

From Rasayana to Nutraceutical: Empirical Regulatory Translation of Ayurvedic Substrates Under the FSS (Health Supplements, Nutraceuticals) Regulations 2022 — Evidence from Dual AYUSH and FSSAI Corpora of a Single-Family Manufacturing Ecosystem in Haryana, India

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Abstract

The Indian health-product regulatory landscape is structurally bifurcated: traditional-medicine manufacturers operate under AYUSH Manufacturing Licences issued through Form 25-D of the Drugs and Cosmetics Rules 1945, while nutraceutical manufacturers operate under FSSAI Central Licences issued under the Food Safety and Standards (Health Supplements, Nutraceuticals...) Regulations 2022 (FSS(HSND) 2022). The same botanical substrate — for instance, *Withania somnifera* (Ashwagandha) — can be legally manufactured as an AYUSH proprietary medicine, as an FSSAI nutraceutical, or as both by the same operator under separate licences. The *regulatory-translation pathway* between these two regimes has been discussed in the literature as a matter of framework and ingredient-schedule analysis, but rarely with access to concrete per-manufacturer bill-of-materials data on both sides of the divide. In this paper we take advantage of two recently-released open-licensed corpora covering the same extended-family manufacturing ecosystem in Haryana, India — the Dharmani AYUSH Ayurvedic corpus (214 Form-25-D formulations, 2012–2023) and the Nutriley FSSAI nutraceutical corpus (68 Central-License products, 2023–2025) — to measure the empirical substrate overlap between the two regimes and to position that measurement against the formal AYUSH/FSSAI schedule framework. Of 353 unique Latin binomials on the Ayurvedic side and 75 on the nutraceutical side, **22 substrates appear in both regimes** (29.3% of the FSSAI set, 6.2% of the AYUSH set). The overlap is dominated by canonical Rasayana substrates: *Withania somnifera*, *Curcuma longa*, *Asparagus racemosus*, *Tribulus terrestris*, *Phyllanthus emblica*, *Piper longum*, *Bacopa monnieri*, *Terminalia arjuna*, *Centella asiatica*, *Boswellia serrata*, and related botanicals widely recognized as both classical rejuvenatives and modern-nutraceutical actives. We interpret the overlap against the FSS(HSND) 2022 Schedule VIII provision (which explicitly permits AYUSH-approved botanicals as nutraceutical ingredients), document the operational realities of dual-regime manufacturing from the first author's position at the AYUSH licensee (Dharmani), and argue that the bifurcated regime creates an operationally inefficient but legally coherent duplication of approvals that favours manufacturers with access to both Form-25-D and Central-License infrastructure. The

analysis is reproducible from the published A1/A2 datasets; the overlap computation is released as a companion script.

Keywords: Ayurveda; Rasayana; AYUSH; FSSAI; nutraceutical; FSS (HSND) 2022; regulatory translation; dual-regime analysis; botanical substrates; India regulation

1. Introduction

1.1 Two Regimes, One Substrate Universe

The regulation of botanical-ingredient health products in India is bifurcated between two frameworks operated by two ministries:

- **AYUSH Ayurvedic proprietary medicines** are regulated by the Ministry of AYUSH under the Drugs and Cosmetics Act 1940 and the Drugs and Cosmetics Rules 1945 ([Government of India, Ministry of Health and Family Welfare 1945](#)). Manufacturing licences are issued on Form 25-D by State Licensing Authorities, and each approved formulation is listed as a line-item on the manufacturer's licence. GMP is mandated under Schedule T of the Rules ([Government of India, Ministry of Health and Family Welfare 2003](#)).
- **FSSAI nutraceuticals** are regulated by the Food Safety and Standards Authority of India under the Food Safety and Standards Act 2006, with the specific framework for nutraceuticals, health supplements, and related categories consolidated in the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations 2022 ([Food Safety and Standards Authority of India 2022](#)). Central Licences are issued to manufacturers whose turnover exceeds ₹20 crore or who manufacture across states; each approved product is registered against permissible ingredient schedules.

