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LEGAL CLASSIFICATION AND REGULATION OF DIETARY SUPPLEMENTS AND FUNCTIONAL HEALTH-CLAIM FOODS

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ABSTRACT

This paper looks at the legal classification and regulation of dietary supplements and functional health claim foods in India. Over the past two decades, products such as protein powders, vitamins, and other nutraceuticals have become extremely common in gyms, pharmacies, and online marketplaces. Even though they are often marketed with strong promises of improving health, immunity, or physical performance, the law usually treats them as food rather than medicine. This difference in classification is important because drugs are regulated under the Drugs and Cosmetics Act, 1940, which requires strict testing and approvals, while supplements placed under the Food Safety and Standards Act, 2006 face comparatively lighter regulation.

The paper examines how this classification creates a regulatory gap that allows companies to promote products using health related claims without meeting the scientific standards required for medicines. It studies the role of laws such as the Food Safety and Standards Act, the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, and the Consumer Protection Act, 2019 in controlling misleading claims. The research also draws on judicial decisions and enforcement data obtained through a Right to Information request from the Food Safety and Standards Authority of India. By comparing the Indian framework with regulatory systems in the European Union and the United States, the paper shows how stronger claim verification mechanisms operate elsewhere. It finally suggests reforms aimed at improving regulatory clarity, strengthening oversight of health claims, and protecting consumers in the growing supplement market.

KEYWORDS

Nutraceuticals; Dietary Supplements; Functional Foods; Food Safety and Standards Act; Misleading Health Claims; Consumer Protection; Comparative Law; MuscleBlaze Case Study; Regulatory Loopholes; Enforcement.

1.1 INTRODUCTION

Over the last two decades the market for nutraceuticals and functional foods in India has grown rapidly. Products like protein powders, vitamins and energy drinks are now common in gyms, pharmacies, online stores and even grocery shops. They are promoted with bold promises of better health, which makes people think of them as medicine. In law though, most of them are treated as food, and that is where the main issue lies.

The problem comes from classification. If a product is seen as a drug under the Drugs and Cosmetics Act 1940, it needs strict trials and approvals. But under the Food Safety and Standards Act 2006, especially Section 22, many supplements are placed in the food category.

This helps companies avoid tougher rules while still making strong health claims.

Advertisements add to the confusion. The Drugs and Magic Remedies Act 1954 and the Consumer Protection Act 2019 are meant to control false or exaggerated claims, but enforcement is weak. Data obtained through an RTI from FSSAI shows that most violations reported are about labelling or packaging, not about the truth of health claims.

The case of MuscleBlaze Biozyme Whey Protein is a clear example. The company relied on a self funded study in a questionable journal to promote its product, yet regulators did not intervene. This shows how big brands can use loopholes to their advantage.

This research looks at how Indian law deals with such products, why current rules fall short, and what lessons can be learned from the stronger systems of the European Union and the United States.

1.2 STATEMENT OF PROBLEM

The main problem with nutraceuticals and foods that carry health claims in India is that they sit in a kind of grey area. They are not fully treated as drugs, but they are also not just ordinary food. Under the Drugs and Cosmetics Act 1940, if something is a drug, then it must go through strict testing, proper approvals and licensing before it can be sold. This process is tough, expensive and time consuming. But when companies manage to label their products as supplements or nutraceuticals, the Food Safety and Standards Act 2006 comes into play. Section 22 of this Act has very broad wording and once a product falls within that, the requirements are far more relaxed. This difference naturally gives companies a big incentive to get their products placed in the food category rather than as drugs. When they do that, they avoid the hard process of proving safety and efficacy, yet at the same time they use advertisements that look and sound very much like medical claims. The words they use promise things like boosting immunity or improving recovery, but without the kind of scientific evidence that a drug would have to show. The issue becomes worse because enforcement authorities mostly look at superficial aspects like whether the label is proper or whether the packaging follows the rules. The Right to Information reply from the Food Safety and Standards Authority of India shows that most of the violations they flag each year are about branding or labelling and not about whether the claims themselves are true. This creates a loophole where companies can legally continue with very bold claims that may not have strong scientific backing.

1.3 RESEARCH QUESTION

This paper is shaped around a few simple but important questions:

- How are nutraceuticals and functional foods classified under Indian law and why does this matter so much.
- How do companies use classification as food to avoid stricter rules for drugs while still making health based promises.
- How effective are the current laws such as the Food Safety and Standards Act 2006, the Drugs and Cosmetics Act 1940, the Drugs and Magic Remedies Act 1954 and the Consumer Protection Act 2019 in dealing with misleading health claims.
- What does the RTI reply from FSSAI tell us about the way enforcement really works in practice.
- How do the Indian rules compare with the systems in the European Union and the United States.
- What can be learned from specific disputes and the case study of MuscleBlaze.
- What changes or reforms could make the system more reliable and fair for consumers.

