follow GMPs to ensure product quality and safety.
- Advertising and Claims: Advertisements and claims made about products must be truthful and not misleading.
- Ingredients: Only approved ingredients can be used, and their sources must be declared.
- Quantity and Quality: Products must meet specified quantity and quality standards.
- Import and Export: Import and export of dietary supplements are regulated by the FDD and other authorities.
- Compliance with Traditional Medicine regulations: If products are labeled as Traditional Medicine, they must comply with specific regulations3.

Additionally, dietary supplements are classified into three categories:

- Category 1: Vitamins and minerals
- Category 2: Herbal and botanical products
- Category 3: Other dietary supplements (e.g., amino acids, probiotics)

2. The following organizations oversee dietary supplement regulations in Cambodia

- Food and Drug Department (FDD): Charged with overseeing dietary supplement regulations and guaranteeing their efficacy, quality, and safety.
- Ministry of Health (MoH): This body is in charge of the FDD and establishes general health regulations, which include dietary supplement regulations.

2.1. In particular, the FDD is in charge of

- Enforcing compliance through inspections
- Granting permits to importers and producers
- Registering dietary supplement items
- Establishing safety regulations
- Controlling labelling and advertising

2.2. In India, the regulatory body overseeing dietary supplements is the

- Food Safety and Standards Authority of India (FSSAI): Charged with policing dietary supplements and guaranteeing their efficacy, safety, and quality.
- Ministry of Health and Family Welfare (MOHFW): This organization is in charge of the FSSAI and establishes general health guidelines, which include dietary supplement guidelines.

2.3. The FSSAI is specifically in charge of

- Enforcing compliance through inspections
- Granting permits to importers and producers
- Registering dietary supplement items
- Establishing safety regulations
- Controlling labelling and advertising

3. Regulatory requirements for manufacture, sale and import of dietary supplements in India

In India, the following regulations control the manufacturing, importation, and sale of dietary supplements:

- Food Safety and Standards Authority of India (FSSAI): This regulatory agency is in charge of making sure food products, including dietary supplements, are safe and of high quality.
- Food Safety and Standards Act, 2006: This law governs food product import, manufacturing, and distribution, including dietary supplements.
- Food Safety and Standards (Health Supplements) laws, 2016: The production, distribution, and import of dietary supplements are particularly governed by these laws.

4. Regulatory requirements for manufacture of dietary supplements in India

4.1. Important prerequisites

- Good manufacturing practices (GMPs) compliance
- License from FSSAI for production
- Adherence to labeling and packaging rules
- Product registration with FSSAI
- Limitations on specific substances and statements

To acquire a license for dietary supplements from the FSSAI, take the following actions:

- Ascertain the kind of license: Choose if you require a labeling/repacking license or a manufacturing license.
- Make the right category selection: "Health Supplements" is where dietary supplements belong.
- Collect the necessary paperwork:
    - Documentation related to business registration
    - Proof of identity and address for the directors, partners, and owners
    - Documentation proving you own the property (rental agreement, ownership deed, etc.)
    - List of nutritional supplements to be produced or sold
    - Design of labels and packaging
    - NOC from local authorities (where applicable)
    - Details about the formula and ingredients
    - Analysis certificates for every ingredient
- Report on toxicology, if relevant

- Complete Form A: Fill out the application and pay the necessary cost via the FSSAI's online portal, foscos.fssai.gov.in.
- Upload documents: Include all of the collected paperwork in the online application.
- Self-Declaration: Submit a self-declaration regarding compliance with FSSAI regulations.
- Inspection: To ensure that your property complies with regulations, the FSSAI may do an inspection.
- License issuance: If all is OK, the FSSAI will grant a license that lasts between one and five years.
- Renewal: To avoid fines, renew your license prior to its expiration.

4.2. Extra specifications for dietary supplements

- Make sure that the Health Supplements standards, 2016 of the FSSAI are followed.
- Labelling and packaging must also adhere to the standards of the FSSAI.
- The FSSAI must approve the ingredients, and the products must be made in a facility registered with the FSSAI.