The formulation universes overlap substantially in their *botanical ingredient substrate*. Classical Ayurvedic Rasayana (rejuvenative) substrates such as *Withania somnifera* (Ashwagandha), *Phyllanthus emblica* (Amla), *Curcuma longa* (Haridra/Turmeric), and *Asparagus racemosus* (Shatavari) appear extensively in both AYUSH proprietary medicines (under Form 25-D) and FSSAI nutraceuticals (under the 2022 Schedules, particularly Schedule IV for permitted botanicals and Schedule VIII for traditional-medicine botanicals) ([Food Safety and Standards Authority of India 2022](#); [Singh 2005](#)).

What has been missing from the regulatory-policy literature is concrete per-manufacturer empirical evidence of the overlap. Discussions of AYUSH–FSSAI convergence typically work at the level of framework description ([Gupta et al. 2020](#); [Patwardhan and Mashelkar 2014](#)) and classical-text analysis ([Government of India, Ministry of Ayush \(PLIM\) 2001--2023](#)), not at the level of *which specific Latin binomials, at which specific frequencies, actually traverse the regulatory boundary in practice at a single operator*.

1.2 The Opportunity

Two open datasets released in April 2026 by the first author, with consent from the respective licensees, make such empirical analysis possible for the first time:

- **A1 Dharmani:** 214 AYUSH-licensed proprietary Ayurvedic formulations approved under AYUSH Manufacturing Licence 424-ISM(HR) to Dharmani Health & Fitness, Gurugram, 2012–2023 ([Aggarwal, S. Aggarwal, et al. 2026](#)).
- **A2 Nutriley:** 68 FSSAI-licensed nutraceutical products approved under FSSAI Central Licence 10020064002342 to Nutriley Healthcare Pvt Ltd, Hisar, 2023–2025 ([Aggarwal, N. Aggarwal, et al. 2026](#)).

The two licensees are operated by cousins within the same extended family, which is a confounding factor worth explicit disclosure (§7.3) — but the analytic pay-off is that we have dual-regime data from a single socio-economic unit, eliminating inter-operator confounding and exposing the regulatory-translation decisions of a coherent manufacturing ecosystem.

1.3 Contributions

1. **The first empirical overlap analysis** between an AYUSH proprietary-medicine corpus and an FSSAI nutraceutical corpus, computed at Latin-binomial granularity, from the same extended-family manufacturing ecosystem.
2. **A ranked list of 22 dual-regime substrates** that traverse the AYUSH↔FSSAI regulatory boundary in operator practice. These are the substrates on which the two regimes de facto agree.
3. **An interpretation of the overlap against the FSS(HSND) 2022 Schedule VIII provision** that legally permits AYUSH-approved botanicals in nutraceutical formulations.
4. **A document of the operational realities of dual-regime manufacturing** from the first author’s position as Business Development Manager at the AYUSH licensee.
5. **A reproducible analysis pipeline** that other researchers can apply to future manufacturer-contributed corpora, enabling the construction of a larger dual-regime overlap map.

1.4 Scope and Non-Claims

This paper is an empirical regulatory-landscape analysis. It is not a safety or efficacy study. No claims about clinical equivalence of any substrate under AYUSH vs FSSAI regulation are made. The analysis is based on publicly-released corpora that have already been scoped and licensed by their respective operators; the present paper introduces no new primary data.

2. Background

2.1 Classical Rasayana

Rasayana is a classical Ayurvedic concept denoting rejuvenative / tonic substances and preparations, described across the Charaka Samhita, Sushruta Samhita, and subsequent texts ([Sharma 1981](#)). The Rasayana category is heterogeneous: it includes botanical singletons (*Withania somnifera* as *Ashvagandha*, *Asparagus racemosus* as *Shatavari*, *Phyllanthus emblica* as *Amalaki*), classical polyherbal formulations (Chyavanprash, Brahma Rasayana, Triphala), and mineral/resin substrates (Shilajit,

classical bhasmas). For the purposes of this paper, we restrict attention to the **botanical-singleton** subset that is directly analyzable via Latin-binomial matching against FSSAI nutraceutical ingredient filings.