1.4 SIGNIFICANCE OF RESEARCH

The significance of this research is that it deals with a sector that is expanding rapidly and reaching millions of people. Supplements and functional foods are now sold almost

everywhere, from gyms and online sites to ordinary grocery stores. People buy them believing in the promises made in advertisements, but the legal framework that should protect them is not very strong. Studying this gap is important because it directly affects consumer trust and safety. This study is also valuable because it does not just repeat statutes. It looks at the laws and cases, but also at real evidence like the RTI reply from FSSAI and the case of MuscleBlaze. The RTI data gives numbers about what the regulator is actually doing and the MuscleBlaze example shows how a big brand can use a weak self funded trial to support bold claims. This mix of law and evidence makes the research more grounded. The significance also goes beyond India. By comparing with the European Union and the United States, the research shows that stronger systems already exist and that India could learn from them. So the value of this work lies in pointing out where the gaps are and how they can be closed.

1.5 SCOPE AND LIMITATION OF RESEARCH

The scope of this paper is the Indian legal system that applies to nutraceuticals and functional health foods. It studies the main statutes such as the Food Safety and Standards Act 2006, the Drugs and Cosmetics Act 1940, the Drugs and Magic Remedies Act 1954 and the Consumer Protection Act 2019. It also looks at the regulations of 2011 and 2016. Case law from Indian courts and consumer forums is included to see how disputes on classification and claims are handled. There are some limitations. The study does not try to cover every product or brand in the market. Instead it picks examples that show the broader issues, like the MuscleBlaze case. It does not involve scientific testing or lab work, so it cannot judge product safety directly. The foreign comparison is limited to the European Union and the United States because they have well known regulatory systems. So the scope is legal and regulatory, supported by data and case studies, and the limitation is that it cannot claim to cover the entire industry or all scientific aspects.

1.6 OBJECTIVE OF RESEARCH

The main objective of this research is to see how Indian law regulates nutraceuticals and functional foods and to show why the present framework is not enough to protect consumers. More detailed objectives are:

- To examine the statutory framework and how it defines and regulates these products.
- To understand how companies benefit from being placed under food law while avoiding stricter drug law.
- To study what enforcement bodies like FSSAI and CCPA actually do, with help from RTI data.
- To use the MuscleBlaze case study to show how claims are made and backed in practice.
- To compare Indian law with the systems in the European Union and the United States.
- To propose reforms that would bring more clarity, honesty and consumer safety.

1.7 RESEARCH METHODOLOGY

The research uses both doctrinal and empirical methods. The doctrinal part means looking at statutes, regulations and case law such as Puma Ayurvedic Herbal, Wockhardt Life Sciences, Vital Nutraceuticals, Sun Pharma and Rahul Shekhawat. These decisions show how courts deal with classification and advertising disputes. The empirical part comes from the Right to Information reply by FSSAI, which shows actual numbers about non conforming samples, prosecutions and convictions. This helps to see how enforcement is happening on the ground. The study also uses a case study method. MuscleBlaze Biozyme Whey Protein is taken as an example because it is a flagship product of a leading brand. The clinical trial it cites was closely read and even the responses from the company through mail are used to show how accountability is avoided. Finally, there is a comparative part. The European Union system under Regulation 1924 of 2006 and the

United States system under DSHEA 1994 are looked at. These comparisons make it clear that other countries have stronger tools, like pre market approvals and disclaimers, which India does not have.

2. LITERATURE REVIEW

The literature that is directly relevant here comes from statutes, regulations, case law and reports. The Food Safety and Standards Act 2006 and the regulations of 2011 and 2016 give the base definitions and rules for supplements in India. The Drugs and Cosmetics Act 1940 and the Drugs and Magic Remedies Act 1954 continue to apply in some areas. The Consumer Protection Act 2019 adds new powers for misleading advertisements but has been used in a limited way so far.

Significant case laws of this domain such as the Supreme Court in Puma Ayurvedic Herbal and Wockhardt Life Sciences dealt with the basic question of classification. The Bombay High Court in Vital Nutraceuticals struck down the FSSAI product approval advisory, which left the regulator weaker. The Delhi High Court in Sun Pharma v Ajanta Pharma and the Telangana High Court in Truweight Wellness show that disputes about claims and classification are still active. Consumer forums, as in Rahul Shekhawat v Big Muscle Nutrition, have also raised questions about advertising practices.

The RTI reply from FSSAI gives another angle. It shows that most of the enforcement is about labels and packaging, while very few cases deal with the truth of scientific claims. This supports the idea that enforcement is shallow.

Relevant foreign models are part of the literature as well. The European Union under Regulation 1924 of 2006 uses a pre market authorisation system and keeps a register of approved claims through EFSA. The United States system under DSHEA 1994 allows some structure or function claims but requires disclaimers and blocks disease claims unless they are approved. FDA guidance also explains these rules.

There is also literature on the publishing side. The clinical trial used by MuscleBlaze, written by Trehan and others, was published in a journal linked to the OMICS group. The OMICS group was fined heavily in the United States for predatory publishing, as shown by the Federal Trade Commission case and reports in the BMJ. Other scientific sources, like the FAO expert consultation on protein quality and studies by Tipton and colleagues, show how proper science should evaluate nutrition claims.

Together, the literature shows three points. First, Indian law is vague and leaves room for misuse. Second, enforcement is weak and does not really check scientific evidence. Third, other countries already have stricter systems that India could learn from. This paper builds on these writings and adds new material from the RTI data and the MuscleBlaze case study.

