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From Registry Safety Records to Consumer Warnings: Concordance in Japanese and Korean Functional Foods with Label-Identified Natural Sources

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ABSTRACT: Safety information recorded upstream in a functional-food registry may not be represented in the downstream product-warning field. This cross-sectional study estimated registry-field concordance for Japanese and Korean functional foods with label-identified natural sources using separate country-specific estimands. Label-identified natural origin was assigned only when an official ingredient label named a plant, fungal/algal, microbial, or animal/marine source; it did not assert verified product provenance. The sole author manually reviewed all 932 distinct Japanese labels and 328 distinct Korean official ingredient labels in the analytical cohorts against locked rules before the final concordance rerun. Japan contributed 1,731 label-identified notifications. Among 310 notifications with an interaction indicator and a detected assessment-field warning cue, after detected no-warning cues were excluded, 236 contained strict medication wording (76.1%; 95% company-cluster bootstrap confidence interval 70.5–81.5) and 257 met the liberal professional-advice definition (82.9%; 77.6–87.8). Korea contributed 4,295 label-identified products; 3,377 of 3,762 eligible products contained wording representing every applicable official caution domain (89.8%; 87.5–91.6). Registry-wide contextual estimates were 79.1% in Japan and 88.1% in Korea. The low Korean fungal/algal estimate was concentrated in two recognition codes. These estimates describe concordance between registry fields, not legal compliance, consumer comprehension, or causal regulatory performance. The antecedent-aligned framework identifies records for contextual review.

1. INTRODUCTION

Safety-related content documented in a functional-food assessment may not reappear in the registry warning intended for consumers. The issue is especially relevant when an official ingredient label names a plant, fungal/algal, microbial, or animal/marine source. Plant-derived products, for example, are sold as foods but may be taken with prescribed medicines and over long periods.

Natural-source labels do not make an interaction predictable. Reports on herbs and other bioactive products relate risk to dose, species, the material used, extraction, concomitant medicines, and the user [1,2,3,4,5,6]. The registries do not observe all of these factors. They do contain two different texts: the assessment records the safety issue considered upstream, whereas the product warning is what a reader encounters downstream. The analysis concerns the relation between those fields.

Japanese audits have located incomplete, inconsistent, or product-specific safety information in registry records and marketed materials [7,8,9]. Korean consumers, in a separate study, asked for cautions that state the action to take [10]. Other work shows that label wording changes product choice and perceived benefit [11,12,13], and Japanese readers have not always found or

interpreted critical safety content [14]. Those findings describe the information supplied or the way it is received. They do not give the record-level proportion carried from an assessment or official caution into its associated warning.

The Japanese interaction field cannot serve as that denominator without further reading. A completed entry may describe an interaction, deny one, or state that another warning is unnecessary. Only the first provides an upstream reason to expect medication wording later in the record. The assessment narrative was therefore screened, and detected no-warning contexts were removed before the intake-warning field was examined.

Prior Japanese studies have evaluated the evidence used for functional claims [15,16,17,18] and the conditions of market entry and oversight [19,20,21]. Korean studies have examined recognized ingredients and the functional-claims system [22,23]; cross-jurisdictional reviews have compared claims and premarket controls [1,24,25]. The within-record movement of an applicable safety item has not been quantified in that work.

The question is whether the downstream warning represents the safety content that its own registry has made applicable. Applicability comes from the screened assessment text in Japan and from caution domains attached to an exactly linked recognized ingredient in Korea. These were retained as separate estimands. The primary cohorts were also limited to records whose official functional-ingredient label explicitly names a biological source; this rule identifies the label wording and does not verify provenance.

2. MATERIALS AND METHODS

2.1 Study design and data sources

The common snapshot date was fixed at 19 August 2026 before outcome classification. Ten files from the Consumer Affairs Agency Foods with Function Claims search supplied the Japanese input [26]. Across 113 shared columns, they contained 11,362 distinct notification identifiers before the sale-status restriction. The Korean input came from Food Safety Korea service C003 and the individually recognized ingredient service [27]. Hashes were retained for the untouched downloads before selection, linkage, or text coding began.

2.2 Cohorts and record linkage

After the sale-status restriction was applied in Japan, eligibility required nonblank ingredient, functional-claim, intake-warning, interaction, and safety-assessment fields. The resulting cohort contained 3,383 notifications.

For Korea, product rows were joined to official ingredient records with the Ministry of Food and Drug Safety recognition code assigned to an individually recognized functional ingredient. Exact code agreement produced 5,298 product-code pairs covering 4,994 products and 328 codes. Ingredient names were not used as keys because synonyms, incidental ingredients, and partial strings generated false candidates. For products carrying several codes, the applicable caution domains were pooled; the warning had to represent every domain in that pooled set.