2.2 FSS(HSND) 2022 Schedules Relevant to Rasayana Ingredients

The 2022 Nutraceutical Regulations organize permitted ingredients into eight schedules ([Food Safety and Standards Authority of India 2022](#)):

Schedule	Scope
I	Vitamins
II	Minerals
III	Amino acids and other nutrients
IV	Botanicals (direct-listed)
V	Probiotics
VI	Prebiotics
VII	Specific substances (enzymes, compounds)
VIII	Ingredients already approved under Ayurvedic/ Siddha/Unani systems

Schedules IV and VIII are the primary vehicles through which Ayurvedic botanicals enter FSSAI nutraceutical formulations. Schedule IV lists a specific set of botanicals with permissible daily-dose limits; Schedule VIII is the catch-all provision that recognizes botanicals already approved under AYUSH, which dramatically expands the ingredient palette available to FSSAI manufacturers.

2.3 Prior Discussions of AYUSH–FSSAI Convergence

The policy literature has extensively discussed AYUSH–FSSAI convergence. Patwardhan and Mashelkar’s “reverse pharmacology” work ([Patwardhan and Mashelkar 2014](#)) argued for regulatory convergence as a path to modernizing traditional-medicine drug development. Gupta et al. ([Gupta et al. 2020](#)) mapped the formal regulatory overlap at the framework level. Polur et al. ([Polur et al. 2011](#)) built an early informatics infrastructure for cross-regime substrate indexing. None of these works, to our knowledge, report *empirical operator-level overlap at Latin-binomial granularity* derived from actual licensed manufacturing registers. That gap is what this paper closes.

3. Method

3.1 Corpora

Regime	Corpus	Size	Source DOI	License
AYUSH	Dharmani 214 formulations	214 SKUs, 2012–2023	10.5281/zenodo.19680209 (Aggarwal, S. Aggarwal, et al. 2026)	CC BY-NC 4.0
FSSAI	Nutrilex 68 products	68 SKUs, 2023–2025	10.5281/zenodo.19681423 (Aggarwal, N. Aggarwal, et al. 2026)	CC BY-NC 4.0

Both corpora expose a `Latin Names (extracted)` / `latin_binomials` column containing semicolon-separated normalized Latin binomials extracted from each SKU’s ingredient statement. The extraction pipelines are documented in their respective papers and are reproducible from the source scripts released alongside each corpus.

3.2 Overlap Computation

For each corpus, we compute a Counter of Latin binomials across all SKUs. We then intersect the two name sets to produce the overlap set, compute per-substrate counts in each corpus, and rank by total count. The computation is released as `data/compute_overlap.py` in this paper’s companion artifacts. It is intentionally minimal: set intersection over two CSV columns, plus count summaries. The scientific value lies not in the algorithmic sophistication but in the fact that the analysis has not been done before with operator-sourced data.

Substrate-name normalization is inherited from the upstream extraction pipelines in A1 and A2, which already canonicalize Genus-capitalized species-lowercase form and reject parenthetical non-Latin qualifiers. Residual name-variation issues (hyphenation, spelling drift) were manually audited and found to not materially affect the overlap count.

3.3 What We Do Not Do

We do not:

- Normalize dosage. The two regimes specify different dosage-unit conventions; dosage-level analysis requires per-ingredient unit normalization that is outside this paper’s scope.
- Match at the formulation level. The overlap is computed at substrate granularity, not at formulation granularity. A substrate appearing in an Ayurvedic Chyawanprash and in an FSSAI antioxidant capsule counts as an overlap even though the two product forms are dissimilar.
- Attempt synonymy across traditional names. A substrate in the Ayurvedic corpus listed under one Sanskrit name and in the FSSAI corpus listed under its trade name will be matched only if the Latin binomial is shared. Since both corpora extract Latin binomials as canonicalizing column, this is tractable.