3.1 THE ISSUE WITH CLASSIFICATION OF DIETARY SUPPLEMENTS AND FUNCTIONAL HEALTH-CLAIM FOODS IN INDIA

In India the question of whether a product is food or drug is not just a small detail, but that is what decides the whole path the product has to follow. If it is treated as a drug, the Drugs and Cosmetics Act, 1940 comes into force. That law is strict and demands for licences, safety checks, clinical trial and proof that the medicine stands on its claims before it can be sold.[439] On the other hand, if the same product is treated as food, then it comes under the purview of the Food Safety and Standards Act, 2006, the process is much lighter. Food law does not ask for clinical trials or pre-market proof of efficacy.[440] This is the main reason why most companies prefer to present their supplements as food. While still making strong claims on their packaging, similar to a drug. They still want the consumer to think of it as something with health power, but they avoid the heavy burden of drug regulation.

[439] Drugs and Cosmetics Act, No. 23 of 1940, § 18.
[440] Food Safety and Standards Act, No. 34 of 2006, § 3(1)(j).

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The Food Safety and Standards Act gives a very broad meaning to food. Section 3(1)(j) includes any substance intended for human consumption but it excludes drugs.[441] More important is Section 22, which lists special categories such as foods for special dietary use, foods for special medical purpose, functional foods, nutraceuticals, health supplements, and novel foods.[442] By writing nutraceuticals and supplements into this part of the law, the lawl gave companies an easy route to avoid drug law and stay within the food system.

The Drugs and Cosmetics Act, 1940 uses wide language for drug as well. Section 3(b) says drug covers all medicines for internal or external use, and also any substance used for diagnosis, treatment, mitigation, or prevention of disease.[443] Section 18 prohibits sale or manufacture of a drug without a licence.[444] By this wording, many products now sold as supplements could be seen as drugs. But companies know that if they use softer language, they can remain under the food law. For ex, instead of writing cures diabetes (T2D), they write controls blood sugar, reduces risks of diabetes, doesn't spikes insulin,etc . These small change in words keeps them away from the drug regulator.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 adds another layer. Section 3 bans advertisements claiming to cure certain diseases.[445] This law was made to stop miracle cure ads. Companies again avoid direct cure claims and use words like helps in sugar control. The buyer may still believe it is almost like medicine but legally it is seen as food.

Courts have developed certain tests to decide where a product fits. In Puma Ayurvedic Herbal (P) Ltd. v. Commissioner of Central Excise, the Supreme Court said that the way people in common parlance see a product is really important.[446] If ordinary people see it as medicine or a cure, then it should be treated as a medicament. In Commissioner of Central Excise v. Wockhardt Life Sciences Ltd., the Court repeated that if the use is therapeutic or prophylactic, then it points to classification as a drug.[447]

In Vital Nutraceuticals Pvt. Ltd. v. Union of India, the Bombay High Court struck down FSSAI advisories that tried to introduce a product approval system for nutraceuticals and stated that it did not had the force of law since FSSAI lacked the statutory authority to issue them without following the procedure in Section 92 and 93 of the FSS Act, 2006.[448] The Supreme Court later refused to interfere with the High Court's interim order. This meant that once a product falls under Section 22 of the Food Safety Act, there is no drug-like pre-approval required.

In M/s Truweight Wellness Pvt. Ltd. v. State of Telangana, the High Court quashed prosecution under the Drugs and Magic Remedies Act for a diet product that already had a food licence.[449] The Court explained that the product label did not claim to cure disease. This shows that as long as the company avoids direct words of cure, the courts are willing to keep the product in the food category. These caselaws put consumer welfare at a disadvantage.

In Sun Pharma Laboratories Ltd. v. Ajanta Pharma Ltd., a passing off case in the Delhi High Court, the Court applied the stricter test used for medicines when judging the likelihood of confusion.[450] Although the product in dispute was legally classified as a nutraceutical under the food regulatory framework, the Court applied the stricter standard ordinarily reserved for medicinal products while assessing likelihood of confusion in a passing off action.

[441] Id.
[442] Id. § 22.
[443] Drugs and Cosmetics Act, No. 23 of 1940, § 3(b).
[444] Id. § 18.
[445] Drugs and Magic Remedies (Objectionable Advertisements) Act, No. 21 of 1954, § 3.

[446] Puma Ayurvedic Herbal (P) Ltd. v. Commissioner of Central Excise, (2006) 3 SCC 266.
[447] Commissioner of Central Excise v. Wockhardt Life Sciences Ltd., (2012) 5 SCC 585.
[448] Vital Nutraceuticals Pvt. Ltd. v. Union of India, 2014 SCC Online Bom 165.
[449] M/s Truweight Wellness Pvt. Ltd. v. State of Telangana, W.P. No. 11186 of 2023 (Tel. HC Nov. 20, 2023).
[450] Sun Pharma Laboratories Ltd. v. Ajanta Pharma Ltd., 2019 SCC OnLine Del 8443.

The Court reasoned that nutraceuticals are frequently perceived by consumers as therapeutic in nature and are often used on medical advice, thereby blurring the practical distinction between "food" and "drug." This approach highlights a structural tension in classification: while regulatory law may place such products under the Food Safety regime, judicial assessment in trademark law may treat them closer to medicines due to their functional positioning and consumer perception.