2.3 Safety antecedents and warning outcomes

Japanese eligibility was determined without reference to the intake-warning field. A notification entered the outcome set only when the interaction indicator was present, the assessment narrative contained a warning cue, and no no-warning cue was detected. Negative, conflicting, and undetermined assessments remained in the audit files but not in the primary denominator.

Strict coverage meant that the warning named medicines generally, identified a medicine or drug class, or used an unmistakable condition-specific expression such as diabetes medicine. This kept the outcome tied to the medication-interaction antecedent; clinic attendance or treatment status alone did not qualify. A sensitivity analysis additionally required interaction and action terms to occur near one another, although valid advice can appear elsewhere in a warning.

A liberal outcome was retained separately. It credited an explicit instruction to consult a physician, pharmacist, or other health professional. Because such advice could concern pregnancy, symptoms, or another adverse event rather than the assessment-field interaction, this measure is reported only as an upper bound to strict medication coverage.

2.4 Korean warning domains

Applicability in Korea came from the official caution rather than a universal warning checklist. Four domains could be activated. Medicine terms, named drug classes, or concurrent-use wording activated medication interaction. Pregnancy, lactation, childhood, or older age activated vulnerable population. The adverse-event domain asked for more than an isolated symptom, requiring adverse-event framing or a stop-use instruction, and allergy, hypersensitivity, or individual-susceptibility wording activated the fourth domain.

Only applicable domains entered the comparison. A product warning was scored against the domains found in its linked caution, so detail in one domain could not compensate for omission of another. A domain absent from the caution, conversely, was never counted as missing.

2.5 Label-identified natural-origin ontology and manual review

Source assignment began with the wording of the official functional-ingredient label; chemical plausibility was not used to infer origin. Explicit plant, fungal/algal, microbial, and animal/marine cues were coded nonexclusively. One detected domain yielded the corresponding class, whereas two or more yielded multiple-domain label-identified. With no explicit source cue, the label remained source-unresolved/other—a category that was not interpreted as synthetic. Japanese labels were classified at notification level. For Korea, recognition-code ingredient labels were classified first and their domain flags were unioned across the codes linked to each product. Unqualified chemicals, nutrients, metabolites, trade names, and generic extraction or fermentation terms did not establish origin.

Country-specific lexical dictionaries operationalized the source definition. The locked Japanese dictionaries contained 150 plant, 29 fungal/algal, 31 microbial, and 47 animal/marine cues; the corresponding Korean dictionaries contained 184, 25, 31, and 46 cues. Representative inclusions were labels explicitly naming potato, mushroom, Bifidobacterium, or oyster in Japan and Dichrostachys glomerata, Ecklonia cava, lactic-acid bacteria, or fermented oyster in Korea. Names and extract ratios do not by themselves establish equivalent preparations [28]. Generic extraction wording and unqualified chemicals were excluded. Embedded-substring boundaries also prevented the fruit character within the Japanese term for lactosucrose and the Korean oyster syllable within terms meaning vine from creating false source assignments.

Every distinct label represented in the analytical cohorts was checked: 932 Japanese labels and 328 Korean official ingredient labels. Each decision was compared with the locked country-specific dictionary and its boundary rules. The label assignments and ontology version natural-origin-v1.2.0-2026-08-19 were fixed before the concordance rerun. Because the same author developed and checked the rules, this step provides an internal audit rather than independent validation or an inter-rater estimate.

2.6 Warning-concordance codebook validation

The under-recognition review began with every record that failed at least one warning rule. The review file kept the identifier, antecedent, warning, and failed rule together. After identical normalized passages were collapsed, every remaining template was read. Missed abbreviations, near-synonyms, spelling variants, consumer expressions, and false-positive boundaries were resolved before the codebook was frozen.

Positive matches underwent a separate over-recognition review. Japanese treatment-only matches were removed from strict medication coverage, while general professional advice remained confined to the liberal outcome. In Korea, the checks covered duplicate keys, empty warnings, domains pooled across codes, and agreement between applicable and observed domains. These are developer audits, not independent adjudication.

2.7 Statistical analysis

Company was the resampling unit for the percentile confidence intervals. In each of 100,000 fixed-seed replicates, eligible Japanese notifiers or Korean manufacturers were sampled with replacement, and all eligible records belonging to a selected company travelled with it. Repeated selection therefore repeated that company's records. The reported point estimate remained the observed record-level fraction.

This resampling scheme preserves within-company dependence and asks how the record-level fraction varies when eligible companies are reweighted. It does not quantify sampling error from drawing records from either registry, because the cohorts

are censuses of eligible records. Label-identified records define the primary population. Registry-wide estimates provide context, and source-class estimates are descriptive.

Country-specific binary logistic regressions with a logit link were secondary to the concordance estimates and modeled each registry's primary binary coverage outcome. Finite-sample-corrected sandwich standard errors accounted for notifier or manufacturer clustering. Both models included a year variable centered at 2020—notification year in Japan and product-approval year in Korea—and ln(ingredient count + 1), although ingredient count followed the structure of each registry: separators plus two conjunction forms in the Japanese functional-ingredient label, and comma-separated raw-material entries in Korea. Clinical-trial evidence and reported use of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) completed the Japanese specification; multiple-code linkage completed the Korean model.

