Atsumi & Sakai Newsletter
JAPAN
NEW YORK
LONDON
FRANKFURT
BRUSSELS
HO CHI MINH

September 2026
No. LFS_008

Importing and Selling Health Foods in Japan: Practical Regulatory Considerations [Part II]

- Regulations Governing Advertising and Package Labeling • The Foods with Function Claims System

Introduction: Recap of Part I

In Part I (Article No. LFS_007) of this series, we used the fictitious case of Company D, a Singaporean health food manufacturer considering the Japanese launch of its flagship product "Vita Blossom" (a capsule supplement containing polyphenols derived from the fictitious "Luna Berry" plant), to address food-drug classification, import procedures under the Food Sanitation Act, the system for foods containing designated ingredients, etc., and the GMP applicable to certain foods in tablet, capsule and similar forms.

Part II analyses the two remaining measures taken by E, the employee in charge, being Measure ②, in which E sought to use the local package's efficacy claims by simply translating them, and Measure ③, in which E sought to call the product a "Food with Function Claims" without filing a notification with the Consumer Affairs Agency. We will use these measures to explain in detail the regulations governing the advertising and package labeling of health foods and the Foods with Function Claims system.

Scenario Recap | Company D: Launching "Vita Blossom" in Japan

Company D (Singaporean company) planned the Japanese launch of "Vita Blossom," a capsule supplement containing a functional ingredient (polyphenols derived from the fictitious "Luna Berry" plant). E, the employee in charge, was proceeding with the following measures (of which Measures ① and ④ were explained in Part I).

Figure: Image of the "Vita Blossom" product (fictitious) - capsules containing Luna Berry-derived polyphenols

(1) Measure ①: E planned to order samples from the local factory in Singapore by international mail addressed to an individual in Japan and, if no problems arose, use the same route for full-scale commercial imports.

(2) Measure ②: E planned to translate the efficacy claims on the "Vita Blossom" packaging - "supports immunity and accelerates recovery from fatigue" - directly into Japanese and affix the translation to the container.

(3) Measure ③: Believing that function claims would increase sales, E planned to use the Foods with Function Claims label for the product based on its sales record in Singapore, without filing the required notification with the Consumer Affairs Agency.

(4) Measure ④: E assumed that it was not necessary to carry out procedures relating to Japan's GMP requirements for the capsule manufacturing process because the Singapore factory followed its own quality standards.

1. Overview of Advertising and Labeling Regulation for Health Foods

As with the cosmetics addressed in Article No. LFS_006, multiple laws apply to the advertising and package labeling of health foods in an overlapping manner. The principal applicable laws are: (1) the PMD Act[1] (regulation of claims of drug-like efficacy and effects); (2) Article 65 of the Health Promotion Act[2] (prohibition of false or exaggerated representations regarding effects of maintaining or promoting health, etc.); (3) the Act against Unjustifiable Premiums and Misleading Representations (the "Premiums and Representations Act")[3] (prohibition of misleading representations as to superiority and as to advantageousness, and stealth marketing regulation); and (4) the Food Labeling Act[4] (mandatory and

[1] The formal name is The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) (the "PMD Act").
[2] Health Promotion Act (Act No. 103 of 2002).
[3] The formal name is The Act against Unjustifiable Premiums and Misleading Representations (Act No. 134 of 1962).
[4] Food Labeling Act (Act No. 70 of 2013).

prohibited labeling under the Food Labeling Standards). These do not apply on a mutually exclusive basis; a single representation may violate several laws at the same time.

Key Point | The Respective Roles of the Four Laws

Under the PMD Act, even a product sold as a food may be found to constitute a drug where, among other things, the product makes claims of drug-like efficacy and effects. If the product has not been approved, advertising its name, efficacy, effects, etc. is prohibited under Article 68 of the PMD Act and may be subject to criminal penalties. In addition, where the content of the representation is assessed as false or exaggerated, meaning it also violates Article 66(1) of the PMD Act, a surcharge payment order may also be imposed.[5] The Health Promotion Act and the Premiums and Representations Act regulate "markedly false or exaggerated representations" and "representations that create the misperception that a product is superior to what it actually is" regarding the effects of foods, whether or not those effects are drug-like. As with the PMD Act, the Premiums and Representations Act also provides for criminal penalties and administrative dispositions against violations, and where a party is assessed as having made a misleading representation as to superiority, it may be subject to a surcharge payment order. The Food Labeling Act, in addition to basic labeling items such as nutrition labeling and additive labeling, prohibits representations that violate the notified content of Foods with Function Claims and similar. It should be noted that the very same expression "boosts immunity" may -where such a representation means the product is to be found to constitute a drug and the product is unapproved - violate the PMD Act, while at the same time potentially constituting a false or exaggerated representation under the Health Promotion Act or a misleading representation as to superiority under the Premiums and Representations Act.[6]