5. Good Manufacturing Practices (GMP) compliance for dietary supplements in India

5.1. Regulatory Framework

- Food Safety and Standards Act, 2006: The primary legislation governing food safety in India, including dietary supplements.
- Food Safety and Standards (Dietary Supplements) Regulations, 2019: Specific regulations for dietary supplements, including GMP requirements.
- Indian Standard (IS) 14433:2018: A standard for dietary supplements, including GMP guidelines.

5.2. GMP Requirements

- Quality Management System (QMS): Set up a QMS to guarantee that dietary supplement design, production, testing, and distribution adhere to quality and safety requirements.
- Personnel: Ascertain that those engaged in testing, manufacturing, and quality assurance possess the required education, training, and expertise.
- Facilities and Equipment: To avoid contamination and guarantee effective manufacturing, keep clean, well-ventilated, and orderly facilities and equipment.
- Raw Material Control: Source high-quality raw materials from approved suppliers and conduct regular testing to ensure identity, purity, and potency.
- Production Process: To guarantee consistency and quality, create and adhere to a clear production process that includes blending, mixing, and packaging.
- Testing and Validation: To guarantee adherence to quality standards, test and validate raw materials, materials used during production, and final products on a regular basis.
- Packaging and Labelling: Make sure the labelling and packaging are correct, comprehensive, and in compliance.
- Record Keeping: To guarantee traceability and compliance, keep precise and thorough records of the production, testing, and distribution processes.
- Deviation Management: Create protocols for locating, looking into, and fixing GMP rules that are not being followed.
- Continuous Improvement: To guarantee continued compliance and advancement, evaluate and upgrade GMP processes on a regular basis5.

5.3. Certifications and Audits

- FSSAI License: Mandatory for all food businesses, including dietary supplement manufacturers.
- GMP Certification: Issued by third-party auditors, such as NSF International or the National Sanitation Foundation.
- ISO 9001:2015 Certification: A quality management system certification demonstrating a company's commitment to quality and customer satisfaction.
- Regular Audits: Conduct internal audits and third-party audits to ensure ongoing compliance with GMP guidelines.

5.4. Consequences of Non-Compliance

- Fines and Penalties: imposed for non-compliance by regulatory bodies.

- Product Recalls: Items that don't adhere to safety and quality regulations must be recalled.
- Loss of Reputation: Damage to a company's reputation and customer trust.
- Business Closure: In severe cases, non-compliance can lead to business closure.

5.5. GMP Compliance Checklist

- Is your facility licensed by FSSAI?
- Do you have a QMS in place?
- Are your personnel properly trained and qualified?
- Are your facilities and equipment clean and well-maintained?
- Do you conduct regular testing and validation?
- Are your packaging and labelling compliant?
- Do you maintain accurate records?
- Have you established deviation management procedures?
- Do you conduct regular audits and continuous improvement?

6. Labelling and packaging rules compliance for Dietary Supplements in India

6.1. Labelling Requirements

- Product Name: The label needs to make the product name more visible.
- Ingredients: A list of ingredients must be included, along with their quantities or proportions.
- Nutritional Information: It is necessary to offer nutritional information, which includes macro- and micronutrients.
- Instructions for Use: Detailed usage instructions must be provided.
- Warning Statements: Warning statements, such as potential allergens or interactions, must be displayed.
- Manufacturer's Details: You need to mention the name, address, and phone number of the manufacturer.
- FSSAI License Number: It is required to have the FSSAI license number visible.
- Batch Number and Expiration Date: It is necessary to provide the batch number and expiration date6.

6.2. Packaging Requirements

- Packaging Material: Non-toxic and non-reactive materials are required for packaging.
- Sealing: To stop tampering, packaging needs to be correctly sealed.
- Label Attachment: Labels need to be fastened to the packing in a secure manner.
- Package Size: The size of the package should be appropriate for the product and easy to open.

6.3. Regulatory Guidelines

- Food Safety and Standards (Packaging) Regulations, 2011: Regulates packaging materials and containers.
- Food Safety and Standards (Labelling) Regulations, 2019: Regulates labelling requirements for food products, including dietary supplements.
- Indian Standard (IS) 13432:2018: Provides guidelines for packaging and labelling of dietary supplements.