The complete-case regressions retained 310 Japanese records—236 covered and 74 uncovered—within 188 notifier clusters, and 3,762 Korean products—3,377 complete and 385 incomplete—within 200 manufacturer clusters. Adjusted odds ratios (ORs), 95% CIs, and two-sided Wald p values describe associations; none of them is a causal effect. For Korea, approval year records product vintage rather than the date of the warning now on file; the 2026 records are also incomplete.

Numerical reproduction. An independently assembled route regenerated the classifications, primary counts, interaction-indicator counts, source-class composition, registry-wide estimates, and Korean domain results. All 61 implementation checks agreed, including assignment of 1,260 ingredient labels to one of six classes. The secondary regressions were also fitted by two different procedures: standardized-predictor L-BFGS-B and raw-scale Newton-IRLS. Their seven estimates, 95% CIs, and p values agreed within 0.0001; standardized condition numbers were 1.45 for Japan and 1.17 for Korea.

Deleting each of the five largest companies in turn did not reverse a regression coefficient, and neither did removal of incomplete 2026 records. Computation used Python 3.12.13, pandas 2.2.3, NumPy 2.3.5, and SciPy 1.17.0. These checks were applied to the secondary models; the concordance fractions are the principal results.

Reconstruction remains possible at row level because identifier, eligibility decision, antecedent class, applicable and observed domains, concordance flag, source assignment, and supporting label evidence are retained together. Before Japanese files were appended, columns and identifiers were checked. Korean links preserve the normalized recognition code and never substitute an ingredient name or a description-based inferred match.

Missingness was handled where it arose rather than imputed into a linkage key or text outcome. A blank Japanese assessment could remain in the source cohort but could not pass the warning-positive screen. Texts containing both warning and no-warning cues were also omitted from the primary estimate. In Korea, a blank product warning failed every applicable domain, while a product with no applicable caution entered no all-domain denominator. A phrase could cover more than one activated domain but could not introduce a domain absent from the linked caution. Secondary-model covariates were handled by complete-case analysis.

3. RESULTS AND DISCUSSION

3.1 Cohort integrity

Label wording identified a biological source for 1,731 of 3,383 Japanese notifications (51.2%) and 4,295 of 4,994 Korean products (86.0%). The complete distributions across plant, fungal/algal, microbial, animal/marine, multiple-domain, and source-unresolved/other classes appear in Table 1.

The identifier audit found neither duplicated Japanese notification identifiers nor duplicated Korean product-recognition-code pairs. Source-unresolved/other was retained whenever the label itself lacked explicit source wording, irrespective of whether the chemistry could be read as natural.

The two cohort routes are displayed separately in Figure 1. The Japanese branch narrows 1,731 label-identified notifications to 310 records passing the assessment screen, of which 236 meet the strict and 257 the liberal warning rule. The Korean branch narrows 4,295 label-identified products to 3,762 with an applicable caution domain, of which 3,377 contain every required domain. These changes arise from different registry rules; they are not stages of one attrition process.

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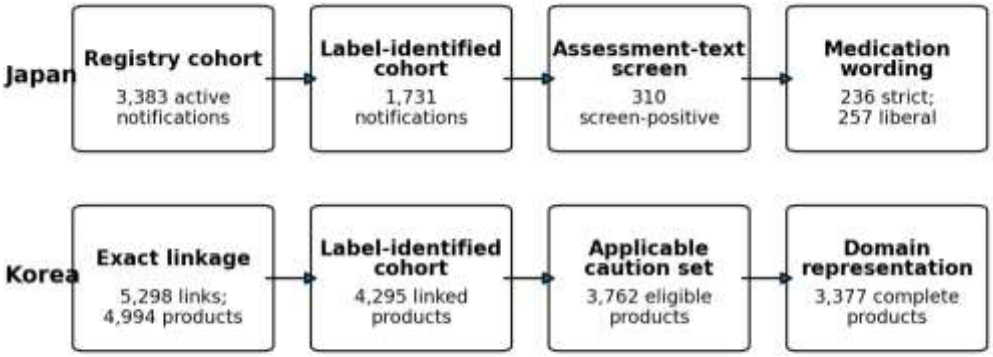

Figure 1. Label-identified cohort pathways and operational text-concordance denominators

Note. The sole author reviewed all 932 distinct Japanese and 328 distinct Korean ingredient labels represented in the analytical cohorts.