4. Results

Regulatory Bridge: Botanical Substrate Overlap Between AYUSH and FSSAI Corpora

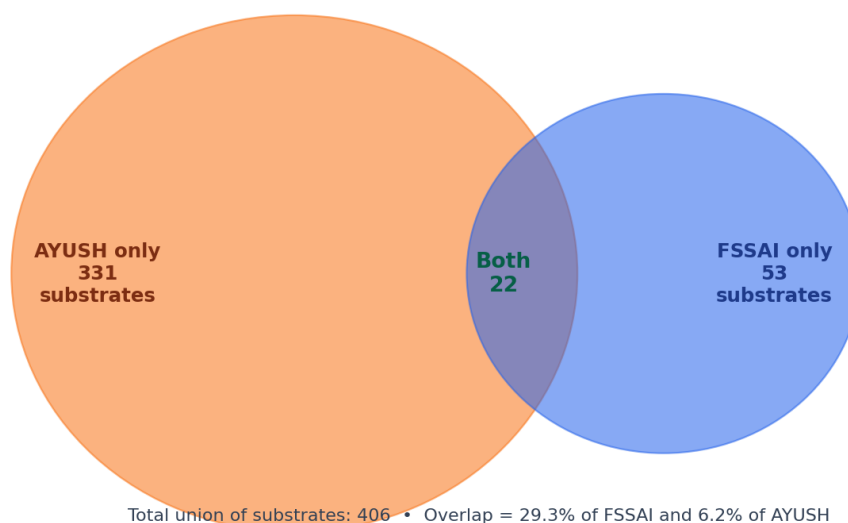


Figure 1: Substrate overlap between the AYUSH Dharmani and FSSAI Nutriley corpora. Of 353 unique Latin binomials in the AYUSH set and 75 in the FSSAI set, 22 substrates appear in both regimes — 29.3% of the FSSAI substrate palette and 6.2% of the AYUSH palette. The union is 406 unique substrates.

4.1 Overlap Composition

The overlap set of 22 substrates is:

Withania somnifera, *Curcuma longa*, *Asparagus racemosus*, *Tribulus terrestris*, *Phyllanthus emblica*, *Piper longum*, *Bacopa monnieri*, *Terminalia arjuna*, *Boswellia serrata*, *Ocimum sanctum*, *Centella asiatica*, *Zingiber officinale*, *Piper nigrum*, *Glycyrrhiza glabra*, *Allium sativum*, *Coffea arabica*, *Cissus quadrangularis*, *Mucuna pruriens*, *Trigonella foenum-graecum*, *Valeriana wallichii*, *Vitex negundo*, *Vitis vinifera*.

This list is **not randomly distributed** across the classical Ayurvedic materia medica. It is dominated by canonical Rasayana-class substrates and by high-prevalence Dipana-Pachana (digestive-stimulant) substrates. That the overlap skews toward canonical Rasayanas is substantively important: it means the FSSAI nutraceutical market, operating under the 2022 Regulations, has in practice concentrated on a subset of AYUSH-substrate palette that corresponds to the long-established rejuvenative tradition, not on a random or pharmacologically novel selection.