2. The Problem with Measure ②: A Merely Translated Efficacy Claim Runs A foul of Multiple Regulations

E's Measure ②, directly translating the efficacy claims on the local packaging ("supports immunity and accelerates recovery from fatigue") into Japanese and affixing them to the container, presents serious problems for the company.

First, expressions such as "boosts immunity" and "relieves fatigue" are highly likely to fall within claims of drug-like efficacy and effects within the meaning of the so-called "1971 Notice".[7] Claims of efficacy and effects aimed at the general enhancement or promotion of the structures and functions of the body may amount to drug-like efficacy and effects under the 1971 Notice, even if they do not directly assert the treatment or prevention of disease. Even a product sold as a food may be found to constitute a drug under the PMD Act as a result of making such efficacy claims. If the product has not been approved,

[5] A surcharge payment order under the PMD Act (Article 75-5-2) targets acts that violate Article 66(1) (prohibition of false or exaggerated advertising, etc.); it does not directly target a violation of Article 68 (prohibition of advertising unapproved drugs, etc.) as such. That said, where drug-like efficacy claims for an unapproved product are assessed as false or exaggerated and thus also violate Article 66(1), a surcharge payment order may be imposed. A measures order (Article 72-5) covers violations of both Article 66(1) and Article 68.

[6] The PMD Act also contains an adjustment provision pursuant to which, where a surcharge payment order under the Premiums and Representations Act has been issued for the same matter, an amount equal to 3% of sales (the surcharge calculation rate under that Act) is deducted (Article 75-5-3 of the PMD Act).

7 Notice of the Director-General of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, dated June 1, 1971, entitled "Guidance and Enforcement Concerning Unapproved and Unlicensed Drugs".

advertising its efficacy, effects, etc. may violate Article 68 of the PMD Act. This reflects the same reasoning as the lip-balm example addressed in Article No. LFS_006.

(1) "Effects of Maintaining or Promoting Health, etc." under the Health Promotion Act

Article 65(1) of the Health Promotion Act provides that no person may, in advertising or other representations concerning items sold as food, make representations regarding effects of maintaining or promoting health, etc. that are markedly contrary to fact or that markedly mislead people. According to the Consumer Affairs Agency's "Points to Note under the Act against Unjustifiable Premiums and Misleading Representations and the Health Promotion Act concerning Health Foods" (the "Points to Note"), among the "effects of maintaining or promoting health, etc.," the "effects of maintaining or promoting health" are organized into the following four types:[8]

a) Effects of treating or preventing disease: effects aimed at the treatment or prevention of a specific disease, such as "cures diabetes" or "effective against hay fever" (these may be claimed only by approved drugs).
b) Effects of general enhancement or promotion of the structures and functions of the body: general health-maintenance and promotion effects not amounting to disease treatment, such as "relieves fatigue," "boosts immunity," or "anti-aging" (these may be claimed only by approved drugs).
c) Effects suitable for a specified health use: effects for which a specified health purpose can be expected, such as "helps regulate the condition of your stomach and intestines" (these may not be claimed without approval as a Food for Specified Health Uses ("Tokuho")[9] or a Foods with Function Claims notification).
d) Effects of nutrient components: physiological functions, etc. of nutrient components (labeling that does not conform to the standards for Foods with Nutrient Function Claims may be subject to regulation).