Table 1. Label-identified natural-origin composition, source-class concordance, and source-unresolved context

Country and source class	Registry records (%)	Eligible	Covered/eligible, % (95% company-cluster bootstrap CI)
Japan—label-identified total	1,731 (51.2)	310	236/310; 76.1 (70.5–81.5)
Japan—plant	989 (29.2)	235	177/235; 75.3 (69.0–81.1)
Japan—fungal/algal	20 (0.6)	0	0/0; not estimable
Japan—microbial	375 (11.1)	33	23/33; 69.7 (53.3–89.7)
Japan—animal/marine	256 (7.6)	24	22/24; 91.7 (79.2–100.0)
Japan—multiple-domain	91 (2.7)	18	14/18; 77.8 (58.8–94.1)
Japan—source-unresolved/other	1,652 (48.8)	269	222/269; 82.5 (77.1–87.5)
Korea—label-identified total	4,295 (86.0)	3,762	3,377/3,762; 89.8 (87.5–91.6)
Korea—plant	2,582 (51.7)	2,264	2,084/2,264; 92.0 (90.4–93.5)
Korea—fungal/algal	247 (4.9)	203	135/203; 66.5 (56.9–75.5)
Korea—microbial	684 (13.7)	534	455/534; 85.2 (77.8–90.7)
Korea—animal/marine	549 (11.0)	541	504/541; 93.2 (89.1–96.1)
Korea—multiple-domain	233 (4.7)	220	199/220; 90.5 (82.4–96.2)
Korea—source-unresolved/other	699 (14.0)	692	546/692; 78.9 (68.6–86.8)

The units in Table 1 cannot be pooled. Japan follows assessment and warning fields within one notification, whereas Korea follows an official ingredient caution into an exactly linked product warning. No Japanese fungal/algal record entered the warning-eligible denominator, so concordance for that class is not estimable; source-unresolved/other is also contextual, because an unstated biological source cannot be recoded as synthetic origin. Table 1 is consequently a within-registry description of composition and concordance, not a country ranking.

3.2 Japan: assessment context and warning wording

Strict medication wording appeared in 236 of 310 label-identified Japanese notifications meeting the assessment-text screen (76.1%; 95% company-cluster bootstrap CI 70.5–81.5). The liberal definition covered 257 of 310 (82.9%; 95% CI 77.6–87.8), and registry-wide strict coverage was 458 of 579 (79.1%; 95% CI 75.0–82.9). When every label-identified notification carrying an interaction indicator formed the denominator, strict wording appeared in only 404 of 616 (65.6%; 95% CI 59.8–71.2). This lower indicator-based figure is the reason the antecedent field must be aligned before a downstream omission is counted. The remaining liberal contextual estimates appear in Table 2.

Table 2. Japanese label-identified warning concordance and registry-wide context

Japanese population and definition	Covered	Total	% (95% company-cluster bootstrap CI)
Label-identified, assessment-text screen, strict	236	310	76.1 (70.5–81.5)
Label-identified, assessment-text screen, liberal	257	310	82.9 (77.6–87.8)
Label-identified, interaction indicator, strict	404	616	65.6 (59.8–71.2)
Label-identified, interaction indicator, liberal	451	616	73.2 (67.2–78.9)
Registry-wide assessment-text screen, strict	458	579	79.1 (75.0–82.9)
Registry-wide assessment-text screen, liberal	482	579	83.2 (79.4–86.9)

Within label-identified Japanese screen-positive records, strict coverage was 75.3% for plant notifications (177/235), 69.7% for microbial notifications (23/33), 91.7% for animal/marine notifications (22/24), and 77.8% for multiple-domain notifications (14/18); no fungal/algal notification met the assessment-text screen. Given the small non-plant denominators and wide intervals, no stable ordering of source classes can be read from these figures. They describe how the label-identified estimate is composed. They do not support a biological mechanism, or a claim that one source class communicates safety better than another.

The 74 Japanese screen-positive records without strict medication wording separated into two groups: 21 contained general professional-advice language, whereas 53 met neither definition. A consultation instruction may concern the assessed interaction, but pregnancy, symptoms, or another issue is also possible and the registry does not adjudicate among those readings. Accordingly, 236/310 remains the primary strict estimate and 257/310 the liberal upper bound.

The proximity rule excluded seven of the 310 Japanese records. Strict medication wording was present in 234 of the remaining 303 records (77.2%; 95% company-cluster bootstrap CI 71.7–82.4); 255 met the liberal definition (84.2%; 79.0–89.0). This analysis shows how the estimate responds to a narrower text rule. It cannot establish which assessment reading is correct because no adjudicated reference standard is available.

Year, clinical-trial evidence, and reported PRISMA use were imprecisely associated with strict coverage in the Japanese secondary model: the respective ORs were 0.93 per year (95% CI 0.82–1.06), 0.70 (0.04–11.96), and 0.74 (0.35–1.56). Ingredient count differed. A one-unit increase in ln(ingredient count + 1) corresponded to an OR of 33.30 (7.48–148.23), although the wide interval leaves the magnitude poorly determined and the count may also index warning length, product complexity, or

notifier portfolios. The 236/310 concordance estimate, rather than these descriptive coefficients, remains the principal Japanese result.