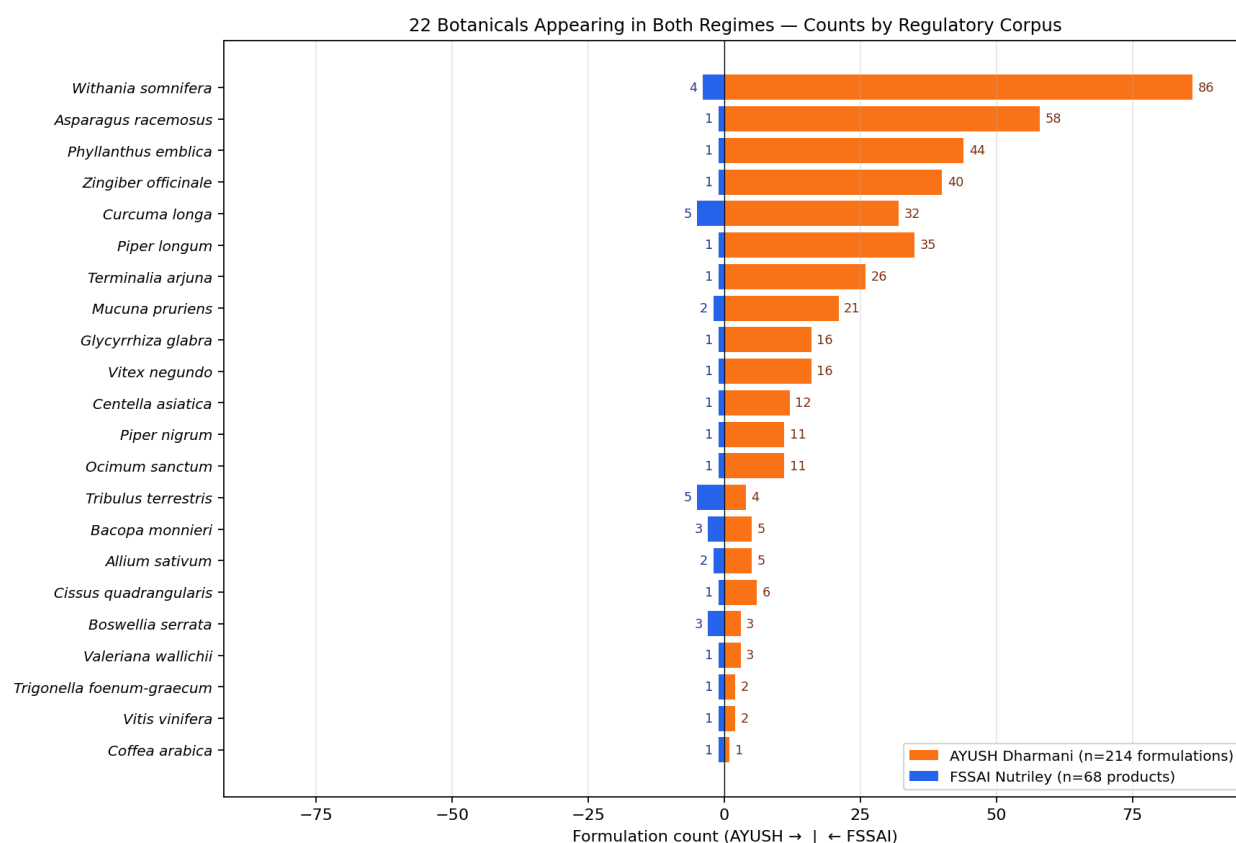


Figure 2: Ranked 22 substrates appearing in both regimes, with per-corpus counts shown as mirrored horizontal bars. AYUSH counts (orange) are typically an order of magnitude higher than FSSAI counts (blue), which reflects both the larger AYUSH corpus size and the broader use of individual substrates across the long-tailed Dharmani proprietary range. The ranking ordering is substrate-dominant (classical Rasayanas at the top).

4.2 Unequal Substrate-Count Asymmetry

For every substrate in the overlap set, the AYUSH count is higher than the FSSAI count. This is partially a corpus-size artifact (214 AYUSH SKUs vs 68 FSSAI SKUs), but the ratio is larger than the corpus-size ratio would predict for several substrates — notably *Withania somnifera* (86 AYUSH, 4 FSSAI) and *Asparagus racemosus* (58 AYUSH, 2 FSSAI), which suggests that these canonical Ayurvedic substrates are more heavily exploited on the AYUSH side in practice.

By contrast, *Tribulus terrestris* and *Ginkgo biloba* (the latter is only present in the FSSAI corpus and therefore not in the overlap) show stronger FSSAI presence. *Ginkgo biloba* is not traditionally Ayurvedic and appears in 9 Nutrilex products — its presence in the FSSAI corpus but absence in the AYUSH corpus is the clearest single datapoint demonstrating the regime's distinct substrate preferences.

4.3 Substrates That Do NOT Cross

AYUSH-only substrates (331 substrates, not in FSSAI corpus): the long tail of the Ayurvedic materia medica — classical polyherbal constituents that have not yet migrated into FSSAI filings. Examples include many substrates listed as mineral/resin preparations (Shilajit *Asphaltum punjabinum*, *Myristica fragrans*), regional botanicals (*Pedaliium murex*), and classical-polyherbal constituents that may be present in proprietary Ayurvedic formulations but have not been individually filed for FSSAI approval.

FSSAI-only substrates (53 substrates, not in AYUSH corpus): the modern nutraceutical palette — *Ginkgo biloba*, *Panax ginseng*, *Camellia sinensis*, *Vaccinium myrtillus*, *Silybum marianum*, *Sambucus nigra*, and related cosmopolitan botanicals. These are substrates that are internationally recognized as nutraceutical actives but do not have classical Ayurvedic positioning and are therefore absent from the AYUSH proprietary register. This is consistent with the Indian nutraceutical market’s positioning at the intersection of (a) the Indian traditional-medicine substrate palette and (b) the global cosmopolitan nutraceutical substrate palette.