7. Product registration with FSSAI

7.1. Pre-Requisites

- FSSAI License: To produce and market dietary supplements, make sure you possess a current FSSAI license.
- Product Formulation: Complete the formulation of your product and make sure it conforms with FSSAI guidelines.
- Labelling and Packaging: Verify that the labels and packaging of your products adhere to FSSAI guidelines.

7.2. Product Registration Process

- Create an Account: Sign up and create an account on the FSSAI website ((link unavailable)).
- Fill Product Details: Fill in the product details, including product name, description, ingredients, nutritional information, and labelling details.
- Upload Documents: Upload the necessary files, including:

  - Formulation of products
  - Designs for labels and packaging
  - Analysis Certificate (CoA)
  - The manufacturers' statement
- Cover Fees: Depending on the product category, the registration fees for products range from Rs. 1,000 to Rs. 5,000.
- Submit Application: After submitting the form, a Unique Application Number (UAN) will be issued.
- Review and Verification: The documents and application are reviewed and verified by the FSSAI.
- Product Registration: Upon approval, a Product Registration Certificate bearing a special registration number will be sent to you.

7.3. Essential Records

- Product Formulation: A thorough description of the product's composition, including quantities and substances.
- Labelling and Packaging designs: Copies of labelling and packaging designs.
- Certificate of Analysis (CoA): For both the final product and each ingredient, a CoA issued by an accredited laboratory is required.
- Declaration from Manufacturers: A statement from the manufacturer attesting to the product's compliance with FSSAI guidelines.
- FSSAI License: A copy of the license from FSSAI.

7.4. Timeline

- Application Submission: 1-2 days
- FSSAI Review and Verification: 15-30 days
- Product Registration: 30-60 days (depending on the complexity of the application)

7.5. Fees

- Product Registration Fees: Rs. 1,000 - Rs. 5,000 (depending on the product category)
- Lateness Fees: Rs. 500 - Rs. 2,000 (if the application is submitted late)

8. Limitations on specific substances and statements

8.1. Restricted Substances

- Herbs and Botanicals: Some botanicals and herbs, such as ephedra, are prohibited or subject to restrictions.
- Steroids and Hormones: It is forbidden to use steroids and hormones, such as testosterone.
- Caffeine and Theobromine: 200 mg of caffeine and 100 mg of Theobromine per serving are the limits.
- Prohibited Substances: Certain substances are prohibited, including thalidomide, chloramphenicol, and aristolochic acid.

8.2. Labelling and Claim Limitations

- Therapeutic Claims: It is illegal to make statements that a product cures or prevents a condition.
- Medical Claims: It is forbidden to make statements that a product is a medication or a substitute for medication.
- Nutritional Claims: FSSAI criteria must be followed, and claims must be backed up by scientific data.
- Exaggerated Claims: It is forbidden to make false or exaggerated claims.

8.3. Specific Substance Limits

- Vitamins and Minerals: Limits apply to vitamins and minerals, like vitamin A (10,000 IU per serving) and iron (45mg per serving).
- Amino Acids: Limits apply to amino acids, like L-tryptophan (500mg per serving).
- Glycosaminoglycans: Limits apply to glycosaminoglycans, like glucosamine (500mg per serving).

9. Regulatory requirements for sale and import of dietary supplements in India

9.1. Sale of Dietary Supplements

- FSSAI License: To offer dietary supplements, you must have an FSSAI license.
- Product Registration: Prior to sale, register products with the FSSAI.
- Labelling and Packaging: Adhere to the FSSAI's guidelines for labelling and packaging.
- Advertising and Claims: Verify that advertising and claims are accurate and not misleading.
- Quality Control: Verify that goods are produced in a GMP-compliant facility and that they meet quality standards.

9.2. Import of Dietary Supplements

- FSSAI Import License: For every product, get an import license from FSSAI.
- Product Approval: Prior to import, obtain FSSAI approval for every goods.
- Labelling and Packaging: Adhere to the FSSAI's guidelines for labelling and packaging.
- Quality Control: Verify that goods are produced in a GMP-compliant facility and that they meet quality standards.
- Certification: Get your certification from an accredited body like the National Sanitation Foundation or NSF International.

9.3. Regulatory Framework

- Food Safety and Standards Act, 2006: The primary legislation governing food safety in India, including dietary supplements.
- Food Safety and Standards (Dietary Supplements) Regulations, 2019: Specific regulations for dietary supplements, including sale and import requirements.
- Indian Standard (IS) 14433:2018: A standard for dietary supplements, including sale and import requirements.