3.3 Korea: propagation of official ingredient cautions

Complete representation of every applicable domain occurred in 3,377 of 3,762 label-identified Korean products (89.8%; 95% company-cluster bootstrap CI 87.5–91.6). Coverage for the individual domains varied only from 93.5% for medication interaction to 95.0% for adverse-event risk or response; the four domain-specific numerators, denominators, and intervals are reported in Table 3. Registry-wide, 3,923 of 4,454 products represented every applicable domain (88.1%; 95% CI 85.5–90.2). The all-domain outcome is lower than the individual-domain results because omission of any applicable domain makes the product incomplete.

Table 3. Korean label-identified official-caution coverage and registry-wide context

Korean population and warning domain	Covered	Required	% (95% company-cluster bootstrap CI)
Label-identified—medication interaction	1,155	1,235	93.5 (91.6–95.2)
Label-identified—vulnerable population	3,398	3,611	94.1 (92.4–95.5)
Label-identified—adverse-event risk or response	2,391	2,518	95.0 (93.2–96.3)
Label-identified—allergy or hypersensitivity	2,592	2,746	94.4 (92.3–95.9)
Label-identified—all required domains	3,377	3,762	89.8 (87.5–91.6)
Registry-wide—all required domains	3,923	4,454	88.1 (85.5–90.2)

Product vintage had a positive association with complete coverage in the Korean secondary model (OR per year 1.24; 95% CI 1.18–1.29). Ingredient count went in the other direction: a one-unit increase in ln(ingredient count + 1) corresponded to an OR of 0.50 (0.37–0.68). Products linked to multiple recognition codes also had lower estimated odds (OR 0.54; 95% CI 0.34–0.87). These coefficients identify records with more complex warning obligations for review but do not establish why complexity is associated with incomplete coverage. Current registry text is not an archive of the warning at approval, so the year association cannot establish historical improvement.

Table 4. Secondary company-clustered logistic models in label-identified cohorts

Country and predictor	Odds ratio	95% CI	*p* value
Japan: notification year	0.93	0.82–1.06	0.271
Japan: ln(ingredient count + 1)	33.30	7.48–148.23	<0.001
Japan: clinical-trial evidence	0.70	0.04–11.96	0.806
Japan: reported PRISMA use	0.74	0.35–1.56	0.425
Korea: product-approval year	1.24	1.18–1.29	<0.001
Korea: ln(ingredient count + 1)	0.50	0.37–0.68	<0.001
Korea: multiple recognition codes	0.54	0.34–0.87	0.012

The Korean fungal/algal result did not extend across the class. Complete coverage was observed for 135 of 203 products (66.5%), while all 68 incomplete products belonged to two recognition codes: 2010-35 (HK shiitake mycelium, 84/124 complete) and 2015-6 (Ecklonia cava extract, 7/35 complete). What appears at class level is therefore the mixture of products attached to those codes in this registry snapshot, not a fungal or algal mechanism.

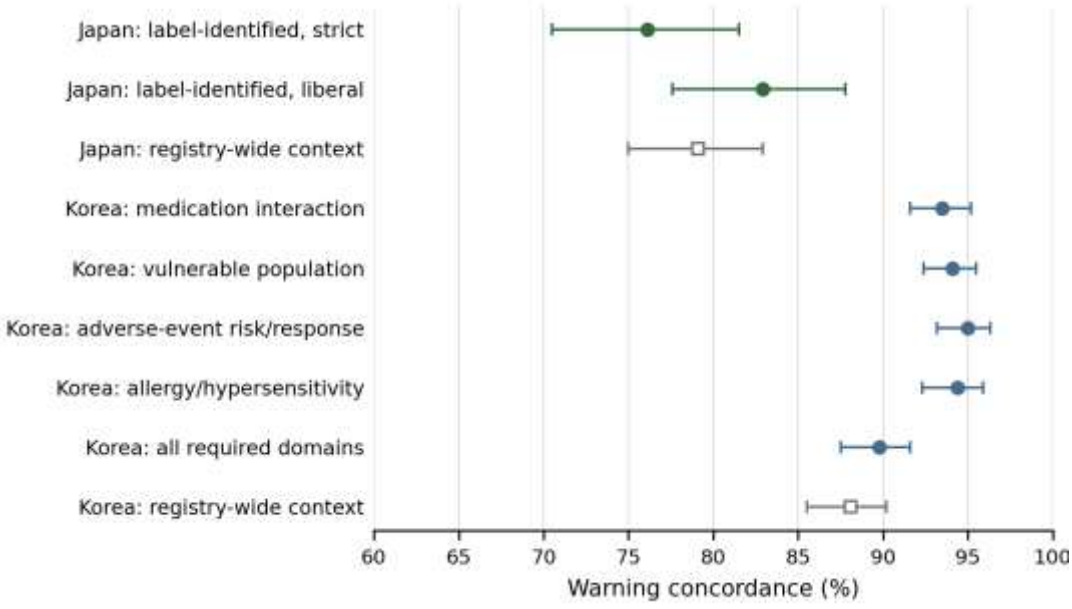

Figure 2. Company-cluster bootstrap intervals for primary and registry-wide concordance estimates

Note. Filled circles indicate label-identified cohort estimates; open squares indicate registry-wide context; intervals are company-cluster bootstrap intervals.

