World Journal of
Pharmacy and Medical Science

ISSN: 3049-3501
Impact Factor: 3.2
CODEN (USA): WJPMAA

Review Article
2025 Volume 1, Issue 5
Page No.: 07-19

ADULTERATION IN DIETARY SUPPLEMENTS: CURRENT TRENDS, ANALYTICAL CHALLENGES, AND REGULATION IN INDIA

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Article Received: 17 October 2025 Article Review: 07 November 2025 Article Accepted: 29 November 2025

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DOI: https://doi.org/10.5281/zenodo.17801956

How to cite this Article: Kandi Subhashini, Elapati Saipriya, Yerra Saiprathyusha, Lunavath Renuka, Dommati Soniya (2025). ADULTERATION IN DIETARY SUPPLEMENTS: CURRENT TRENDS, ANALYTICAL CHALLENGES, AND REGULATION IN INDIA. World Journal of Pharmacy and Medical Science, 1(5): 07-19. https://doi.org/10.5281/zenodo.17801956

ABSTRACT
Adulteration of dietary supplements remains a significant global concern, driven primarily by economic incentives, insufficient regulatory oversight, and the rapid expansion of online and e-commerce markets. This review provides a comprehensive assessment of current adulteration trends, associated public-health risks, and emerging analytical approaches for detection. Challenges in identifying adulterants arise from the complex composition of supplement matrices, sample-preparation limitations, and variability in method validation across laboratories. Advances in chromatographic, spectroscopic, electrochemical, and mass spectrometry-based techniques supported by chemometrics, green analytical chemistry, and artificial intelligence have greatly enhanced the sensitivity and reliability of adulteration detection; however, their routine implementation is still limited. A comparative evaluation of global regulatory frameworks, including the FDA (USA) and EFSA (EU), alongside the Indian regulatory scenario involving FSSAI, CDSCO, and AYUSH, highlights critical gaps in surveillance and enforcement. Evidence from adverse-event reports, case studies, and WADA/NADA contamination incidents underscores the urgent need for stronger regulation, improved testing of high-risk products, and increased accountability of online marketplaces. Future progress depends on harmonized global standards, rapid screening technologies, and sustained public-awareness initiatives to ensure safe and authentic dietary supplement use.

KEYWORDS: Dietary Supplements, Adulteration, Validation, Regulatory frameworks, FSSAI-CDSCO-WADA-NADA.

INTRODUCTION

Food adulteration has long been regarded as a “profanity against mankind,” primarily driven by financial motives within the food and dietary supplement industries, where regulatory oversight is often less stringent. The deliberate alteration of supplements through the inclusion of undeclared or falsified ingredients poses a serious threat to public health. Such fraudulent practices can occur at any stage of the supply chain, from manufacturing to distribution. The COVID-19 pandemic further underscored the global demand for verified and trustworthy sources of food and dietary supplements, reinforcing the need for effective quality control and authentication systems.

Dietary supplements are products designed to complement the diet by providing concentrated sources of essential nutrients such as vitamins, minerals, amino acids, fatty acids, enzymes, or botanicals. The global dietary supplement market has grown exponentially in the past decade, driven by increasing health awareness and preventive healthcare trends. As of 2023, the industry surpassed USD 170 billion and continues to expand steadily. In India, this sector valued at approximately USD 6 billion in 2024 is growing rapidly due to urbanization, changing lifestyles, and a growing preference for nutraceutical and Ayurveda-based products.[1]

Supplements are often promoted as safe, natural alternatives to pharmaceuticals, increasing their appeal among consumers and athletes. Their easy availability through pharmacies, supermarkets, and online platforms has further contributed to widespread consumption. However, inadequate regulatory monitoring and

misleading marketing claims have allowed substandard and adulterated products to proliferate in the market.

The consumption of such products can cause severe health consequences, including cardiovascular complications, liver toxicity, hormonal imbalance, and unintentional doping violations under World Anti-Doping Agency (WADA) regulations. These safety issues highlight the urgent need for strict quality assurance, advanced analytical monitoring, and enhanced consumer awareness.

This review critically examines adulteration in dietary supplements, focusing on current trends, analytical challenges, and the evolving regulatory framework in India aimed at ensuring product integrity, authenticity, and consumer safety.[2]

Figure 1: Common types of food adulteration and simple household detection methods used for their preliminary detection.

Adulteration

Adulteration refers to the deliberate or accidental substitution, contamination, or addition of inferior, unauthorized, or harmful substances in a product, thereby reducing its purity, quality, and safety. In the context of dietary supplements, adulteration often involves the inclusion of undeclared pharmacologically active compounds such as stimulants, anabolic steroids, or other synthetic drugs to enhance the products claimed effects.

Adulteration of dietary supplements has emerged as a growing global concern due to its significant impact on consumer health and product integrity. These adulterants may be added intentionally to improve performance-related claims or may occur inadvertently due to poor manufacturing practices. Such contamination can lead to severe health consequences, including toxicity, hormonal imbalances, cardiovascular risks, and other adverse effects.

For athletes, adulteration carries even more serious implications. Under the *World Anti-Doping Agency (WADA)*'s strict liability rule, the presence of a banned substance in an athlete's sample irrespective of intent or awareness constitutes a doping violation, leading to penalties such as suspension or disqualification.