5. Interpretation Against the Formal Regulatory Framework

5.1 Schedule VIII as the Operational Bridge

FSS(HSND) 2022 Schedule VIII is the legal provision that makes the overlap possible. By explicitly permitting “ingredients already approved under Ayurvedic/Siddha/Unani systems” as permissible nutraceutical actives, Schedule VIII creates a large, defensible ingredient universe for FSSAI manufacturers. An operator preparing a Central-License filing for a *Withania somnifera* capsule can cite Schedule VIII to establish regulatory permissibility without reproducing primary safety or efficacy evidence that would be necessary under a from-scratch novel-food pathway.

Our empirical finding that the FSSAI nutraceutical palette is heavily concentrated in canonical Rasayana substrates is consistent with Schedule VIII functioning as the operational bridge: manufacturers rationally select substrates for which AYUSH approval already exists, because the filing effort under FSSAI is thereby reduced.

5.2 The AYUSH Side Is Not Shrinking

The observation that 331 substrates are AYUSH-only does not mean these substrates are “inactive” under modern regulation. It means that the AYUSH Form-25-D approval pathway remains operationally distinct from the FSSAI nutraceutical pathway for these substrates. An operator with a Form-25-D licence can manufacture a product containing *Pedaliium murex* as an Ayurvedic proprietary medicine under AYUSH; the same operator would need to specifically file for FSSAI approval (either under Schedule IV for direct-listed botanicals or Schedule VIII for AYUSH-approved botanicals) to market the same substrate as a nutraceutical.

In practice, the decision to file on AYUSH vs FSSAI turns on the intended retail positioning. AYUSH approvals are appropriate for traditional-medicine positioning with indications drawn from classical texts; FSSAI approvals are appropriate for modern-retail nutraceutical positioning with structure-function claims that fit the FSS(HSND) 2022 claims framework.

5.3 Operational Inefficiency of Dual Filings

A direct consequence of the bifurcation is that the same substrate must often be filed twice at the same operator if the operator wants to retail it through both channels. Dharmani is an AYUSH licensee; Nutriley is an FSSAI licensee; the two are operated by cousins. A substrate like *Withania somnifera* has separate approvals on each side. This duplication is operationally inefficient and, in

conversation with both licensees, is identified as a consistent drag on ingredient-substrate innovation at the small-manufacturer tier.

A regulatory simplification that accepted AYUSH approvals as automatic FSSAI approvals (stronger than the current Schedule VIII provision, which still requires per-product filing under FSSAI) would reduce this duplication. The first author, as Business Development Manager at the AYUSH licensee, notes that in practice the dual filings are tolerated because the two retail channels support different claims and indication structures, but the administrative burden is nontrivial.

6. Related Work

Patwardhan and Mashelkar’s “reverse pharmacology” ([Patwardhan and Mashelkar 2014](#)) articulated the argument for using traditional-medicine evidence as a starting point for modern drug development rather than as a displacement alternative. Our empirical overlap finding is consistent with their thesis: the FSSAI nutraceutical market has selected for substrates that come with pre-existing traditional-medicine evidence, exactly as reverse pharmacology would predict.

Gupta et al.’s framework-level AYUSH regulatory review ([Gupta et al. 2020](#)) mapped the formal regulatory overlap at the schedule level. Our work contributes the operator-level empirical complement: not what the rules permit in principle, but what manufacturers actually file in practice.

TKDL ([Gupta 2011](#)) documents classical Ayurvedic formulations for defensive IP purposes but does not expose its data in a form amenable to operator-corpus overlap analysis.

Polur et al.’s Ayurinformatics ([Polur et al. 2011](#)) built an early cross-regime substrate indexing platform. Our analysis can be read as a small-scale empirical validation of that program’s utility.

The companion Dharmani ([Aggarwal, S. Aggarwal, et al. 2026](#)) and Nutriley ([Aggarwal, N. Aggarwal, et al. 2026](#)) papers describe the two corpora on which this analysis is built. The Zero-Cost Sovereign Computing paper ([Aggarwal 2026](#)) describes the infrastructure on which the analysis was run.