3.4 Comparative interpretation and implications

Japan's two strict estimates show what follows from defining the antecedent before counting an omission. Medication wording appeared in 65.6% of label-identified notifications carrying an interaction indicator, and in 76.1% of those retained by the assessment-text screen; liberal screened coverage was 82.9%, and the registry-wide strict estimate 79.1%. The 10.5-percentage-point difference is attributable to the denominator definition. It does not prove that every detected assessment warning cue was medication-specific.

Korea begins one step later, with caution domains fixed by exactly linked recognition codes. Every applicable domain appeared in 89.8% of label-identified products and in 88.1% registry-wide. Both systems evidently lose some information, and the two estimates can be read side by side to that extent. The antecedents are not commensurate, however, so no national ranking can be built from them.

That transition-level perspective fills a gap between three established lines of work. Evidence-quality studies test the support for functional claims [15,16,17,18]. Research on labeling and consumer response addresses notice, inference, and choice [2,11,12,13,14]. Regulatory analyses weigh market access, innovation, and risk [1,19,20,21,23,24,25]. What the present estimates add is a distinct step: whether safety content applicable upstream remains represented in the downstream registry warning. Evidence quality, field-to-field representation, and consumer comprehension call for different evidence and different interventions, and registry concordance makes the middle one measurable at record level.

A missed expression lowers estimated coverage, whereas a permissive match raises it. The failed-template review addressed the former and the positive-match audit the latter. A discordant record still requires inspection: assessment and warning fields may reflect different dates, and an earlier context may no longer be present in the current record. Manufacturing controls and documented composition-label differences provide further reasons to examine the stored antecedent, warning, and linkage before interpreting an individual case [29,30].

The biological-source restriction did not create the aggregate result; registry-wide estimates were close to those obtained for label-identified records in both countries. It defines the population in the research question without assigning an origin that the label does not state. The low Korean fungal/algal estimate is also highly concentrated: every incomplete product in that category was linked to recognition code 2010-35 or 2015-6. Review should therefore begin with the product, its code, and the missing domain rather than with the biological class. Japanese non-plant estimates require similar caution because their denominators are small.

Several questions cannot be answered from these snapshots. They contain neither a history of each warning nor every marketed package, and they do not show whether consumers noticed the text or whether a discordance affected health. Those questions require longitudinal label archives, package evidence, user studies [11,12,13,14], or exposure-linked clinical data. The classification has a separate boundary: labels without explicit source wording remain source-unresolved/other, the warning rules lack an exhaustive external positive set, and the sole-author audit supplies no inter-rater estimate. Independent recoding would be needed to estimate reviewer agreement. The present results are consequently limited to the prespecified domains in exactly linked registry records.

4. CONCLUSION

Antecedent screening changes the Japanese result. Strict coverage is 65.6% when all 616 interaction-indicator notifications form the denominator and 76.1% among the 310 assessment-screen-positive records. In Korea, 89.8% of eligible label-identified products represent every caution domain supplied by the linked official ingredient record. The two percentages describe different points in different registry systems and are not a national ranking. Their similarity to the corresponding registry-wide estimates also shows that the label-based source restriction is not driving the aggregate pattern.

The records left by the analysis are specific enough for follow-up. In Japan they are screen-positive notifications without medication wording. In Korea they are product-code pairs with an unrepresented domain, especially those involving codes 2010-35 and 2015-6 or several linked codes. The retained antecedent, warning, and linkage permit bilingual review of those cases. They do not establish noncompliance, recover past package text, measure comprehension, or estimate a clinical effect.

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AUTHOR CONTRIBUTIONS

Soyoung Choi: Conceptualization, Data Curation, Formal Analysis, Methodology, Software, Validation, Visualization, Writing—Original Draft, Writing—Review & Editing.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

ETHICS STATEMENT

The study analyzed publicly available administrative records and involved no human participants or identifiable personal data; institutional ethics approval was not required.

DATA AVAILABILITY STATEMENT

This study used publicly available registry records. Japanese Foods with Function Claims records were obtained from the Consumer Affairs Agency, Government of Japan, through the Foods with Function Claims Notification Information Search (accessed 19 August 2026).

Korean health functional food product–ingredient records and individually recognized functional-ingredient records were obtained from the Ministry of Food and Drug Safety, Food Safety Korea OpenAPI service C003 and the individually recognized

health functional food information service, respectively (accessed 19 August 2026). Access to the full Korean records requires a Food Safety Korea access key.