Studies have shown that supplements marketed for bodybuilding, energy enhancement, or weight loss is the most frequently adulterated categories. Analytical investigations worldwide have reported undeclared anabolic steroids, stimulants, and other pharmacological agents in many commercial products. This highlights the urgent need for rigorous quality control, transparent labeling, and stronger regulatory enforcement to safeguard consumer trust and public health.[3]

Types of adulteration

1. Unintentional adulteration

Unintentional adulteration refers to the accidental contamination or substitution of the original crude drug due to carelessness, lack of knowledge, confusion, or improper handling during collection, processing, or storage. Unlike intentional adulteration, this type is not done with fraudulent intent, but results from ignorance, negligence, or misidentification of similar-looking substances. Such adulteration can still lead to loss of potency, microbial contamination, and potential health risks.

Table 1: Types and Examples of Unintentional Adulteration.

Type of Unintentional Adulteration	Description	Example
1. Confusion due to morphological similarity	Crude drugs with similar shape, color, or odor are mistakenly mixed or substituted during collection.	*Indian Dill* confused and mixed with *Caraway*.
2. Adulteration due to lack of knowledge	Collectors or suppliers without proper identification skills mix unrelated materials unintentionally.	Mixing of *wrong plant species* resembling the genuine one.
3. Adulteration due to careless handling	Inadequate cleaning or sorting leads to inclusion of foreign matter like soil, stones, or debris.	*Roots and rhizomes* contaminated with *soil or sand particles*.

4. Inclusion of excess vegetative parts	Non-therapeutic parts of the same plant (stems, petioles) are collected and mixed with the intended part.	*Senna leaves* mixed with stems or petioles.
5. Microbial spoilage or deterioration	Improper drying or storage leads to growth of fungi, bacteria, or insects, reducing quality and safety.	*Improperly stored crude drugs* developing mold or microbial contamination.
6. Deterioration due to physical conditions	Excessive heat, moisture, or poor packaging degrades volatile or active compounds in crude drugs.	*Fennel*, *clove*, and *coriander* losing essential oil content due to heat or moisture exposure.

2. Intentional, deliberate/deliberately adulteration

Intentional adulteration refers to the deliberate substitution or addition of inferior, cheap, or fraudulent materials in place of the original crude drug to increase profit or compensate for unavailability. The adulterants are often morphologically similar to the genuine drug but contain lower concentrations of active constituents, resulting in reduced therapeutic efficacy and potential health hazards such as allergic reactions, toxicity, or even life-threatening diseases.

Table 2: Types and Examples of Intentional Adulteration.

Type of Intentional Adulteration	Description	Example
1. Substitution with inferior commercial varieties	The genuine crude drug is replaced with a cheaper, inferior material that looks similar but has less therapeutic value.	*Indian Senna* adulterated with *Dog Senna*; *Tragacanth* adulterated with *Hog Tragacanth*.
2. Adulteration by artificially manufactured substances	Artificial or synthetic substances are made to resemble the appearance of the genuine crude drug.	*Ergot* adulterated with *flour dough*; *Coffee berries* adulterated with *compressed chicory*.
3. Use of vegetative parts of the same plant	Unwanted plant parts such as stems or petioles are mixed with the main drug during collection.	*Senna leaves* mixed with stems and petioles.
4. Substitution by superficially similar but cheaper natural substances	A natural drug of similar morphology is used as a substitute, regardless of differences in chemical or therapeutic properties.	*Caraway* used as an adulterant for *Indian Dill*.
5. Addition of worthless heavy or toxic materials	Heavy or toxic substances are added to increase the weight of the crude drug for profit.	*Hardwood* added to *Liquorice root*.
6. Addition of synthetic principles	Synthetic chemicals are added to mimic the properties of natural ingredients.	*Citral* used in place of *lemon oil*.
7. Substitution with exhausted drugs	Previously used or extracted crude drugs are reprocessed and sold as fresh by adding coloring or flavoring agents.	*Exhausted clove* adulterated with coloring and flavoring materials.

Adulteration in crude drugs and dietary supplements may be intentional or unintentional, both compromising purity, safety, and efficacy. Intentional adulteration involves deliberate substitution for economic gain, while unintentional adulteration results from carelessness or misidentification**.** Both highlight the need for strict quality control, proper identification, and training to ensure product authenticity and safety.[4]

Main Categories of Adulterated Dietary Supplements

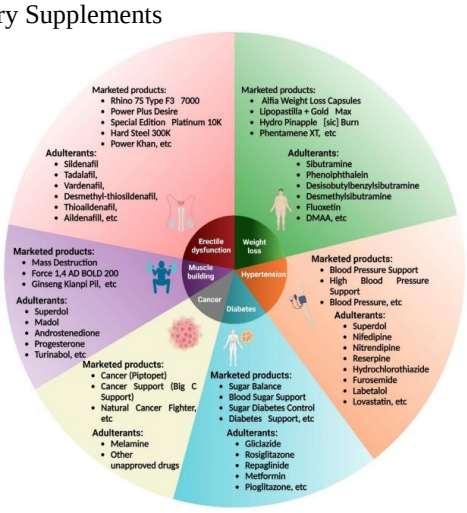

Figure 2: Different types of dietary supplements and their associated adulterants.

Adulterated dietary supplements are generally classified into three main categories, based on the type of undeclared or illegal substances added to enhance their effects.

1. Sexual Enhancement Adulterants (Erectile Dysfunction- ED group)

This class of adulterants includes a wide range of approved and unapproved pharmaceutical substances, along with their structural analogues and synthetic derivatives**,** intentionally added to products marketed for sexual performance enhancement. These compounds exert their therapeutic action primarily by inhibiting phosphodiesterase type 5 (PDE5) enzymes, which regulate blood flow in penile tissue and are the pharmacological targets of approved drugs such as sildenafil, tadalafil, and vardenafil.