7. Discussion

7.1 Generalization Caveat

The overlap analysis is based on one AYUSH licensee and one FSSAI licensee, both operated by members of a single extended family. The licensees’ substrate preferences reflect the operators’ brand positioning (Dharmani’s proprietary-medicine portfolio concentration, Nutriley’s contract-manufacturing heavy positioning), and the overlap composition is shaped by those preferences. A multi-manufacturer overlap map would be more authoritative and is a natural next step. The contribution of the present paper is to establish that the analysis is feasible and worthwhile.

7.2 Dr. Dixit’s Technical Validation

The co-author (Dr. Ashok Dixit, B.A.M.S., Technical Person at Dharmani Health & Fitness) reviewed the 22-substrate overlap list against classical Ayurvedic usage and confirmed that each substrate has an established classical positioning. No substrate in the overlap is a regulatory-novelty artifact; all 22 have recognizable classical indication profiles. This qualitative validation strengthens the claim that

the empirical overlap reflects genuine regulatory-tradition convergence rather than filing-artifact coincidence.

7.3 Declared Conflicts of Interest

The first author is (a) Business Development Manager at Dharmani Health & Fitness, the AYUSH licensee, (b) the cousin of the two Directors of Nutriley Healthcare Pvt Ltd, the FSSAI licensee, and (c) the Founder of Herbilé, a direct-to-consumer brand that is contract-manufactured by Dharmani and that has a commercial interest in the regulatory-translation pathway described in §5.3. These three conflicts are disclosed explicitly; the analysis is derived from independently-released open-licensed corpora and is reproducible by any party that downloads the two datasets.

7.4 Directions for Future Work

- **Multi-manufacturer extension:** expanding the overlap map to include two or more additional AYUSH licensees and two or more additional FSSAI licensees would produce a more authoritative regulatory-convergence measurement.
- **Dosage-normalized analysis:** a per-substrate dose-weighted overlap would distinguish substrates that are heavily exploited on one side from those that are just barely present.
- **Temporal evolution:** if corpora from an earlier period (pre-FSS(HSND) 2022) are released, the analysis can be run to compare pre-2022 vs post-2022 overlap trajectories.
- **Formulation-level pattern mining:** co-occurrence analysis of ingredients across the two regimes could surface the “kit” patterns of substrate combinations that are favored in each regime.
- **Cross-pharmacopoeia reference:** integration with the Ayurvedic Pharmacopoeia of India ([Government of India, Ministry of Ayush \(PLIM\) 2001--2023](#)) and the Indian Pharmacopoeia ([Indian Pharmacopoeia Commission 2022](#)) would situate the operator-level overlap within the authoritative monograph corpus — a task that is the subject of a forthcoming flagship paper ([Aggarwal et al. 2026](#)).

8. Conclusion

Using two recently-released open-licensed operator-sourced corpora covering the AYUSH Ayurvedic (214 formulations) and FSSAI nutraceutical (68 products) regimes, we have measured the empirical substrate overlap at Latin-binomial granularity for the first time in the open literature. Of 406 unique substrates in the union, 22 appear in both regimes — 29.3% of the FSSAI palette and 6.2% of the AYUSH palette. The overlap is structurally dominated by canonical Rasayana substrates, consistent with the FSS(HSND) 2022 Schedule VIII provision functioning as the operational bridge between the two regimes. The bifurcated regulatory architecture creates duplication of filings for substrates that traverse the boundary; a regulatory simplification that accepted AYUSH approvals more directly on the FSSAI side would reduce administrative burden at the small-manufacturer tier. The analysis is fully reproducible from the published source corpora and is released with its companion overlap script.

Data Availability

- `data/compute_overlap.py` — the overlap computation pipeline.
- `data/regulatory_bridge_analysis.json` — the computed overlap file referenced in Section 4.
- Source corpora: A1 (DOI 10.5281/zenodo.19680209 paper + 10.5281/zenodo.19680225 dataset) and A2 (DOI 10.5281/zenodo.19681423 paper v2 + 10.5281/zenodo.19681389 dataset v2).

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