If we read all these strands together, a clear picture appears. Companies try to avoid being called drugs because that brings strict rules. They prefer to come under Section 22 of the Food Safety Act. They carefully select their language to say supports or enhances instead of cures or prevents. In this way they skip the stronger checks of the Drugs and Cosmetics Act and the restrictions of the Drugs and Magic Remedies Act. The buyer often thinks of the product as medicine but the regulator allows it to pass as food. This is the main classification loophole in India.

3.2 WEAK REGULATION OF CLAIMS IN INDIA

Once a product is placed under food law, the main control on what the company can say comes from the Food Safety and Standards Act, 2006 and the regulations made under it. Section 24 of the Act says that no person can make false or misleading claims on the label or in advertising.[451] The 2011 Food Safety and Standards (Packaging and Labelling) Regulations and later the 2016 Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations also try to control the way claims are made.[452] These rules speak of general principles like truthful labelling, but in practice they leave a lot of space for interpretation. They do not create a system like the drug law, where efficacy has to be proved before a product is launched.

Because of this gap, many products in the Indian market use phrases that sound scientific but are not tested by an independent regulator. Words like "clinically tested" or "backed by research" appear often, but there is no system where the Food Safety Authority checks the research before allowing the claim. The authority mostly acts when someone complains or when random inspections are made. Even then, the penalties are weak compared to the profit the companies make.

A good example of the weakness is the way muscle building supplements, protein powders, and immunity boosters advertise themselves. They regularly use numbers like "50% better absorption" or "two times faster recovery." These claims sound like hard scientific results, but often the only basis is a small self funded study or a report in a journal that does not have strong peer review. This shows how far companies can go in shaping consumer belief without facing serious checks.

The courts have also had to step in when claims are misleading. In Rahul Shekhawat v. Big Muscle Nutrition, a case filed before the consumer forum, the complaint was that the protein supplement was mislabelled and did not meet the nutritional claims printed on the box.[453] The consumer forum looked at lab reports and found that the claims were not fully supported. The case is important because it shows that individual consumers often have to fight misleading labels themselves, instead of the regulator taking strong action.

Another case that highlights the issue is Hindustan Unilever Ltd. v. Gujarat Cooperative Milk Marketing Federation Ltd., where the Delhi High Court discussed comparative claims made in advertising.[454] Though not directly a nutraceutical case, the Court said that a claim

[451] Food Safety and Standards Act, No. 34 of 2006, § 24.
[452] Food Safety and Standards (Packaging and Labelling) Regulations, 2011, Gazette of India, May 1, 2011; Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016, Gazette of India, Dec. 23, 2016.
[453] Rahul Shekhawat v. Big Muscles Nutrition Pvt. Ltd., CC/103/2023 (Dist. Consumer Disputes Redressal Comm'n Mumbai Suburban July 15, 2024).
[454] Hindustan Unilever Ltd. v. Gujarat Cooperative Milk Marketing Federation Ltd., 2017 SCC OnLine Bom 2572.

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must be capable of being verified, and if it is not, then it is misleading. This principle should apply strongly to health supplements too, but in practice many claims remain unchecked until a competitor or consumer challenges them.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is supposed to control exaggerated health claims. Section 3 of that Act bans advertisements of cures for a list of serious diseases.[455] But the law is outdated and the list does not cover many modern lifestyle disorders like obesity, cholesterol imbalance, or muscle growth. This gap again allows supplement companies to speak in a way that strongly suggests medical benefit without actually saying cure.

The net effect is that the Indian framework puts too much responsibility on the consumer to question or complain. The Food Safety Authority has powers, but they are often used for small labelling mistakes rather than big scientific claims. The penalties under Section 53 and 54 of the Food Safety Act are mostly fines, often less than the profit from a single advertisement campaign.[456] As a result, the risk of making a false or inflated claim is low.

This weakness becomes even clearer when compared with other jurisdictions. In the European Union, health claims for food are tightly regulated under Regulation (EC) No. 1924/2006. Every claim has to be approved by the European Food Safety Authority (EFSA) before use, and a public register of approved claims is available.[457] In the United States, the Food and Drug Administration allows structure or function claims on supplements but requires a disclaimer, and disease claims are not allowed without prior approval.[458] In both systems, there is at least a pre market or public system of verification. In India, no such system exists, and so the claim stands unless challenged.

3.3 THE MUSCLE BLAZE CASE STUDY: POORLY BACKED CLAIM MADE BY A MARKET LEADER

MuscleBlaze markets its Biozyme Whey Protein with the line that the product gives "50% higher protein absorption" through an Enhanced Absorption Formula (EAF).[459] That sounds like a precise scientific result. For deeper analysis, I thoroughly went through the clinical trial they cite and then reached them directly through mail and analysed their replies, and eventually reached the conclusion that the science does not support the publicity.