REFERENCES

[1] Intrasook, J., Tsusaka, T.W., Anal, A.K., 2024. Trends and current food safety regulations and policies for functional foods and beverages containing botanicals. *Journal of Food and Drug Analysis 32*(2), 118–145. https://doi.org/10.38212/2224-6614.3499

[2] Chiba, T., Tanemura, N., 2022. Differences in the perception of dietary supplements between dietary supplement/medicine users and non-users. *Nutrients 14*(19), 4114. https://doi.org/10.3390/nu14194114

[3] Bushra, R., Aslam, N., Khan, A.Y., 2011. Food-drug interactions. *Oman Medical Journal 26*(2), 77–83. https://doi.org/10.5001/omj.2011.21

[4] Izzo, A.A., Ernst, E., 2009. Interactions between herbal medicines and prescribed drugs: an updated systematic review. *Drugs 69*(13), 1777–1798. https://doi.org/10.2165/11317010-000000000-00000

[5] Zhang, Y., Ip, C.M., Lai, Y.S., Zuo, Z., 2022. Overview of current herb-drug interaction databases. *Drug Metabolism and Disposition 50*(1), 86–94. https://doi.org/10.1124/dmd.121.000420

[6] Cheng, W., Xia, K., Wu, S., Li, Y., 2023. Herb-drug interactions and their impact on pharmacokinetics: an update. *Current Drug Metabolism 24*(1), 28–69. https://doi.org/10.2174/1389200224666230116113240

[7] Kobayashi, E., Nishijima, C., Sato, Y., Chiba, T., 2019. Evaluation of safety information of the Foods with Function Claims based on adverse event reports in Information System on Safety and Effectiveness for Health Foods Database. *Food Hygiene and Safety Science (Shokuhin Eiseigaku Zasshi) 60*(4), 119–125. https://doi.org/10.3358/shokueishi.60.119

[8] Mori, M., Shimauchi, A., Yajima, S., Nishio, H., Tamaki, H., Sakai, C., Osanai, A., Ino, Y., Teramachi, H., Nakamura, M., Iguchi, K., 2020. Survey of label information of Foods with Function Claims. *Yakugaku Zasshi 140*(3), 443–448. https://doi.org/10.1248/yakushi.19-00156

[9] Chiba, T., Tousen, Y., Nishijima, C., Umegaki, K., 2022. The prevalence of dietary supplements that claim estrogen-like effects in Japanese women. *Nutrients 14*(21), 4509. https://doi.org/10.3390/nu14214509

[10] Park, S.-J., Yang, S.-B., 2019. A study on improvement of labeling on the caution for intake for health functional food. *The Korean Journal of Food and Nutrition 32*(3), 202–207. https://doi.org/10.9799/ksfan.2019.32.3.202

[11] Tanemura, N., Hamadate, N., 2022. Association between consumers' food selection and differences in food labeling regarding efficacy health information: food selection based on differences in labeling. *Food Control 131*, 108413. https://doi.org/10.1016/j.foodcont.2021.108413

[12] Assadourian, J.N., Peterson, E.D., Navar, A.M., 2025. Label statements and perceived health benefits of dietary supplements. *JAMA Network Open 8*(9), e2533118. https://doi.org/10.1001/jamanetworkopen.2025.33118

[13] Imatoku, N., Hangui, S.-i., 2025. Functional claims and consumer choice in Japan: exploring the role of packaging and regulatory focus. *British Food Journal 127*(12), 4267–4283. https://doi.org/10.1108/BFJ-04-2025-0392

[14] Yamamoto, M., Yamamoto, K., Takano-Ohmuro, H., Yamamoto, R., Saruwatari, J., 2025. Usability evaluation of Foods with Function Claims labelling as health information in Japan: a user-testing study. *Nutrition and Dietary Supplements 17*, 1–18. https://doi.org/10.2147/NDS.S494876

[15] Kamioka, H., Tsutani, K., Origasa, H., Yoshizaki, T., Kitayuguchi, J., Shimada, M., Wada, Y., Takano-Ohmuro, H., 2019. Quality of systematic reviews of the Foods with Function Claims in Japan: comparative before- and after-evaluation of verification reports by the Consumer Affairs Agency. *Nutrients 11*(7), 1583. https://doi.org/10.3390/nu11071583

[16] Kamioka, H., Origasa, H., Tsutani, K., Kitayuguchi, J., Yoshizaki, T., Shimada, M., Wada, Y., Takano-Ohmuro, H., 2023. A cross-sectional study based on forty systematic reviews of Foods with Function Claims (FFC) in Japan: quality assessment using AMSTAR 2. *Nutrients 15*(9), 2047. https://doi.org/10.3390/nu15092047

[17] Kamioka, H., Kitayuguchi, J., Origasa, H., Tsutani, K., 2024. Research quality of clinical trials reported for Foods with Function Claims in Japan, 2023–2024: evaluation based on a revised tool to assess risk of bias in randomized trials. *Nutrients 16*(16), 2744. https://doi.org/10.3390/nu16162744