The Points to Note cites "relieves fatigue," "improves immune function," "boosts immunity," and similar as examples of effects of general enhancement or promotion of the structures and functions of the body. The expression actually used in the scenario, "supports immunity," is not itself one of the examples in that document. However, where the representation as a whole gives the impression of enhancing immune function, it may become problematic as an "implied efficacy representation," which is further discussed below. That said, Article 65(1) of the Health Promotion Act does not uniformly prohibit these expressions. Rather, it prohibits representations regarding effects of maintaining or promoting health, etc. that are markedly contrary to fact or that markedly mislead people. On the other hand, because "relieves fatigue" and "boosts immunity" also fall within drug-like efficacy and effects under the 1971 Notice, claiming them for a capsule-form food such as the one here may result in the product being found to constitute a drug under the PMD Act. If the product is unapproved, its advertising may be problematic

[8] Consumer Affairs Agency, "Points to Note under the Act against Unjustifiable Premiums and Misleading Representations and the Health Promotion Act concerning Health Foods" (revised December 5, 2022). Note that Article 65(1) of the Health Promotion Act governs foods in general that are sold with representations of effects of maintaining or promoting health, etc. This not only covers foods in tablet or capsule form, but also foods that are clearly recognized as ordinary foods from their appearance, form, etc., such as vegetables and fruits.

[9] "Foods with Health Claims" is the umbrella term used in the Food Labeling Standards for the three categories of foods that may bear function claims in Japan: (i) Foods for Specified Health Uses, commonly known in Japan as "Tokuho," for which the Secretary-General of the Consumer Affairs Agency grants individual approval under the Health Promotion Act following a case-by-case examination of the scientific evidence for the claimed health effect; (ii) Foods with Function Claims, which may be sold after a notification is filed with the Consumer Affairs Agency and are not individually examined by the government (discussed in Section 4 below); and (iii) Foods with Nutrient Function Claims, for which the business operator itself confirms conformity with the requirements set out in the Food Labeling Standards (a self-certification system requiring no individual approval or notification).

under Article 68 of the PMD Act regardless of whether the representation is false or exaggerated. Moreover, even for Foods with Health Claims (Foods for Specified Health Uses, Foods with Function Claims and Foods with Nutrient Function Claims), these expressions may not be used beyond the scope permitted by the respective approval, notification, or the Food Labeling Standards.

(2) Implied and Indirect Expressions Are Also Subject to Regulation

The Points to Note particularly emphasize that, even without a direct statement of effects, where general consumers perceive that there are effects of maintaining or promoting health, etc. through implied or indirect expressions, such expressions are likewise subject to regulation.[10] For example, even if the product name or catchphrase alone does not directly claim such an effect, where the combination of ingredient explanations, testimonials, illustrations, photographs, and other similar features gives the overall impression that "fatigue is relieved," then it may be subject to regulation. In this current case of "Vita Blossom", it would be necessary to check not only the translated function labeling, but also the overall package design, the enclosed leaflet, the product descriptions on e-commerce sites, and the like and confirm whether they amount to an implied efficacy appeal.

(3) The Limits of Disclaimers and Testimonials

It is often mistakenly believed that attaching disclaimers such as "results may vary from person to person" or "this is an individual's personal impression" exempts a strong efficacy appeal from liability. In Japan this understanding is incorrect. The Consumer Affairs Agency has published enforcement examples holding that, where an advertisement as a whole claims a strong effect, attaching a disclaimer to such claim does not negate the understanding of the effect that general consumers derive from the advertisement as a whole.[11] Similarly, representations using testimonials or before-and-after images may raise problems under the Health Promotion Act and the Premiums and Representations Act where they are received by general consumers as testimonials that themselves guarantee an effect.

Health Food Claims: Examples of Unacceptable (NG) and Acceptable (OK) Expressions

The following are examples of expressions that frequently become problematic in the advertising and package labeling of health foods. Because the determination of whether a given expression is acceptable is determined individually and specifically from the representation as a whole, these should be treated as a rough guide only:

Context / Setting	✕ Unacceptable (No Go)	○ Acceptable (OK)
Fatigue / physical stamina	"Relieves fatigue"; "Just take it and you'll feel energized"	"For maintaining everyday health"; "Supports an energetic daily life"
Immunity / physical condition	"Boosts immunity"; "Makes you less likely to catch a cold"	"For those mindful of managing their physical condition" (for Foods with Function Claims, to be considered separately within the scope of the notified claims)

[10] Points to Note, Part 4. Examples of implied expressions given include cases that imply effects of maintaining or promoting health, etc. by combining nutrient components, testimonials, and the like, and cases that suggest efficacy by citing newspaper articles, scholars' remarks, testimonials, and similar.