However, many adulterated supplements contain unapproved or modified analogues of these PDE5 inhibitors that have not undergone proper clinical evaluation for safety, efficacy, or dosage control. The presence of such undeclared active ingredients poses serious health risks, including cardiovascular complications, hypotension, and dangerous drug interactions, particularly in individuals taking nitrates or other medications.

Numerous analytical studies have identified these PDE5 analogues in over-the-counter sexual enhancement supplements, revealing the extent of adulteration and regulatory gaps in product surveillance. These findings underscore the urgent need for rigorous analytical screening**,** stronger enforcement of regulatory standards**,** and public education to prevent the misuse and potential harm associated with such adulterated products.

2. Weight Loss Adulterants

This category comprises a diverse range of chemicals with different functional and pharmacological properties, including stimulants, laxatives, diuretics, anorexiants, and psychotropic agents**.** These substances are often added to weight loss and body-shaping supplements to enhance their perceived effectiveness. Among them, the oral anorexiant sibutramine is the most frequently detected adulterant, despite being withdrawn from the global market due to its association with severe cardiovascular side effects, such as hypertension, arrhythmia, and stroke.

Other commonly identified adulterants include nor-pseudoephedrine, pseudoephedrine, amfepramone, phenolphthalein, fluoxetine**,** and various synthetic stimulants and laxatives. These compounds act through different mechanisms ranging from appetite suppression and increased thermogenesis to enhanced diuresis and bowel motility but their unregulated and undeclared presence poses significant health risks.

Consumption of such adulterated supplements can lead to serious adverse effects, including electrolyte imbalances, psychological disturbances, and cardiovascular complications. Analytical investigations have consistently revealed these substances in over-the-counter slimming and metabolic supplements, indicating persistent adulteration practices and gaps in market surveillance. Therefore, there is a critical need for robust analytical detection methods, stringent regulatory enforcement, and consumer education to mitigate the health hazards associated with such products.

3. Sports Performance Enhancement Adulterants

This category of dietary supplements has gained widespread popularity among both professional and amateur athletes due to their claimed benefits in improving physical performance, endurance, and muscle strength. However, manufacturers often introduce anabolic steroids and stimulants as common adulterants substances that are strictly prohibited by the World Anti-Doping Agency (WADA). Such adulteration poses serious health concerns, as these undeclared compounds can lead to adverse physiological effects and result in positive doping tests**,** jeopardizing athletes' careers and reputations.

Several studies published between 2004 and 2021 have reported numerous cases of dietary supplements adulterated with pharmaceutical compounds. These findings, identified through Scopus using the keyword "pharmaceutical adulterant," highlight the ongoing global issue of intentional adulteration in sports supplements and underscore the urgent need for robust analytical monitoring, stricter regulation, and greater consumer awareness to ensure product authenticity and athlete safety.[2]

Current Trends in Adulteration

1. Global Perspective: Commonly Reported Adulterants and Product Types

Globally, adulteration of dietary supplements has emerged as a persistent public-health concern. Surveillance studies consistently report undeclared synthetic drugs, stimulants, anabolic agents, and pharmaceutical APIs in supplements marketed as "natural." Products promoted for weight loss**,** sexual enhancement, and bodybuilding remain the most adulterated categories worldwide. Frequently detected adulterants include sibutramine, phenolphthalein, sildenafil analogues, yohimbine, DMAA, synephrine, anabolic-steroid derivatives, and SARMs.[5,6]

Regulatory agencies such as the U.S. FDA and EFSA continue to issue recalls involving imported or online products, reflecting the challenges of monitoring cross-border e-commerce. Many consumers remain unaware that products labelled as natural may contain potent pharmaceutical substances.[7]

2. Indian Scenario: Market Trends, Reported Cases, Consumer Awareness

India's nutraceutical market has expanded rapidly, driven by lifestyle changes, fitness culture, and online retail growth. However, regulatory oversight has not matched market expansion. FSSAI has issued multiple alerts regarding undeclared steroids, stimulants, and adulterated botanical extracts, especially in protein supplements, pre-workouts, fat burners, and Ayurvedic vitality formulations.[8]

Clinical reports from Indian hospitals also document increasing cases of liver injury and adverse events associated with herbal and dietary supplements. Despite rising incidents, consumer awareness remains low, and many individuals assume herbal or Ayurvedic labels guarantee safety.[9]

3. Sports and WADA-related Cases

Supplements Leading to Doping Violations A substantial proportion of doping violations worldwide involves contaminated supplements containing undeclared anabolic agents, stimulants, prohormones, or SARMs. Athletes often unknowingly consume adulterated products marketed for performance enhancement.

In India, several WADA/NADA sanctions have been linked to contaminated supplements containing DMAA, sibutramine, clenbuterol, and anabolic steroid metabolites. WADA emphasizes athlete education and encourages use of certified, third-party–tested supplements.[10]

4. Online Market and E-Commerce Challenges

The rapid growth of e-commerce platforms has increased the circulation of unregulated, imported, and counterfeit supplements. Products sold online often bypass regulatory scrutiny and may contain prescription drugs, stimulant blends, analogues, or undeclared high-dose botanicals.[11,12]

Anonymous sellers, misleading claims, and proprietary blends with incomplete ingredient information make online marketplaces a high-risk source. While FSSAI has introduced e-commerce safety guidelines, significant implementation challenges remain.[13]

Analytical Challenges in Detection of Adulteration in Dietary Supplements

The detection of adulteration in dietary supplements remains a significant scientific challenge due to the complex and highly variable nature of supplement formulations. These products often contain mixtures of botanicals, vitamins, amino acids, minerals, and proprietary blends, in addition to excipients and processing residues. The rapid emergence of new synthetic adulterants including pharmaceutical APIs, novel designer analogues, and steroid derivatives further complicates routine surveillance. Therefore, advanced analytical tools with high sensitivity, selectivity, and robustness are essential to accurately identify undeclared substances and ensure consumer safety.