[18] Matsumoto, C., Tomiyama, H., Takahashi, O., Maruhashi, T., Matsuzawa, Y., Masaki, N., Muraki, I., Yano, Y., Sugimoto, T., Kabutoya, T., Sawami, K., Tanaka, A., Arima, H., Sata, M., Node, K., 2024. An evidence review project for food with function claims ~Challenges of the Japan society for vascular failure for the promotion of adequate evidences for food with function claims. *Hypertension Research 47*(2), 533–536. https://doi.org/10.1038/s41440-023-01485-7

[19] Sato, K., Kodama, K., Sengoku, S., 2025. The co-evolution of markets and regulation in the Japanese functional food industry: balancing risk and benefit. *Foods 14*(9), 1581. https://doi.org/10.3390/foods14091581

[20] Sato, K., Kodama, K., Sengoku, S., 2023. Optimizing the relationship between regulation and innovation in dietary supplements: a case study of Food with Function Claims in Japan. *Nutrients 15*(2), 476. https://doi.org/10.3390/nu15020476

[21] Nakamura, F., Morisada, M., Dahana, W.D., Katsumata, S., 2026. Consequences of dual certification regulation: the case of Japanese functional food market. *British Food Journal 128*(4), 1376–1392. https://doi.org/10.1108/BFJ-06-2025-0817

[22] Kang, P., Kim, S.Y., Shi, J., Choi, Y.H., Chin, Y.W., 2026. Individually recognized functional ingredients of Korean health functional foods: functional classification, regulatory context, and clinical implication. *Nutrients 18*(4), 637. https://doi.org/10.3390/nu18040637

[23] Heo, S.H., 2024. Solutions to the issues raised from Korea's food with functional claims system. *Food Supplements and Biomaterials for Health 4*(3), e15. https://doi.org/10.52361/fsbh.2024.4.e15

[24] Bailey, R.L., 2020. Current regulatory guidelines and resources to support research of dietary supplements in the United States. *Critical Reviews in Food Science and Nutrition 60*(2), 298–309. https://doi.org/10.1080/10408398.2018.1524364

[25] Shan, F., Liu, L., Li, L., Wang, W., Bi, Y., Li, M., 2025. Management, safety, and efficacy evaluation of nutraceutical and functional food: a global perspective. *Comprehensive Reviews in Food Science and Food Safety 24*(4), e70222. https://doi.org/10.1111/1541-4337.70222

[26] Consumer Affairs Agency, Government of Japan, 2026. Kinōsei hyōji shokuhin no todokede jōhō kensaku [Foods with Function Claims Notification Information Search]. https://www.caa.go.jp/policies/policy/food_labeling/foods_with_function_claims/search. Date accessed: 19 August 2026.

[27] Ministry of Food and Drug Safety, Republic of Korea, n.d. Food Safety Korea OpenAPI services: Geongang gineungsikpum pummok jejo singo (wonjaeryo) [Health functional food product manufacturing reports—ingredients] (service C003) and Geongang gineungsikpum gaebyeol injeonghyeong jeongbo [Individually recognized health functional food information] (service I-0050). https://www.foodsafetykorea.go.kr/api/openApiInfo.do?menu_grp=MENU_GRP31&menu_no=661&show_cnt=10&start_idx=1&svc_no=C003; https://www.foodsafetykorea.go.kr/api/openApiInfo.do?menu_grp=MENU_GRP31&menu_no=661&show_cnt=10&start_idx=1&svc_no=I-0050&svc_type_cd=API_TYPE06. Date accessed: 19 August 2026.

[28] Monagas, M., Brendler, T., Brinckmann, J., Dentali, S., Gafner, S., Giancaspro, G., Johnson, H., Kababick, J., Ma, C., Oketch-Rabah, H., Pais, P., Sarma, N., Marles, R., 2022. Understanding plant to extract ratios in botanical extracts. *Frontiers in Pharmacology 13*, 981978. https://doi.org/10.3389/fphar.2022.981978

[29] Sirois, J., Reddy, S., Nguyen, T., Walker, H., Rendall, J., Bergen, G., Reimers, M., Cermak, E., Tiwary, A., Helmes, E., Palmer, J., Teo, S., Mackle, T., Park, M., Wang, C., 2024. Safety considerations for dietary supplement manufacturers in the United States. *Regulatory Toxicology and Pharmacology 147*, 105544. https://doi.org/10.1016/j.yrtph.2023.105544

[30] Cohen, P.A., Avula, B., Katragunta, K., Khan, I., 2022. Levodopa content of *Mucuna pruriens* supplements in the NIH Dietary Supplement Label Database. *JAMA Neurology 79*(10), 1085–1086. https://doi.org/10.1001/jamaneurol.2022.2184