9.4. Documentation

- FSSAI License: A copy of the FSSAI license.
- Product Registration: A copy of the product registration certificate.
- Import License: A copy of the import license.
- Certificate of Analysis (CoA): A CoA from a recognized laboratory.
- Manufacturer's Declaration: A declaration from the manufacturer stating that the product complies with FSSAI regulations.

9.5. Timeline

- FSSAI License: 30-60 days
- Product Registration: 30-60 days
- Import License: 15-30 days
- Product Approval: 30-60 days

9.6. Fees

- FSSAI License: Rs. 1,000 - Rs. 5,000
- Product Registration: Rs. 1,000 - Rs. 5,000
- Import License: Rs. 1,000 - Rs. 5,000
- Product Approval: Rs. 1,000 - Rs. 5,000

9.7. Consequences of Non-Compliance

- Fines and Penalties: Imposed by FSSAI for non-compliance.
- Product Recall: Mandatory recall of non-compliant products.
- Loss of Reputation: Damage to a company's reputation and customer trust.
- Business Closure: In severe cases, non-compliance can lead to business closure

9.8. Marketing of Dietary Supplements in India

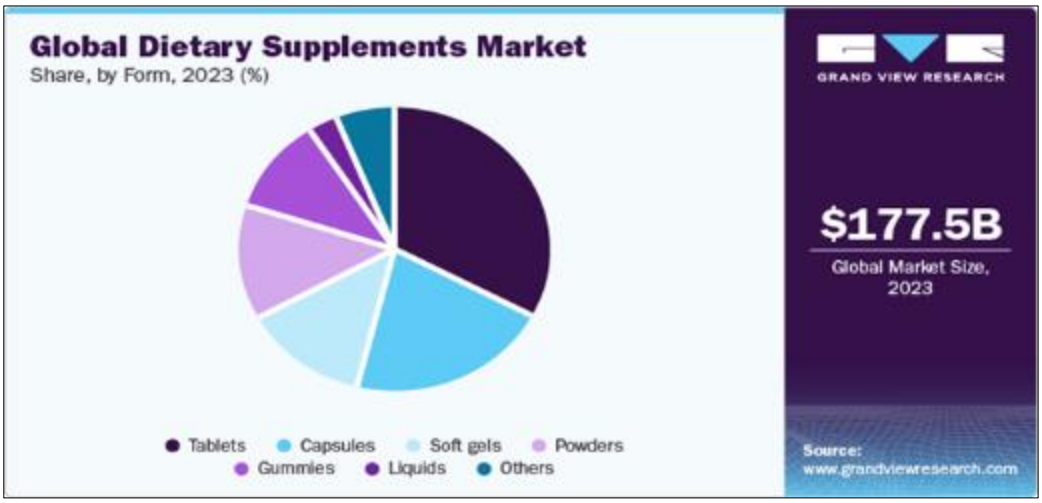

Figure 1 Global Dietary Supplements Market 2023(%)

10. Regulatory requirements for manufacture, sale, and import of dietary supplements in Cambodia

Regulatory requirements for manufacture of dietary supplements in Cambodia:

- Ministry of Health license: To produce dietary supplements, need a license from the Ministry of Health.
- GMP Compliance: Verify that production facilities follow the rules for good manufacturing practices, or GMPs.
- Product Registration: Before a product is manufactured, register it with the National Agency for Drug and Medical Device Regulation (NADMR)7.

10.1. license from the Ministry of Health in Cambodia

In order to produce, market, or import dietary supplements into Cambodia, a license from the Ministry of Health is required.

10.2. License Types

- Manufacturing License: In order to produce dietary supplements in Cambodia, a license is needed.
- Sales License: In Cambodia, this is necessary to sell nutritional supplements.
- Import Licensing: Necessary to bring nutritional supplements into Cambodia.

10.3. Qualifications

- Company Registration: The Ministry of Commerce requires that the company be registered.
- Technical Qualification: The business has to employ a technical staff with the necessary training and expertise.
- Facilities and Equipment: The business needs the right facilities and equipment for production, distribution, and storage.
- Quality Control: The business needs to have a system in place for quality control.