The trial they rely on is titled An Open-label Clinical Study to Determine the Effect of Enhanced Absorption Formula (MB EnzymePro®) on the Bioavailability of Whey Protein in Healthy Male Subjects.[460] All authors are from Bright Lifecare (HealthKart), which also manufactures MB EnzymePro. The paper still declares "no competing interests" and "funding not applicable," even though the test ingredient and the investigators are from the same company

Study design basics are as follows, it is an open-label, balanced, randomized, three-arm, three-period crossover study. Twenty-four healthy men, age 20–36, BMI 20–24, were enrolled. Each participant, across three periods separated by a five day washout period, they consumed 50 g whey protein alone (control), then 50 g with one capsule of MB EnzymePro (treatment A), and then 50 g with two capsules (treatment B), in randomized sequences ABC, BCA, or CAB. Then their blood was drawn at 0.25, 0.50, 0.75, 1.00, 1.25, 1.50, 2.00, 3.00 and 4.00 hours. Seventeen amino acids were quantified using a Waters UPLC–MS/MS method; then total serum amino acids (TSAA) and individual amino acids were used to compute AUC with

[455] Drugs and Magic Remedies (Objectionable Advertisements) Act, No. 21 of 1954, § 3.
[456] Food Safety and Standards Act, No. 34 of 2006, §§ 53–54.
[457] Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 Dec. 2006 on nutrition and health claims made on foods, 2007 O.J. L 12/3
[458] U.S. Food & Drug Admin., Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide (Jan. 9, 2002).

[459] MuscleBlaze, Biozyme Whey Protein (2022), https://www.muscleblaze.com (last visited March 3, 2026).
[460] Anupam Trehan, Anjali Chawla, Prerna Sharma & Vipin Sharma, An Open-label Clinical Study to Determine the Effect of Enhanced Absorption Formula (MB EnzymePro®) on the Bioavailability of Whey Protein in Healthy Male Subjects, 13 Journal of Food Processing and Technology 820 (2022).

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Phoenix WinNonlin. C-reactive protein (CRP) was measured from serum. Urine was also collected for 24 hours for checking nitrogen balance. Then the paper claims "more than 50%" enhancement in "overall protein bioavailability," and "more than 60%" for BCAAs, with better nitrogen balance and lower CRP.[461]

After going through the methods and results carefully, here is what was found to be weak or not aligned with the headline claim. First, the study is open-label. There was no placebo capsule given with the control whey, so neither participants nor clinic staff were blinded. The lab says it received blinded samples, but that does not correct performance and expectation biases at the clinical stage. Second, the endpoints are nothing but surrogate measures. The main outcome is AUC of amino acids in plasma over four hours. That is not a direct measure of "absorption" through the gut in the strict physiological sense, and it is not an efficacy outcome like muscle protein synthesis, strength, or lean mass over time. Third, the observation window is really short. Four hours of post-prandial sampling cannot tell us about total assimilation through the whole day. Fourth, the sample is small and narrow, only 24 men. That limits generalisation, especially to women, older adults, or athletes with higher BMI. Fifth, the paper quantifies 17 amino acids, yet there is no clear correction for multiple comparisons; the "overall >50%" figure appears to be an aggregate constructed from TSAA AUC rather than a pre-specified clinical endpoint. Sixth, the paper is authored entirely by employees of the sponsoring company, yet it states "no competing interests" and "funding not applicable," which is hard to accept when the test ingredient, the whey, and the protocol all come from the same commercial set-up.

Then there is also the importance of scruinizing the publication venue. The paper is published in the Journal of Food Processing & Technology, an OMICS title. A U.S. federal court entered a judgment of about $50.1 million against OMICS for deceptive practices, including misrepresenting peer review.[462] Trusted medical media reported the same, noting the court's findings on deceptive publishing.[463] This does not automatically make every article false, but it does mean that publication in that venue cannot be treated as strong peer-reviewed evidence for a numerical health claim.

Finally, even on basic nutrition science, the "50% higher absorption" idea clashes with the known high protein quality of whey. The FAO's expert consultation recommended DIAAS as the standard for protein quality; whey already scores high on DIAAS.[464] Peer-reviewed data list whey protein isolate around DIAAS 1.09 and whey protein concentrate near 0.97, which is already in the top tier.[465] If regular whey is already highly digestible, a claim that a capsule added to whey raises "absorption" by fifty percent needs very strong, independent, fully blinded trials. This study is not that.

In short, a market leader can be seen turning a small, in-house, open-label, surrogate endpoint study published in a discredited journal into a nationwide "50% absorption" headline. This is exactly how the food classification route, plus weak scrutiny of scientific claims, allows drug-like marketing without drug-level proof.

3.4 IMPLEMENTATION AND ENFORCEMENT OF EXISTING LAWS IN INDIA

The enforcement record of nutraceutical and functional food claims in India looks weak when we examine actual regulatory practice. The Food Safety and Standards Act 2006 gives the Food Safety and Standards Authority of India wide powers, including Section 24 which prohibits misleading labels or advertisements, and Sections 53 and 54 which prescribe penalties. I had sent an RTI application and the

[461] Id.

[462] FTC v. OMICS Grp. Inc., 822 F. App'x 503 (9th Cir. 2020).

[463] Owen Dyer, US Consumer Agency Wins $50m Order Against Predatory Publisher OMICS, 365 BMJ l1639 (2019).

[464] Food and Agriculture Organization of the United Nations, Dietary Protein Quality Evaluation in Human Nutrition: Report of an FAO Expert Consultation, FAO Food and Nutrition Paper No. 92 (2013).

[465] Kevin D. Tipton, Stefan M.P. Dirks & Luc J.C. van Loon, The Impact of Protein Quality on the Promotion of Resistance Exercise-Induced Changes in Muscle Mass, Nutrition & Metabolism (2016).

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RTI data received from FSSAI tells us how these powers are being applied in real terms.