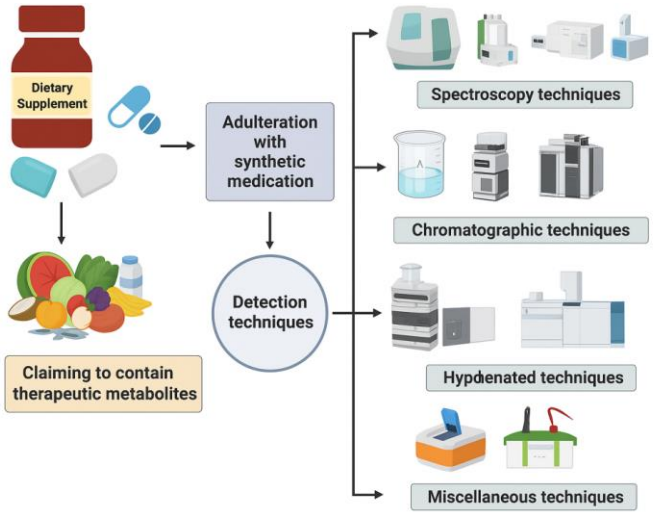

Figure 3: Detection methods for identifying adulteration in dietary supplements.

1. Complexity of Supplement Matrices

Dietary supplements frequently contain heterogeneous, multi-component matrices derived from natural sources, each comprising hundreds of phytochemicals. Such complexity leads to significant analytical obstacles, including:

- Matrix interferences that obscure target analyte signals.
- Overlapping chromatographic peaks that complicate quantification.
- Batch-to-batch variability due to natural origin, seasonal factors, and processing methods.

Botanical blends used in Ayurveda, Traditional Chinese Medicine (TCM), Unani, and polyherbal nutraceuticals show particularly wide chemical variation, making it

difficult to distinguish authentic constituents from synthetic adulterants or substituted species. Ensuring accurate profiling often requires a combination of chromatographic, spectrometric, and chemometric tools.[14,15]

2. Sample Preparation Difficulties

Sample preparation is often the most critical and error-prone step in supplement analysis. Dietary supplements appear in numerous dosage forms capsules, tablets, powders, syrups, soft gels, and gummies each requiring tailored extraction procedures.

Key challenges include:

- Incomplete extraction of target compounds (especially polar adulterants)
- Inappropriate solvent selection, leading to analyte loss.
- Co-extraction of excipients (binders, fillers, lubricants) that reduce sensitivity.
- Large variability in particle size affecting analyte recovery.

Advanced preparation methods such as SPE, QuEChERS, ultrasonic-assisted extraction, and microwave-assisted extraction significantly improve recovery but still require extensive optimization for complex matrices.[16]

3. Analytical Metmhodologies

Chromatographic Techniques (HPLC, UPLC, GC–MS)

Chromatography remains the cornerstone for identifying adulterants in supplements.

- HPLC/UPLC are well-suited for detecting polar pharmaceutical adulterants such as sibutramine, phenolphthalein, PDE-5 inhibitors, synthetic stimulants, and antidepressant analogues.
- GC-MS is ideal for volatile, thermally stable analytes such as anabolic steroid derivatives, synephrine analogues, and amphetamine-type stimulants.

Newer UPLC-PDA and high-resolution GC-MS workflows enable multi residue screening but often require extensive calibration and matrix-specific optimization.[17]

Spectroscopic Techniques (FTIR, NMR)

Spectroscopic tools offer rapid and non-destructive approaches:

- FTIR supports rapid functional group identification and authenticity screening, especially for detecting substituted botanicals or counterfeit ingredients.
- NMR plays a crucial role in structure elucidation, impurity profiling, and metabolomics-based fingerprinting of herbal products. It is particularly effective for identifying novel or modified synthetic adulterants.[18]

Hyphenated Techniques (LC-MS/MS, GC-MS/MS)

Hyphenated MS technologies provide unparalleled sensitivity and selectivity, making them the gold-standard methods for adulterant detection

- **LC-MS/MS:** Detects trace levels of pharmaceuticals, SARMs, steroid analogues, weight-loss drugs, and unapproved designer molecules that escape routine screening.
- **GC-MS/MS:** Excels in confirming the presence of anabolic steroids, stimulant derivatives, and volatile adulterants with high accuracy.

Regulatory agencies increasingly rely on these techniques for surveillance and enforcement.[19]

DNA Barcoding & Metabolomics (Botanical Authentication)

Botanical adulteration including substitution, dilution, and contamination—requires specialized tools:

- DNA barcoding using rbcL, matK, ITS2, or multi-locus strategies enables species-level identification, even in processed herbal products.
- Metabolomics (LC-HRMS, GC-MS, and NMR) provides comprehensive biochemical fingerprints that reveal subtle differences between authentic and adulterated botanicals.