10.4. Procedure for Application

- Submit Application: Together with the necessary paperwork, submit an application to the Ministry of Health.
- Review and Verification: The application and supporting documentation are examined and confirmed by the Ministry of Health.
- Inspection: The equipment and facilities are inspected by the Ministry of Health.
- License Issuance: If the application is accepted, a license is issued.

10.5. Essential Records

- Certificate of Company Registration: A duplicate of the certificate of company registration.
- Technical Team Profile: An overview of the technical team's background and qualifications.

- Description of the Facilities and Equipment: An explanation of the facilities and equipment.
- Quality Control Manual: A duplicate of the manual for quality control.
- Product Information: Details regarding the ingredients, packaging, and labelling of the dietary supplements.

10.6. Timeline

- Application Review: 15-30 days
- Inspection: 15-30 days
- License Issuance: 30-60 days

10.7. Fees

- Manufacturing License: 50,000 - 200,000 Riel (approx. $12.50 - $50 USD)
- Sales License: 20,000 - 50,000 Riel (approx. $5 - $12.50 USD)
- Import License: 20,000 - 50,000 Riel (approx. $5 - $12.50 USD)

10.8. Consequences of Non-Compliance

- Fines and Penalties: Imposed by the Ministry of Health for non-compliance.
- License Revocation: The license can be revoked for serious non-compliance.
- Loss of Reputation: Damage to a company's reputation and customer trust.
- Business Closure: In severe cases, non-compliance can lead to business closure.

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11. GMP Compliance

11.1. GMP Requirements

- Facilities and Equipment: Make certain that the facilities and equipment are hygienic, well-maintained, and appropriate for manufacturing.
- Personnel: Ascertain that staff members possess the required education, training, and experience.
- Raw Materials: Obtain premium raw materials from vetted vendors.
- Manufacturing Process: Create a regulated manufacturing procedure that involves blending, mixing, and packing.
- Quality Control: To guarantee the purity and quality of the product, put in place a quality control system.
- Documentation: Keep thorough and precise records of the distribution, testing, and production processes.

11.2. GMP Certification

- National Agency for Drug and Medical Device Regulation (NADMR) Certification: Obtain GMP certification from NADMR.
- International GMP Certification: Obtain international GMP certification, such as NSF International or the National Sanitation Foundation.

11.3. Advantages of GMP Adherence

- GMP compliance guarantees that dietary supplements fulfil quality and purity requirements, which in turn assures product quality.
- Regulatory Compliance: By adhering to regulations, GMP compliance lowers the possibility of fines and penalties.
- Enhanced Customer Trust: Adhering to GMPs shows a dedication to excellence, which in turn enhances customer trust.
- Competitive Advantage: Your business has an advantage over rivals because of GMP compliance.

11.4. Implications of Non-Compliance

- Penalties and Fines: Imposed for noncompliance by NADMR.
- Product Recall: Items that do not comply must be recalled.
- Reputational Damage: Damage to a company's reputation and customer trust.
- Business Closure: Noncompliance may, in extreme circumstances, result in the closure of a business.

12. Product Registration

12.1. Product Registration Requirements

- Product Details: Give comprehensive product details, such as the name, contents, packaging, and labelling.
- Manufacturing Process: Explain the steps involved in the production process, such as where to find raw materials and quality assurance procedures.
- Quality Control: Provide information about quality control, such as test findings and requirements.
- Labelling and Packaging: Submit labelling and packaging so they can be examined.
- Clinical Evidence: Offer clinical proof of the product's effectiveness and safety.

12.2. Procedure for Product Registration

- Submit Application: Send the National Agency for Drug and Medical Device Regulation (NADMR) the product registration application.
- Review and Verification: The application and any supporting documentation are examined and verified by NADMR.
- Inspection: The production plant is inspected by NADMR.
- Registration: If the application is accepted, the product is registered.

12.3. Essential Records

- Product Registration Application: A duly filled out application.
- Product Information page: A thorough page of product details.
- Manufacturing Process Description: An explanation of the process involved in manufacturing.
- Quality Control Data: This category comprises specifications and test results.
- Packaging and Labelling Materials: Packaging and labelling materials.
- Clinical Evidence: Clinical data demonstrating the safety and effectiveness of the product.