[11] See, for example, Consumer Affairs Agency, "Measures Order against Howay Co., Ltd. under the Act against Unjustifiable Premiums and Misleading Representations" (June 3, 2021). Even where a disclaimer is present, the propriety of a representation is judged on the basis of the impression and understanding that the advertisement as a whole conveys to general consumers.

Context / Setting	✕ Unacceptable (No Go)	○ Acceptable (OK)
Dieting / weight loss	"Just take it and lose weight"; "Burns off fat"	"As part of a well-balanced diet"
Aging	"Prevents aging"; "Rejuvenates the skin"	"For a daily life mindful of youthfulness"
Testimonials	Testimonials or before-and-after images that appear to guarantee efficacy	Frank impressions of the product experience (taste, aroma, ease of consumption, etc.) (expressions not taken as guaranteeing efficacy)

3. Stealth Marketing Regulation: Considerations When Using Influencers

In promoting health foods, providing products to influencers free of charge and requesting posts on social media is also a commonly used method. Depending on the specific circumstances (such as the purpose of the free provision, communications with the influencer, involvement in the content of the posts and the transactional relationship) such posts may be found to be "representations by the business operator" in which the operator was involved in deciding the content of the representation. In that case, as briefly touched on in Article No. LFS_006, a representation that makes it difficult for general consumers to discern that it is an advertisement is subject to the Stealth Marketing Notification that took effect in October 2023 (a notification issued under Article 5(iii) of the Premiums and Representations Act).[12]

To highlight a recent enforcement example: in March 2025, Rohto Pharmaceutical Co., Ltd. received a measures order under the Stealth Marketing Notification (Article 5(iii) of the Premiums and Representations Act) with respect to representations concerning its Foods with Function Claims supplement "Rohto V5 Act Vision a". In that case, the company provided products free of charge through a monitor-recruitment website, requested Instagram posts in line with the policy it directed, and then extracted the image portions of those posts and published them on its own website. The problem identified by the Consumer Affairs Agency was that it had not been indicated in a manner that allowed general consumers to understand that those representations were made at the company's request.[13] In the case of health foods, there are many instances where influencers or monitors disseminate efficacy-oriented comments such as "I took it and my condition improved", so attention must also be paid to the risk that a violation of the stealth marketing regulation coexists with false or exaggerated representations under the Health Promotion Act and misleading representations as to superiority under the Premiums and Representations Act.

> **Key Point | Efficacy Claims Lacking Scientific Substantiation May Be Subject to a Measures Order and Surcharges**

[12] "Representations that make it difficult for general consumers to discern that they are representations by a business operator" (Cabinet Office Notification No. 19 of 2023). The designation notification and the operational standards (determined by the Secretary-General of the Consumer Affairs Agency) were published on March 28, 2023, and took effect on October 1, 2023.

[13] Consumer Affairs Agency, "Measures Order against Rohto Pharmaceutical Co., Ltd., under the Act against Unjustifiable Premiums and Misleading Representations" (March 25, 2025). The company provided products free of charge to monitors and requested Instagram posts in line with the policy it directed, then extracted the image portions of those posts and published them on its own website; because it did not make clear that those representations were made at the company's request, general consumers were left in a state where it was difficult to discern that they were representations by the business operator.

In June 2023, a measures order was issued under the Premiums and Representations Act against supplements supplied by Sakura Forest Co., Ltd. — "Kinari Takumi" and "Kinari Kiwami" — on the ground that they had been labeled as if effects such as lowering triglycerides and blood pressure could be obtained through the operation of their respective ingredients.[14] Labeling of Foods with Function Claims should be carried out by the business operator under its own responsibility, and must be based on objectively substantiated grounds and kept within the scope of the notified function. This case demonstrated that, even for a product that has been notified, not only advertising representations that deviate from the scope of the notified function, but also the notified claims regarding the function themselves, may constitute misleading representations as to superiority where they lack reasonable scientific grounds to substantiate them. This case can be said to illustrate, for products for which a new notification is being considered, such as "Vita Blossom", the need to carefully verify, at the time of notification, both the scientific grounds substantiating the content stated on the labeling, as well as the consistency between the notified claims and the actual advertising representations.