These methods have greatly improved detection of economically motivated adulteration in global herbal supplement markets.[20, 21]

4. Green Analytical Chemistry Approaches

Sustainability has become an important criterion in analytical method development. Tools such as:

- **Analytical Eco-Scale**
- **Green Analytical Procedure Index (GAPI)**
- **AGREE (Analytical GREEnness Metric)**

Are increasingly used to evaluate solvent toxicity, reagent volumes, waste generation, and energy consumption. These frameworks encourage laboratories to adopt greener workflows by favoring micro-scale extraction, solvent replacement, and energy-efficient instrumentation.[22]

5. Validation and Standardization Issues

Despite major progress, several validation challenges remain:

- Lack of certified reference standards for emerging adulterants
- Absence of harmonized global analytical protocols
- Rapid evolution of designer drugs used to evade detection
- Limited monographs and quality standards for botanical ingredients
- Poor inter-laboratory reproducibility for multi-component natural matrices

Regulatory bodies emphasize the need for validated analytical methods exhibiting strong accuracy, precision,

selectivity, robustness, and matrix-specific performance parameters.[23]

Regulatory Framework and Challenges

Regulation of dietary supplements and nutraceuticals is complex and fragmented globally. Differences in definitions, pre-market requirements, permitted claims, and enforcement capacity create regulatory gaps that can be exploited by manufacturers and distributors, particularly in cross-border e-commerce. Effective management of adulteration therefore depends on coordinated pre- and post-market controls, validated analytical surveillance, clear jurisdictional responsibilities, and international information-sharing.

1. Global Regulatory Overview: FDA (USA), EFSA (EU), etc.

Major regulatory authorities adopt different paradigms for nutraceuticals and supplements. In the United States, dietary supplements are regulated under DSHEA (1994): Manufacturers are primarily responsible for ensuring product safety and truthful labelling pre-market, while the FDA conducts post-market surveillance and enforces through recalls, warning letters, and import alerts when adulteration or safety concerns are detected. The reliance on post-market action, rather than mandatory pre-market approval for most supplements, creates an environment where adulterated products can reach consumers before regulatory intervention.[7]

In the European Union, EFSA provides scientific risk assessments for food-related substances, but implementation and enforcement of rules for botanical ingredients, health claims, and novel food ingredients occur at Member-State level, yielding heterogeneity in regulation and enforcement across the EU. Both FDA and EU member states increasingly emphasize enhanced surveillance, rapid analytical screening, international cooperation, and tighter controls on high-risk categories (weight-loss, performance-enhancement, sexual-health products).[5]

2. Indian Regulatory Scenario

FSSAI guidelines for dietary supplements and nutraceuticals

India's primary food regulator, the Food Safety and Standards Authority of India (FSSAI), classifies and regulates products sold as foods, including certain "health supplements" and nutraceuticals, under the Food Safety and Standards Act. FSSAI issues standards, labelling rules, and advisories relevant to nutraceuticals and e-commerce sale of food products; nevertheless, the rapid market expansion has outpaced enforcement capacity and the development of detailed monographs for many botanicals and nutraceutical ingredients.[8]

CDSCO and AYUSH regulatory overlap

Regulatory complexity in India arises from overlapping jurisdictions. The Central Drugs Standard Control Organization (CDSCO) regulates pharmaceuticals which becomes relevant when a marketed supplement contains a pharmaceutical active ingredient or makes therapeutic claims while the Ministry of AYUSH regulates classical and proprietary Ayurvedic, Siddha and Unani products. This tripartite landscape (FSSAI-CDSCO-AYUSH) generates grey zones that may be exploited to market products with pharmacologically active ingredients as "food supplements" rather than drugs, complicating enforcement.[8,9]

Enforcement challenges and case examples

Practical challenges include limited routine laboratory testing capacity relative to market size, high volumes of online transactions, weak traceability of cross-border ingredients and finished products, and delays in inter-agency coordination for investigation and recall. Case series from Indian clinical centers have documented hepatotoxicity and other adverse events associated with adulterated herbal and dietary products, underscoring public-health consequences of regulatory gaps.[9]

3. Labelling, Safety Testing, and Quality Control Requirements

Robust labelling and testing regimes are essential to protect consumers. Core elements include

- Accurate ingredient listing and quantitative declaration of active ingredients; clear distinction between food and medicine claims.
- Routine chemical testing for undeclared APIs, adulterants (stimulants, PDE-5 inhibitors, steroids, SARMs), heavy metals, pesticide residues and mycotoxins.
- Identity testing for botanicals (DNA barcoding, marker-compound quantification) and adoption of validated analytical methods (LC-MS/MS, GC-MS/MS, HRMS) for targeted and non-targeted screening.
- Use of third-party certification schemes and batch-level testing where feasible to reduce risk in high-value or athlete-targeted products.

  International reviews emphasize that without harmonized pre-market controls and mandatory quality standards, reliance on post-market surveillance remains insufficient to fully protect consumers.[7,19]

4. Role of WADA and NADA in Anti-Doping Regulations (for athletes)

Athletes face specific risks from supplement adulteration because undeclared substances can cause adverse analytical findings under anti-doping rules. WADA publishes the annually updated Prohibited List and issues guidance on supplement risk; national organizations (e.g., India's National Anti-Doping Agency, NADA) implement testing, education, and sanctioning. Both WADA and NADA recommend athletes use only certified, batch-tested products and stress education to mitigate inadvertent doping from contaminated supplements.[10]