12.4. Timeline

- Application Review: 15-30 days
- Inspection: 15-30 days
- Registration: 30-60 days

12.5. Fees

- Product Registration Fee: 20,000 - 50,000 Riel (approx. $5 - $12.50 USD)
- Inspection Fee: 10,000 - 20,000 Riel (approx. $2.50 - $5 USD)

13. Labelling

13.1. Required Labelling Information

- Product Name: The product name must be clearly displayed on the label.
- Ingredients: A list of ingredients must be included, along with their quantities or proportions.
- Nutritional Information: Nutritional information, including macronutrients and micronutrients, must be provided.
- Dosage Instructions: Clear dosage instructions must be included.
- Warnings and Precautions: Warnings and precautions, such as potential allergens or interactions, must be displayed.
- Manufacturer's Details: The manufacturer's name, address, and contact information must be included.
- Batch Number and Expiration Date: The batch number and expiration date must be included.
- Country of Origin: The country of origin must be indicated.

13.2. Labelling Requirements

- Language: Labelling information must be in Khmer, the official language of Cambodia.
- Font Size and Style: Font size and style must be clear and readable.

- Label Size: The label size must be sufficient to accommodate all required information.
- Colour: The label colour must be contrasting and easy to read.

13.3. Consequences of Non-Compliance

- Fines and Penalties: Imposed by NADMR for non-compliance.
- Product Recall: Mandatory recall of non-compliant products.
- Loss of Reputation: Damage to a company's reputation and customer trust.
- Business Closure: In severe cases, non-compliance can lead to business closure.

14. Packaging

14.1. Packaging Requirements

- Material: The materials used for packaging must be secure, non-toxic, and appropriate for the product.
- Size and Shape: The packaging needs to match the size and shape of the product.
- Closure: To avoid contamination and tampering, packaging needs to be securely closed.
- Labelling: Product names, components, and dosing directions, among other necessary information, must be labelled on packaging.
- Protection: The product must be shielded from environmental elements (such as moisture, light, and temperature) by its packaging.

14.2. Consequences of Non-Compliance

- Fines and Penalties: Imposed by NADMR for non-compliance.
- Product Recall: Mandatory recall of non-compliant products.
- Loss of Reputation: Damage to a company's reputation and customer trust.
- Business Closure: In severe cases, non-compliance can lead to business closure.

15. Regulatory requirements for sale and import of dietary supplements in Cambodia

15.1. Sale

- Business License: To sell dietary supplements, need a business license from the Ministry of Commerce.
- Product Labelling: Adhere to all labelling requirements, including those pertaining to the product name, ingredients, and nutritional data.
- Clearance for Advertising: Get NADMR clearance for your advertising materials.

15.2. Import

- Import License: For every product, get an import license from NADMR.
- Product Approval: Prior to importation, obtain NADMR approval for each product.
- Certificate of Analysis (CoA): Present a certified laboratory's CoA.

15.3. Regulatory Structure

- Law on Medicines and Medical Devices: The primary legislation governing the manufacture, sale, and import of dietary supplements in Cambodia.
- Dietary Supplement Regulations: Particular guidelines pertaining to the production, marketing, and importation of dietary supplements.
- ASEAN Food Regulatory Manual: Cambodia complies with ASEAN food regulations, which include dietary supplement regulations[7].

15.4. Documentation

- Manufacturing License: A copy of the manufacturing license.
- Product Registration: A copy of the product registration certificate.
- GMP Certificate: A GMP certificate from a recognized organization.
- Import License: A copy of the import license.

- CoA: A CoA from a recognized laboratory.

15.5. Timeline

- Manufacturing License: 30-60 days
- Product Registration: 30-60 days
- Import License: 15-30 days
- Product Approval: 30-60 days

15.6. Fees

- Manufacturing License: 10,000 - 50,000 Riel (approx. $2.50 - $12.50 USD)
- Product Registration: 5,000 - 20,000 Riel (approx. $1.25 - $5 USD)
- Import License: 5,000 - 20,000 Riel (approx. $1.25 - $5 USD)
- Product Approval: 5,000 - 20,000 Riel (approx. $1.25 - $5 USD)

15.7. Consequences of Non-Compliance

- Fines and Penalties: Imposed by NADMR for non-compliance.
- Product Recall: Mandatory recall of non-compliant products.
- Loss of Reputation: Damage to a company's reputation and customer trust.
- Business Closure: In severe cases, non-compliance can lead to business closure.