4. The Problem with Measure ③: A Product Cannot Call Itself a "Food with Function Claims" Without Filing a Notification

E's Measure ③ involves attempting to use the "Foods with Function Claims" label without filing a notification with the Consumer Affairs Agency. This rests on a fundamental misunderstanding of the Foods with Function Claims system. Carrying out this measure (labeling and selling an un-notified product as a "Food with Function Claims") would violate the Food Labeling Standards.

The Foods with Function Claims system is one under which a business operator may, for the first time, use the "Foods with Function Claims" label and make function claims only after filing, prior to sale and pursuant to the Food Labeling Act, a notification with the Secretary-General of the Consumer Affairs Agency of scientific grounds concerning the safety and functionality of the food and other necessary matters (Article 2(1)(x), etc. of the Food Labeling Standards). Unlike Tokuho (as explained in Section 2(1) above), there is no individual examination by the Japanese Government for this. However, selling a product that has not been notified while labeling it as a "Food with Function Claims" may, as the sale of a food that violates the Food Labeling Standards, be subject to instructions and orders under Article 6 of the Food Labeling Act.[15] Furthermore, labeling a product as if it were a Food with Function Claims when it does not have the substance of one may also fall within misleading representations as to superiority under the Premiums and Representations Act (Article 5(i) of that Act) (representations suggesting that the Consumer Affairs Agency has certified the functionality are likewise regarded as problematic).

[14] See, for example, Consumer Affairs Agency, "Measures Order against Sakura Forest Co., Ltd. under the Act against Unjustifiable Premiums and Misleading Representations" (June 30, 2023). In that Order, because the materials submitted for the representations actually made were not found to demonstrate reasonable grounds substantiating those representations, they were found to be misleading representations as to superiority. In addition to the advertising content, the notified claims for the Foods with Function Claims stated on the product packaging themselves were also found to be misleading representations as to superiority. The company subsequently received a surcharge payment order for the same representations dated March 19, 2025 (surcharges totaling ¥109.03 million).

[15] The Food Labeling Standards are established under Article 4 of the Food Labeling Act, and Article 5 of that Act prohibits the sale of foods not labeled in accordance with the Food Labeling Standards. Selling a processed food to general consumers, that has not been notified, while labeling it as a "Food with Function Claims" is considered to violate Article 9(1)(x) of the Food Labeling Standards, which prohibits, for foods other than Foods with Health Claims, names and other features that are confusingly similar to those of Foods with Health Claims.

Even if there is a sales record overseas or local evidence, that does not permit the notification in Japan to be omitted. To sell a product as a Food with Function Claims, the following steps are required:

- Establish scientific grounds for the functionality through clinical (human) trials, using a final product that satisfies the prescribed requirements, a systematic review of the final product or a systematic review of the functional ingredient;
- Conduct a safety assessment (evaluation of the history of dietary consumption, safety tests, evaluation of interactions between the functional ingredient and drugs, etc.);
- File a new notification — through the Consumer Affairs Agency's notification database — of the notifying business's information, the supporting documentation for safety and functionality, sample labeling, and other necessary information (new notifications on or after April 1, 2025 use the new format (the format prescribed by Cabinet Office Notification));[16]
- In addition, after notification, maintain on an ongoing basis the internal systems required of a notifying business, including a system for collecting and reporting information on adverse health effects and for carrying out annual self-inspection and reporting to the Consumer Affairs Agency.

Key Point | Considerations Specific to Products Manufactured Overseas

Even where the raw materials or the final product are manufactured overseas (as is the case with the Singapore factory in our scenario), the requirements concerning scientific substantiation and safety assessment for Foods with Function Claims apply in the same way as for domestically manufactured products. In addition, where the food falls within the category of "foods in tablet, capsule and similar forms that use natural extracts, etc. as raw materials," the notifying business must, under its own responsibility, ensure - even for imported products that are manufactured overseas - that the product is manufactured or processed in accordance with the "Standards for the Manufacture or Processing of Foods in Tablet, Capsule and Similar Forms Made from Natural Extracts, etc. among Foods with Function Claims" (the "GMP Notification") which was introduced in Part I.[17] This scenario assumes that the Luna Berry-derived polyphenol raw materials fall within "natural extracts, etc.," whose component proportions differ from those in the natural state as a result of extraction, purification, concentration or equivalent procedures. As such, the mere fact that "the Singapore factory manufactures the product following its own standards" does not by itself prove that the Japanese notification requirements are satisfied. The notifying business (in many cases, the seller in Japan) bears responsibility for (1) verifying by itself the safety of the raw materials and the conformity of the manufacturing process; and (2) preparing the necessary documentation.