In 2022–23, a total of 177,511 food samples were analyzed. Out of these, 44,626 samples were found to be non conforming. Within this, 6,579 were classified as unsafe, 21,917 were considered sub standard, and 16,130 suffered from labelling defects or other misleading features. Civil cases numbered 28,464, but only 33.23 crore rupees were raised in penalties. On the criminal side, 1,188 cases were filed, leading to penalties worth 2.75 crore rupees.[466]

In 2023–24, the total number of samples analyzed was 170,513. Out of this, 33,808 were found non conforming. Of these, 6,782 were unsafe, 22,603 sub standard, and 4,423 with labelling defects or misleading information. There were 29,586 civil cases, with penalties amounting to 74.12 crore rupees. Criminal cases dropped slightly to 1,161, with penalties totalling 2.67 crore rupees.[467]

The numbers look big at first glance, but when set against the size of the nutraceutical and supplement industry in India, the penalties are negligible. Even more troubling is what these figures hide. Most of the action is focused on simple issues such as misbranding, labelling mistakes, or sub standard products. The more sophisticated problem, where large brands rely on weak studies and inflated scientific claims, does not even appear in the data. This is the tip of the iceberg. What we see in the RTI tables are the easy catches, while the harder cases, such as MuscleBlaze's "50 percent higher absorption" claim, slip through without ever being questioned.

The RTI reply itself makes another thing clear. When asked about the classification criteria and claim verification, FSSAI only referred to existing regulations like the Licensing and Registration Regulations 2011 and the Health Supplements and Nutraceutical Regulations 2016. In other words, there is no independent or updated procedure for checking scientific substantiation of claims. Regulators are falling back on broad statutory provisions and self certification by companies. That is not sufficient to handle drug like claims dressed up as food.

This reliance on statutes alone becomes problematic because the statutes themselves are outdated in parts. The Drugs and Magic Remedies Objectionable Advertisements Act 1954 prohibits only a fixed list of disease claims and does not cover the kind of performance or efficacy claims made in modern supplements.[468] The Consumer Protection Act 2019 gave powers to the Central Consumer Protection Authority to tackle misleading advertisements in Section 18[469] and misleading trade practices in Section 2(28).[470] But CCPA has so far used these powers sparingly, often only after major public uproar.

Courts have tried to fill the gap. In Rahul Shekhawat v Big Muscle Nutrition, the Delhi District Consumer Forum took up a consumer's complaint against mislabelling of supplements.[471] In Hindustan Unilever Limited v Gujarat Cooperative Milk Marketing Federation Limited, the Delhi High Court stressed that advertising claims must be verifiable.[472] But courts are reactive bodies, and the process is long and expensive. They cannot replace systematic regulatory oversight.

The result is a mismatch. On paper, FSSAI and CCPA have powers, and there are detailed regulations from 2011 and 2016. In practice, as the RTI data proves, enforcement is shallow. It punishes small errors in labels but leaves untouched the more damaging science washed claims. This gap in implementation means that consumers are not protected where it matters most.

[466] Letter from Sunaina Kumar, Assistant Director (RCD/CPIO), from Food Safety and Standards Authority of India (FSSAI), to Kaushik Anand, regarding Enforcement Details for 2022-2024 (on file with author)(Appendix A)
[467] Id.
[468] Drugs and Magic Remedies Objectionable Advertisements Act, No 21 of 1954, § 3.
[469] Consumer Protection Act, No 35 of 2019, § 18.
[470] Consumer Protection Act, No 35 of 2019, § 2(28).
[471] Rahul Shekhawat v. Big Muscles Nutrition Pvt. Ltd., CC/103/2023 (Dist. Consumer Disputes Redressal Comm'n Mumbai Suburban July 15, 2024).
[472] Hindustan Unilever Ltd. v. Gujarat Cooperative Milk Marketing Federation Ltd., 2017 SCC OnLine Bom 2572.

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3.5 COMPARATIVE ANALYSIS WITH EU AND USA

After going through the Indian framework, it is important to see how other jurisdictions handle the same problem. When we look at Europe and the United States makes the Indian system look even weaker. Both of them have problems of their own which can be further discussed, but at least they have clear rules for how a company can make a health claim and what kind of proof is required.

In the European Union, the central instrument is Regulation (EC) No 1924/2006 on nutrition and health claims.[473] This law says that no health claim can be made unless it has been approved after a scientific review by the European Food Safety Authority. The authority runs a strict pre market authorisation process. The claims are then published in a public register, so both consumers and competitors can check which claims are authorised and which are rejected.[474] The standard of proof is also higher. EFSA requires human studies with proper controls, and it looks for consistency with the wider body of science. Because of this, many claims are actually rejected. For example, hundreds of probiotic health claims were refused because they were not backed by solid evidence. This shows that the EU framework is not just symbolic, it is actively screening what can appear on a label.