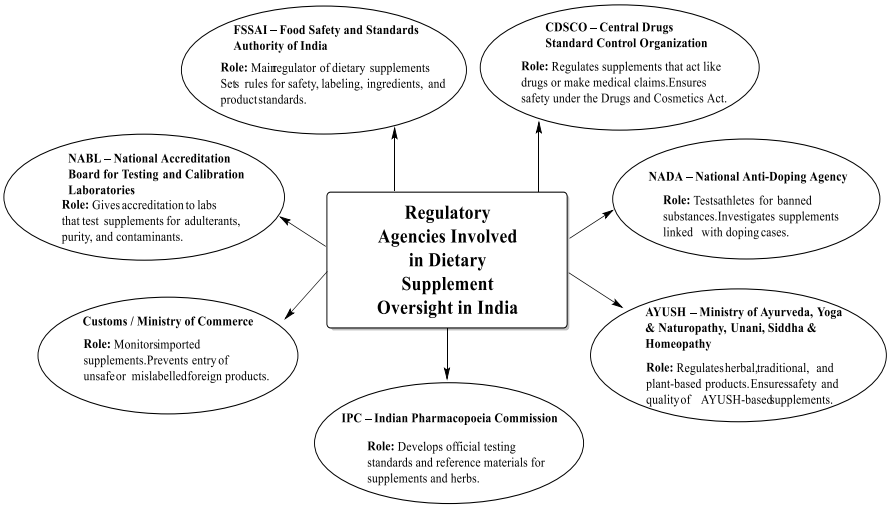

Figure 4: Regulatory framework for dietary supplements in India, showing the major agencies involved and their interlinked roles.

Agencies Regulating Dietary Supplement Adulteration in India

India's regulatory environment for dietary supplements is fragmented, with multiple agencies sharing overlapping responsibilities. This fragmentation contributes to challenges in controlling adulteration, ensuring product quality, and preventing doping-related contamination.[13]

Table 3: Major Agencies and Their Roles.

Agency	Role / Responsibility
FSSAI (Food Safety and Standards Authority of India)	Primary regulatory authority for dietary supplements and nutraceuticals under the Food Safety and Standards Act, 2006. Establishes standards for safety, labelling, contaminants, permissible ingredients, and product claims.
CDSCO (Central Drugs Standard Control Organisation)	Regulates products with therapeutic, pharmacological, or drug-like claims under the Drugs and Cosmetics Act, 1940; intervenes when supplements contain APIs or banned drugs.
NADA (National Anti-Doping Agency)	Implements WADA Code in India, conducts drug testing of athletes, investigates Adverse Analytical Findings (AAFs), and identifies supplement-related doping cases.
IPC (Indian Pharmacopoeia Commission)	Develops reference standards and analytical monographs for herbal drugs, nutraceutical ingredients, and contaminants to improve testing reliability.
NABL (National Accreditation Board for Testing and Calibration Laboratories)	Accredits analytical laboratories that test supplements for adulterants, heavy metals, banned substances, and contaminants under ISO/IEC 17025.

Recommendations for Athletes and Regulators

Contamination of supplements with anabolic steroids, stimulants, hormone modulators, and designer analogues continues to cause unintentional doping cases globally and in India. Current evidence highlights several preventive strategies.[15,18,20]

Recommendations

- Avoid high-risk supplement categories pre-workouts, fat burners, testosterone boosters, and bodybuilding products unless certified by independent third-party programs (e.g., NSF Certified for Sport, Informed-Sport).
- WADA-accredited and national laboratories should maintain analytical agility, updating HR-MS metabolite libraries, using non-targeted screening (NTS), and improving detection of new designer analogues and prohormones.
- Expand WADA's Monitoring Program to track emerging substances (e.g., ecdysterone), allowing early identification before formal prohibition.
- Stronger enforcement by FSSAI and CDSCO is needed to prevent sale of supplements containing active pharmaceutical ingredients (APIs) without disclosure.
- Improved public and athlete awareness regarding supplement fraud, label inaccuracies, and contamination risks.

These strategies enhance product safety and reduce doping violations linked to adulterated supplements.

WADA-Related Adulteration and Contamination Cases in India

India's rapidly growing dietary supplement and sports nutrition market has increasingly faced issues related to

adulteration, contamination, and mislabeling. Due to inadequate regulatory enforcement, inconsistent quality assurance, and the absence of mandatory pre-market testing, several supplements available in India have been found to contain undeclared pharmacologically active substances that appear on the WADA Prohibited List. Such contamination poses a serious risk to athletes, as even trace levels of banned substances can result in Adverse Analytical Findings (AAFs) and doping sanctions.

Global evidence indicates that supplement contamination remains widespread. Studies have reported that 12-58% of sports supplements may contain undeclared anabolic agents, stimulants, or other prohibited substances (30-35). Multiple investigations using LC-MS/MS and HR-MS have identified contamination arising from poor manufacturing controls, cross-contamination, or deliberate adulteration.[31,34,38]

In India, the National Anti-Doping Agency (NADA) has documented several cases where athletes claimed unintentional ingestion due to contaminated supplements. Although contamination claims must be critically evaluated, both Indian and international incidents demonstrate that supplement adulteration is a significant contributor to unintentional doping.[36,39,41]

Table 4: Case Studies of WADA-Related Dietary Supplement Adulteration.