16. Comparison of the regulatory requirements for dietary supplements between India and Cambodia

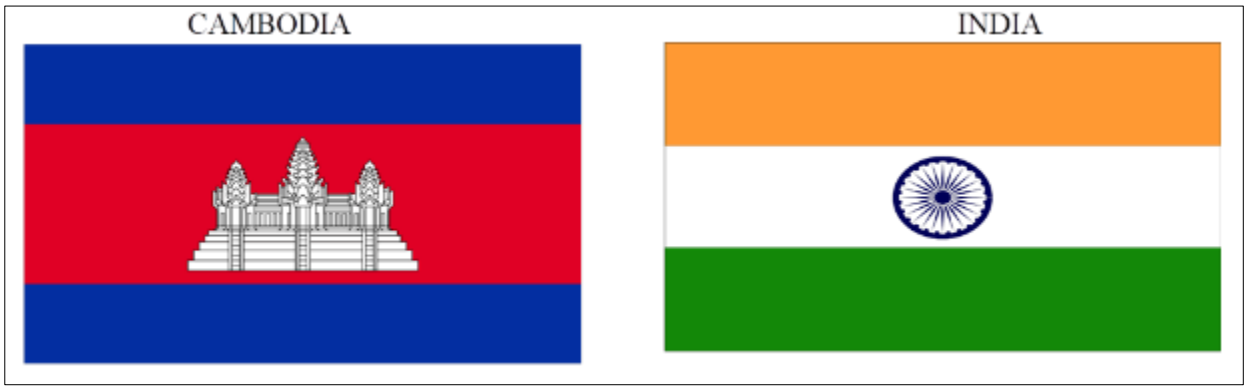

Figure 2 Flag of Cambodia and India

Table 1 Comparison of regulatory requirements for Dietary Supplements between Cambodia and FSSAI (Food Safety and Standards Authority of India)

SL.NO	FEATURES	INDIA	CAMBODIA
01	Regulatory Authority	Dietary Supplements are regulated by the Food Safety and Standard Authority of India (FSSAI) under the Food Safety and Standard Act 2006	Dietary Supplements are regulated by Ministry of Health (MoH) and the Food and Drug Department (FDD) under the Law on Food Safety (2019) and Sub-Decree on dietary supplements (2020)
02	Guidelines	Detailed guidelines for Dietary supplements as per FSSAI Has specific guidelines for Dietary supplements (2006)	Detailed guidelines for dietary supplements as per MoH, under the law on FDD Has specific guidelines for Dietary supplements (2019&2020)
03	Registration Process	Online Registration	Offline Registration

04	Registration Fees	Rs 1000/- to 5000/-	20000 to 50000 Riel
05	Inspection	Primarily managed by CDSCO Operates under Ministry of Health and Family Welfare	Managed by Ministry of Health Specifically, through its Department of Drugs and Food
06	Labelling	FSSAI guidelines for Labelling	DDF guidelines for Labelling
07	Ingredients	FSSAI approved Ingredient List	DDF approved Ingredient List
08	Import and Export	Requires Import and Export License from FSSAI	Requires Import and Export License from DDF
09	Reference Product	More Stringent	Less Stringent
10	Post Marketing Surveillance	More Comprehensive Framework	Limited Framework

17. Conclusion

The present comparative research underscores the necessity of regulatory requirements to be improved and harmonized in order to safeguard consumer safety and promote the expansion of the dietary supplement business in both nations. More detailed standards should be adopted by Cambodia, and India should strengthen its post-market surveillance and enforcement systems. In the end, this research adds to the continuing attempts to create more efficient and uniform laws governing dietary supplements in the area. India and Cambodia can collaborate to establish a more cohesive and flexible regulatory system that guarantees the security and effectiveness of dietary supplements for end users by understanding each other's advantages and disadvantages.

Compliance with ethical standards

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No conflict of interest to be disclosed.

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