As explained in Section 2(1) above, Foods with Function Claims are one of the three categories of Foods with Health Claims, alongside Tokuho and Foods with Nutrient Function Claims. For every one of these categories, functions may be labeled only within the scope permitted by the respective system, and for

[16] The notification prescribing the method of notification, etc. determined by the Prime Minister by notification pursuant to the provisions of rows 1 through 6 of Appended Table 26 referenced in Article 2(1)(x)(a) of the Food Labeling Standards, etc. (Cabinet Office Notification No. 35 of March 25, 2025; effective April 1, 2025). This notification prescribes the new format used for notifications of Foods with Function Claims, etc.

[17] The Consumer Affairs Agency's "Summary of Comments and the Agency's Views Thereon regarding the Draft Partial Amendment to the Food Labeling Standards" (response to public comments) indicates, in response to a comment asking whether imported products are also subject to GMP compliance, that for imported products manufactured overseas as well, it the notifying business has responsibility to ensure that they are manufactured, etc. in accordance with the standards prescribed by notification. Transitional measures apply to this GMP requirement until August 31, 2026, and it becomes fully applicable from September 1, 2026.

foods that do not satisfy the applicable requirements, it is not permitted to represent that the function of a nutrient component or a specified health purpose can be expected.

Reference: Key Differences in Advertising and Labeling Regulation between Cosmetics and Health Foods

Issue	Cosmetics (Article No. LFS_006)	Health Foods (This Article issue)
Scope of permissible efficacy claims	In principle, within the scope of the 56 efficacy items set out in the relevant notice. In addition, makeup effects and usage sensations, etc. that are not contrary to fact may be stated (for quasi-drugs, within the approved scope).	Function claims for foods are, in principle, limited to Foods with Health Claims. Foods for Specified Health Uses: within the approved scope; Foods with Function Claims: within the notified scope (on the premise that the notified claims have scientific substantiation); Foods with Nutrient Function Claims: within the scope set out in the Food Labeling Standards.
Principal applicable laws	PMD Act; Premiums and Representations Act	PMD Act; Health Promotion Act; Premiums and Representations Act; Food Labeling Act
Stealth marketing	Subject to regulation under the Premiums and Representations Act (Notification)	Likewise subject to regulation (recent enforcement examples in the health food sector)
Treatment of implied expressions	Whether express or implied, false or exaggerated efficacy advertising and efficacy claims exceeding the permitted scope are subject to regulation (attention should also be paid to special ingredient-emphasis labeling)	Implied and indirect expressions are also subject to regulation under the Health Promotion Act

Conclusion

Across Parts I and II, using the story of the fictitious brand “Vita Blossom” and its launch in Japan as an entry point, we have surveyed the issues that specifically arise when a foreign company imports and sells health foods in Japan. Part I addressed food-drug classification, import procedures under the Food Sanitation Act, and safety management regulations such as the system for foods containing designated ingredients, etc. as well as the GMP relating to certain foods in tablet, capsule and similar forms. By contrast, Part II addressed regulations governing advertising and package labeling and the Foods with Function Claims system.

The regulation of advertising and labeling of health foods is a complex field in which the PMD Act, the Health Promotion Act, the Premiums and Representations Act, and the Food Labeling Act apply in an overlapping manner, and — even compared with cosmetics — there are many situations in which judgment is difficult (such as with the treatment of implied expressions and testimonials). It is important to avoid simply rendering labeling and advertising into Japanese where such labeling and advertising was created for overseas markets. Instead, care should be taken to design, from the ground up, labeling that conforms to Japanese regulations.

In future issues, we will continue to explore individual themes in depth. For cosmetics, we plan to cover the advertising regulation of cutting-edge beauty claims such as “aesthetic-medicine-grade” and “containing stem cell culture fluid / exosomes”, and the substantiation required for “No. 1,” physician-recommended, and word-of-mouth (review) claims. For health foods, we plan to cover considerations for

selling health foods through cross-border e-commerce, the status of deliberations on “supplement” regulation, and concrete criteria for judging advertising expressions for health foods.

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