Case (Athlete/Group)	Adulterant Found	Category	Findings	Outcome / Penalties
23 Chinese Swimmers China)	Trimetazidine (TMZ)	Hormone & Metabolic Modulator	Trace levels detected Dec 2020–Jan 2021; contamination reported in WADA system in Mar 2021	No sanctions; WADA accepted contamination explanation
Shivpal Singh (India, Javelin)	Methandienone	Anabolic Steroid	Claimed contamination from "Prime Testo Booster"; supported by supplement testing	Ban reduced from 4 years to 1 year due to reduced fault
Rajni Jha (India, Para-Athlete)	Methyltestosterone	Anabolic Steroid	Found in "Nitro 100" whey protein despite compliant label	12-month ban for negligence in supplement verification
Sumit Malik (India, Wrestling)	Methylhexanamine (MHA)	Stimulant	Submitted sealed supplement samples; tested positive at BSCG-certified lab	CAS reduced ban to 17 months citing moderate fault

Summary and Implications

These case studies highlight major vulnerabilities in India's sports supplement ecosystem. Despite regulatory oversight by FSSAI and NADA, several systemic issues persist:

- Lack of mandatory pre-market analytical screening for sports supplements
- Absence of batch-wise testing and transparent supply-chain documentation
- Non-mandatory third-party certification (e.g., BSCG, NSF Certified for Sport)
- Insufficient enforcement against manufacturers producing contaminated products
- Limited athlete awareness regarding supplement verification and doping risk

Research indicates that up to 28% of sports supplements worldwide may be contaminated with anabolic steroids, stimulants, or other banned agents underscoring the need for stronger regulatory surveillance, validated analytical methods (LC-MS/MS, HR-Orbitrap), and harmonized enforcement in India.

Strengthening the regulatory ecosystem is essential to prevent unintentional doping, safeguard athlete health, and maintain the integrity of Indian sports.[32,33]

Public Health Impact and Consumer Awareness

Adulteration of dietary supplements presents a broad and growing public-health challenge. Products marketed as "natural" or "herbal" have been repeatedly shown to contain undeclared pharmaceutical active ingredients, stimulants, anabolic agents, and toxic contaminants; ingestion of such products can produce a spectrum of adverse outcomes ranging from mild gastrointestinal upset to life-threatening organ failure and sudden cardiac events.[7,5] Surveillance studies and clinical case series identify weight-loss, sexual-enhancement, and bodybuilding supplements as disproportionately associated with serious adverse events because these product categories are most frequently spiked to enhance perceived efficacy.[5,6]

Adverse effects and burden of disease

The clinical consequences of supplement adulteration include:

- **Cardiovascular effects:** tachycardia, hypertensive crises, arrhythmias, and myocardial infarction associated with stimulants (e.g., sibutramine analogues, DMAA) or sympathomimetic adulterants.[7]
- **Hepatotoxicity:** acute liver injury and fulminant hepatic failure linked to contaminated herbal products or hidden pharmaceuticals (e.g., anabolic steroids, adulterated weight-loss formulations) documented in several Indian case series.[9]

- **Endocrine and reproductive toxicity:** exogenous anabolic agents and steroids can cause hypogonadism, menstrual irregularities, and long-term fertility impairment.
- **Renal injury and metabolic disturbances:** including acute tubular necrosis or rhabdomyolysis reported after ingestion of adulterated performance enhancers.
- **Allergic and idiosyncratic reactions:** to undeclared botanical species, contaminants, or excipients.

Beyond individual morbidity, the public-health burden includes increased healthcare utilization (emergency admissions, specialist care), diagnostic uncertainty, and costs associated with outbreak investigations and product recalls. In athletes, adulterated supplements have caused inadvertent anti-doping rule violations with career-ending consequences and reputational harms.[10]

Case reports and surveillance evidence

Case reports remain a critical alarm system: tertiary-care case series in India and international poison-control and toxicology reports link severe hepatotoxicity and cardiac events to mislabeled supplements [9,6] . Market-surveillance studies corroborate clinical data by detecting undeclared APIs and designer analogues in seized or purchased supplements.[5] These combined data streams (clinical + analytical surveillance) emphasize that adverse events are not isolated incidents but reflect systematic quality and regulatory gaps.

Consumer knowledge, perception, and misleading marketing

Consumer perception studies show that many users equate "natural," "herbal," or "Ayurvedic" labels with safety and assume regulatory oversight is equivalent to that for medicines a misconception exploited by aggressive marketing and influencer-driven promotions on social media. Proprietary-blend labelling and vague health claims obscure ingredient identity and dose, making risk assessment by consumers impossible. Online marketplaces facilitate rapid dissemination of unverified products and complicate traceability, undermining standard recall procedures and post-market surveillance.[11]

Role of pharmacists, healthcare professionals, and media

Healthcare professionals especially pharmacists and primary-care clinicians are frontline defenders against supplement-related harm. Pharmacists can counsel on evidence-based product selection, identify red flags (unrealistic claims, proprietary blends, offshore manufacture), and advise about drug–supplement interactions. Clinicians should routinely document supplement use in medication histories and report suspected adverse events to national pharmacovigilance systems. Media reporting that accurately communicates risks, recalls, and regulatory actions can substantially improve public awareness and promote safer consumer behavior.[7,19]

Table 5: Adulterants in Dietary Supplements: Clinical Effects and Preferred Analytical Detection Methods.