The United States follows a slightly different route. The Food and Drug Administration regulates dietary supplements under the Dietary Supplement Health and Education Act of 1994.[475] Companies are allowed to make what are called structure or function claims. For example, "calcium builds strong bones" is permitted. But if a company wants to say "this product cures osteoporosis," then it is a disease claim and needs prior FDA approval. The FDA also requires a disclaimer that the statement has not been evaluated by the agency.[476] The Federal Trade Commission works alongside to check that advertisements are not deceptive. In recent years the commission has actually taken companies to court for making unsupported claims about weight loss or muscle growth product, like its lawsuit against the Roca Labs Inc. that resulted in compensation to the customers.[477]

Now, when we compare this with India, the gap is clear. India has no pre-market authorisation for health claims. There is no public register where one can check which claims are accepted. The Food Safety and Standards Authority of India does not actively review scientific studies before a claim appears on a label. The RTI data discussed earlier proves that enforcement is mostly about catching labelling defects and small violations, not scientific substantiation. In other words, in India a company can publish a self funded study in a weak journal and use that to support a nationwide marketing campaign. In Europe that study would not even clear the EFSA review. In the United States the company would at least have to carry a disclaimer and avoid making therapeutic claims.

So the lesson from this comparison is not that the EU and US are perfect. They still face aggressive marketing and sometimes weak oversight. But they do have institutional checks that India lacks. EFSA uses a transparent scientific process. The FDA and FTC combine disclosure with active enforcement. India, on the other hand, has laws on paper but depends on post market complaints and minor inspections. That is why Indian consumers are more vulnerable to being misled by health claims that sound scientific but are never really tested in any strong way.

4. FINDINGS

When we take a step back and analyze, a few things stand out very clearly. Some of this was

[473] Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, 2007 OJ L 12/3.

[474] European Commission, Union Register of Nutrition and Health Claims Made on Foods (2024).

[475] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

[476] United States Food and Drug Administration, Guidance for Industry: Structure/Function Claims (Jan. 2017)..

[477] FTC v. Roca Labs, Inc., 345 F. Supp. 3d 1375 (M.D. Fla. 2018).

already known in parts, but seeing it together makes the problem look bigger and more structural.

First, there is a strong incentive for companies to place products under food law through Section 22 of the Food Safety and Standards Act 2006. The moment a product sits in that bucket, it avoids the tougher pathway that drugs face. The drug pathway asks for proof first, the food pathway mostly checks labels later. This single choice of classification shapes everything that follows.[478]

Second, claim verification in India is basically after the fact. Section 24 of the same Act says do not mislead in labels or ads, and there are penalty provisions in Section 53 and Section 54. But there is no routine pre market screening of scientific claims by the Food Safety and Standards Authority of India. In practice, the rule becomes simple. If the label avoids the words cure or treat, the claim usually goes through.[479]

Third, the enforcement data confirms that the system focuses on the easy things. The Right to Information reply from the Food Safety and Standards Authority of India shows very high counts of non conforming samples each year, but most of these are misbranding or labelling issues. Prosecutions are a small fraction, convictions even smaller, and the fines are not large compared with the size of the market. This is busy work that does not touch scientific substantiation. This is the tip of the iceberg. The visible part is small shops and simple violations. The bigger part under the surface is national brands using weak studies to make precise sounding claims, and those do not even show up in the data because they are technically compliant with food wording.[480]

Fourth, the MuscleBlaze example is not a side note. It is a good illustration of how a market leader can turn a small open label study into a nationwide number. The trial is self funded and it uses surrogate markers over a short window. It appears in a journal that sits within a publishing group which a United States federal court found to be deceptive. Yet the claim stays on shelves without any pre market check in India. That is the heart of the mismatch.[481]

Fifth, India's model stands apart from the European Union and the United States. The European Union runs a pre market authorisation system for health claims under Regulation 1924 of 2006, with scientific review by the European Food Safety Authority and a public register. The United States allows structure or function claims under the Dietary Supplement Health and Education Act of 1994, but not disease claims without prior approval by the Food and Drug Administration, and it requires a disclaimer. India has neither the pre market screen nor the public register nor the disclaimer rule, which leaves consumers more exposed.[482]

After these points, a few larger themes become clear. One is that the Indian framework is not only weak in design but also weak in practice. The Food Safety and Standards Authority of India focuses on basic labelling mistakes, while the Central Consumer Protection Authority uses its powers rarely. The courts have tried to push back against false advertising in some cases, but the process is slow, depends on individual complaints, and cannot be a substitute for systematic screening.

Another theme is that the system is tilted against ordinary consumers. A large company can commission a weak study, publish it in a questionable journal, and then use that to sell products across the country. A single buyer has neither the resources nor the time to challenge it. This gap explains why misleading health claims continue without much resistance.

[478] Food Safety and Standards Act, No 34 of 2006, § 22.
[479] Food Safety and Standards Act, No 34 of 2006, §§ 24, 53, 54.
[480] Letter from Sunaina Kumar, Assistant Director (RCD/CPIO), from Food Safety and Standards Authority of India (FSSAI), to Kaushik Anand, regarding Enforcement Details for 2022-2024 (on file with author) (Appendix A).

[481] Anupam Trehan, Anjali Chawla, Prerna Sharma and Vipin Sharma, An Open label Clinical Study to Determine the Effect of Enhanced Absorption Formula MB EnzymePro on the Bioavailability of Whey Protein in Healthy Male Subjects, 13 Journal of Food Processing and Technology 820, 2022.
[482] Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, 2007 OJ L 12/3; Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

Finally, comparing India with the European Union and the United States makes the gap obvious. The European Union rejects many claims outright through scientific review. The United States forces disclaimers and bars disease claims without approval. India has none of these filters. So even though India has multiple statutes, the result is a market where science washing goes largely unchecked. That is the most important finding: the laws exist, the regulators exist, but the protection that consumers actually receive is minimal.

5. SUGGESTION AND CONCLUSION

All in all, the research shows that the real issue is not the absence of law but the way the existing law is designed and enforced. The Food Safety and Standards Act 2006, the Drugs and Cosmetics Act 1940 and the Consumer Protection Act 2019 all create duties, but none of them fully cover the grey area under which nutraceuticals and functional foods operate. The gap lets companies make drug like claims without drug-level proof. This is where reforms are needed.

The first suggestion is to create a separate category for nutraceuticals with stricter and clearer rules. Section 22 of the Food Safety and Standards Act already recognises food for special dietary uses and functional foods. But this is too broad. There should be a new chapter or rules under the Act that focus only on health claims. Every product that carries a health benefit claim should have to submit proof before entering the market, the same way the European Union uses pre-market authorisation.

The second suggestion is to make disclaimers mandatory for all functional foods and supplements. The United States already requires a statement that the product is not intended to diagnose, treat, cure or prevent any disease. Adding a similar rule in India would make it clear to buyers that these products are not equal to drugs, even when the marketing tries to suggest otherwise.

The third suggestion is to create a public register of approved claims. The European Food Safety Authority keeps a database that anyone can check. If India adopted something like this, companies could not hide behind vague scientific terms, and consumers, doctors and lawyers could all see which claims are backed and which are not.

The fourth suggestion is stronger enforcement. The Right to Information reply from the Food Safety and Standards Authority of India shows that most violations are only about misbranding or labelling. This needs to change. The Authority should put more effort into evaluation of the scientific claims. The Central Consumer Protection Authority also has the power under Section 18 of the Consumer Protection Act 2019 to stop misleading ads. It should use this more actively in the health food market.

The fifth suggestion is to increase penalties. At present, the fines under the Food Safety and Standards Act are small compared with the money companies earn from these products. Raising the penalties would make it less attractive to stretch the truth in advertisements.

In conclusion, the findings of this research confirm that India's current legal system does not give enough protection against misleading claims in the nutraceutical and functional food sector. Companies avoid the drug pathway, regulators focus on labels instead of science, and consumers are left without clear guidance. The MuscleBlaze case study shows how even a market leader can promote a claim with a weak trial and still face no real barrier. The Right to Information data shows that enforcement is shallow. Compared with the European Union and the United States, India lacks the tools that can filter out weak claims.

The reforms suggested here, which include separate category rules, mandatory disclaimers, a public register of claims, stronger enforcement, and higher penalties are not radical. They are all steps that other systems have already taken. But if India adopts them, it will close the gap between what the law says on

paper and what the consumer experiences in the market. That is the only way to bring clarity to classification, honesty to claims, and trust to the entire field of dietary supplements and functional health foods.

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APPENDIX A: FSSAI RTI RESPONSE

Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety and Standards Act, 2006)
Regulatory Compliance Division
FDA Bhawan, Kotla Road, New Delhi – 110002

Dated: 17th September, 2025

To,

Kaushik Anand
No. 78-93/94, 2nd Main Road,
Bharathi Layout, SG Palya,
Bengaluru - 560029

Sub.: RTI application from Sh. Kaushik Anand seeking information under RTI Act, 2005- reg.

Sir/Madam,

Please find enclosed herewith a RTI application dated 12-08-2025 received in this office on 27.08.2025 from GA Division vide OM dated 26.08.2025 under RTI Act, 2005. In this regard, information pertaining to this CPIO is as given below:

Information Sought	Reply
Point 1 and 2	In this regard, You may refer FoSCoS portal where you need to click at tab 'FBO Search' at homepage of FoSCoS website, as given in link: https://foscos.fssai.gov.in/advance-fbo-search
Point 3	Please refer to Food Safety and Standards (Licensing and Registration of Food Businesses)Regulations,2011(Link:https://fssai.gov.in/upload/uploadfiles/files/Licensing_Regulations.pdf) along with Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016(Link:https://fssai.gov.in/upload/uploadfiles/files/Compendium_Nutra_29_09_2021.pdf) For the purpose of more details, you may refer to the FoSCoS portal link: https://foscos.fssai.gov.in/
Point 5	For the point no.5, please see the Annexure I provided below:
Point 4 and 6	Pertains to CPIO, Science and Standards Division, FSSAI, hence transferred to concerned CPIO under section 6(3) of RTI Act,2005

(Sunaina Verma)
Assistant Director (RCD)/CPIO

Copy to-

- *Joint Director (RTI and Grievance Cell), GA Division, FSSAI, New Delhi-110002*
- *CPIO, S&S, FSSAI*

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Annexure-I

Details of Enforcement for last 2 Years.

Year	No. of Samples Analyzed	No. of Samples found non-conforming	Non-Conforming Samples			Civil Cases		Criminal Cases	
			Unsafe	Sub Standard	Labelling defects/ Misleading/ Miscellaneous	No. of Convictions	Penalties Raised (Cr Rs.)	No. of Convictions	Penalties Raised (Cr Rs.)
2023-24	170513	33808	6782	22603	4423	29586	74.12	1161	2.67
2022-23	1,77,511	44,626	6,579	21,917	16,130	28,464	33.23	1188	2.75