Adulterant class / example	Representative clinical effects	Preferred analytical detection
Sibutramine and analogues	Hypertension, tachycardia, arrhythmia	LC-MS/MS, HRMS (targeted & non-targeted)
PDE-5 inhibitor analogues (sildenafil analogues)	Hypotension, visual disturbances, interactions with nitrates	HPLC-MS/MS, LC-HRMS
Anabolic steroids / SARMs	Hepatotoxicity, endocrine disruption, virilization	GC-MS/MS, LC-MS/MS
Stimulants (DMAA, synephrine)	Cardiovascular events, seizures	GC-MS, LC-MS/MS
Toxic botanicals / adulterated herbs	Hepatotoxicity, allergic reactions	DNA barcoding + metabolomics, NMR, LC-HRMS

Table (text) Representative adulterants, clinical effects, and detection methods

(Hachem et al., 2022; Gessen et al., 2023; Nagral et al., 2021)

Strategic Recommendations to Reduce Public-Health Risks from Adulterated Dietary Supplements

1. Improve surveillance coordination

A unified national surveillance framework is needed, in which laboratory market-testing programs, adverse-event monitoring systems, poison-control data, and public-health registries are interconnected. This integrated approach would enable faster recognition of contaminated or high-risk supplement batches.[5]

2. Enforce mandatory testing for high-risk categories

Products consistently associated with adulteration such as weight-loss, performance-enhancing, and sexual-health supplements should undergo compulsory third-party batch certification. Certified batches should display clear verification marks to help consumers identify safe products.[10]

3. Strengthen training for pharmacists and clinicians

Continuing medical and pharmacy education should include modules on dietary-supplement safety, prevalent adulterants, product-verification strategies, and national reporting systems. Improved knowledge among healthcare professionals will support better patient counseling and earlier detection of adverse reactions.

4. Implement large-scale public awareness initiatives

Targeted media outreach and educational campaigns should clarify that "natural" does not always mean safe. These initiatives should guide consumers on identifying reputable brands, checking manufacturer licences, and recognizing verified quality-testing labels.

5. Increase accountability of online marketplaces

E-commerce platforms must be required to authenticate sellers, maintain transparent documentation, remove suspicious or non-compliant products quickly, and collaborate with regulatory agencies during recalls and investigations.[11]

Future Perspectives and Recommendations

1. Advancement of Rapid Screening Methods and Portable Detection Tools

Future progress in supplement-quality control requires the development of fast, cost-effective, and field-deployable analytical tools**.** Portable devices such as handheld Raman spectrometers**,** near-infrared (NIR) analyzers**,** and paper-based microfluidic assays can enable frontline inspectors and customs authorities to detect adulterants without the need for full laboratory infrastructure.

Recent work shows that handheld Raman and NIR devices can successfully detect pharmaceutical adulterants in herbal formulations with high sensitivity and minimal sample preparation.[24]

Paper-based sensors and electrochemical microdevices are emerging as ultra-low-cost platforms suitable for resource-limited settings.[25]

2. Integration of Artificial Intelligence (AI) and Chemometrics in Adulteration Detection

AI-assisted analytical workflows especially machine-learning (ML) and deep-learning (DL) models are transforming the detection of adulterants in complex supplement matrices. Chemometric tools such as PCA, PLS-DA, ANN, and SVM can classify spectral fingerprints, identify unknown contaminants, and flag atypical batches with high accuracy.

AI models have demonstrated significant improvement in sensitivity and classification accuracy for LC-MS, FTIR, and NIR datasets used in adulteration screening.[26]

Deep-learning strategies using MS spectral fingerprints also show superior predictive capacity for identifying illegal pharmaceutical adulterants in botanical supplements.[27]

3. Strengthening Regulatory Surveillance and Global Harmonization

As adulteration becomes increasingly transnational, harmonized regulatory standards and shared global surveillance systems are essential. Collaboration among agencies such as FDA (USA), EFSA (EU), TGA (Australia), FSSAI (India) and WHO can bridge gaps in testing standards, reporting of adverse events, and information sharing on high-risk products.

Recent studies emphasize the need for international alignment of nutraceutical regulations and stronger post-market surveillance to reduce cross-border circulation of adulterated supplements.[28]

A global rapid-alert system similar to RASFF (EU) is suggested for supplements, enabling joint recall actions and exchange of laboratory findings.[29]

4. Enhancing Public Education and Promoting Industry Accountability

Sustainable risk reduction requires consumer awareness**,** transparent industry practices, and mandatory quality-assurance systems. Public education initiatives should emphasize the dangers of "natural = safe" misconceptions and train consumers to identify authentic manufacturers, licensed products, QR-coded batch certificates, and third-party testing seals.

Education programs have been shown to significantly improve consumer decision-making and reduce use of unverified supplements.[30]

Industry accountability is equally critical requiring companies to maintain traceable supply chains, transparent ingredient sourcing, and robust quality-control documentation.[31]

CONCLUSION

Dietary supplement adulteration has emerged as a critical public-health and regulatory challenge, driven by complex supply chains, inadequate oversight, and the rapid growth of unmonitored online markets. Despite major advances in modern analytical science, routine detection of adulterants is still hindered by matrix complexity, inconsistent method validation, and gaps in surveillance capacity. These limitations allow hazardous substances including pharmaceuticals, stimulants, steroids, and WADA-prohibited agents to reach consumers and athletes, contributing to avoidable toxicity, disease burden, and doping violations.

A coordinated global response is urgently required. Strengthening regulatory frameworks, enforcing mandatory testing for high-risk categories, and improving inter-agency collaboration especially among FSSAI, CDSCO, AYUSH, WADA, and NADA are essential to curb adulteration at its source. Equally vital are large-scale public education initiatives, clearer labeling standards, and stronger accountability for manufacturers and e-commerce platforms.

Future progress will depend on integrating rapid on-site screening tools, AI-enabled detection systems, robust

chemometric models, and harmonized international regulatory guidelines. Together, these advancements can transform current monitoring practices and ensure safer, evidence-based access to dietary supplements. Ultimately, protecting consumers requires sustained collaboration between scientists, regulators, healthcare professionals, and industry stakeholders to build a transparent and trustworthy supplement marketplace.

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