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

- Food-Drug Classification and Import Procedures • Safety Management Regulations

Introduction: Starting with a Single Scenario

In our previous issue (No. LFS_006), we introduced the fictitious launch of a foreign cosmetics brand in Japan as a case study to survey and explain the overall framework for classifying foods and cosmetics and the regulations governing advertising. This issue focuses on the import of food, particularly health foods (including Foods with Health Claims). It aims to examine the regulatory requirements that specifically apply when a foreign company imports health foods manufactured overseas into Japan for sale.

Because importing and selling health foods raises a wide range of issues, we have covered the topic in two parts. Part I addresses (1) whether a product may be imported as a "food" in the first place (i.e., whether it is classified as a food or drug); (2) import procedures under the Food Sanitation Act (notification to a quarantine station and customs clearance); and (3) safety management regulations specific to foods in supplement form. Part II will discuss (1) regulations governing advertising and package labeling; and (2) labeling systems for making function claims, including the Foods with Function Claims system. We have developed the following fictitious scenario to provide an overview of the issues that arise.

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

Company D is a health food manufacturer headquartered in Singapore. Its flagship product, "Vita Blossom", is a capsule supplement containing a functional ingredient – polyphenols, which is derived from the fictitious "Luna Berry" plant. Marketed throughout Southeast Asia under the concept of "daily wellness support," it has become popular in Singapore and Malaysia.

In August 2026, Company D decided to enter the Japanese market. E, the employee in charge, assumed that foods would be subject to simpler regulations than cosmetics and began taking the following steps.

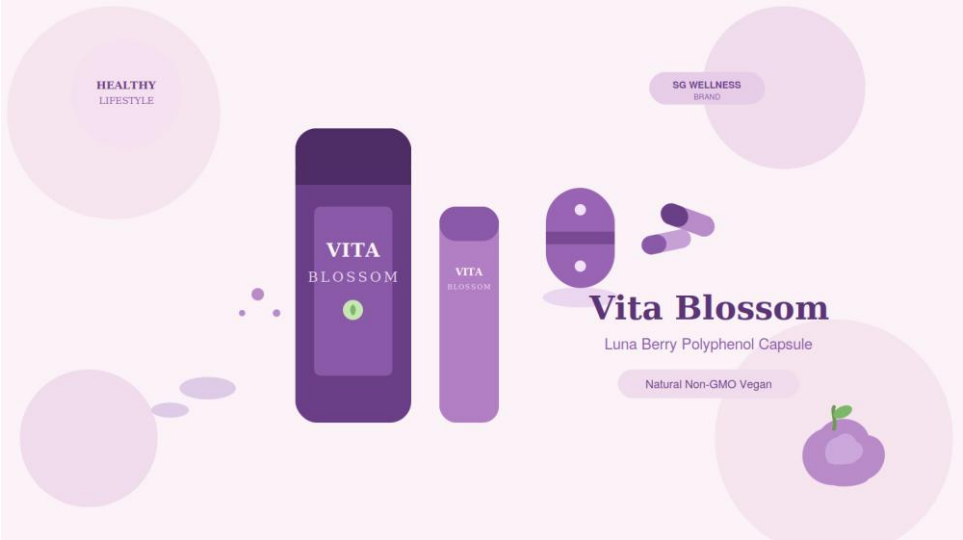

Figure: Image of the "Vita Blossom" product (fictitious) - capsules containing Luna Berry-derived polyphenols

E's Proposed Measures and the Potential Pitfalls

E planned to take the following four measures. Part I focuses on Measures ① and ④, while Part II will primarily address Measures ② and ③.

(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 (discussed in Part II).

(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 (discussed in Part II).

(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. Threshold Question: Can the Product Be Imported as a "Food"? (Food-Drug Classification)

Before examining E's proposed measures, the threshold question is whether "Vita Blossom" may be imported and sold as a food, or should instead be classified as a drug under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "PMD Act"). The criteria for determining whether a product presented as a food constitutes a drug are set out in a notice of the Director-General of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, entitled

"Guidance and Enforcement Concerning Unapproved and Unlicensed Drugs" issued in June 1971 (the "1971 Notice").[1]

The 1971 Notice provides that drug classification is determined through a comprehensive assessment of the nature of the ingredients (raw materials), product form, stated purpose of use, claimed efficacy and effects, dosage and administration, sales methods, and explanations given at the time of sale. If a product contains an ingredient used exclusively as a drug (including an ingredient included on the list of drug ingredients), it is, in principle, classified as a drug regardless of the other factors. Even where the product consists only of ingredients that do not fall into this category, it will generally be treated as a drug if any of the following applies: (1) it makes drug-like efficacy claims; (2) it has a form used exclusively for drugs, such as an ampoule; or (3) its dosage or administration is drug-like.[2]

For "Vita Blossom", the first step is to determine whether any of its raw materials, including its functional ingredient, are classified as drug ingredients. A considerable number of raw materials that are marketed overseas as food ingredients are treated as drug ingredients under Japan's food-drug classification, including certain herbs, crude drugs and certain vitamin derivatives. The starting point for assessing whether the product may be imported as a food is therefore to check each raw material against the ingredient (raw material) lists published by the Ministry of Health, Labour and Welfare ("MHLW").[3]

Key Point | Restrictions Based on Product Form Have Been Relaxed

Tablets, capsules and other drug-like "forms" were themselves once treated as a factor in determining whether a product constituted a drug. Today, however, reflecting the widespread consumption of foods in tablet and capsule form, a product clearly identified as a "food" will generally not be classified as a drug based on its form alone. This does not change the fact that a product remains subject to regulation if its ingredients, claimed efficacy or effects, or dosage and administration are drug-like. Instructions that specify when and how much to take with a particular disease in mind - for example, "take three tablets before meals until symptoms improve" - may be regarded as drug-like dosage and administration.

2. Problem with Measure ①: Failure to Follow Import Procedures under the Food Sanitation Act

Measure ① - ordering the samples through a personal-import route and then using the same route for full-scale commercial imports – this rests on a serious misunderstanding.

When food or related products are imported into Japan for sale or for use in business, Article 27 of the Food Sanitation Act requires the importer, prior to customs clearance, to submit a "Notification Form for Importation of Foods, etc." to the Quarantine Station (Food Inspection Division) that has jurisdiction

[1] Notice No. 476 of the Director-General of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, dated June 1, 1971, "Guidance and Enforcement Concerning Unapproved and Unlicensed Drugs" (addressed to prefectural governors). The attached "Standards for the Scope of Pharmaceuticals" sets out the specific criteria for food-drug classification.
[2] The detailed framework under the 1971 Notice - including the interpretation of drug-like efficacy claims and the treatment of implied claims - was discussed in part in our previous issue. Because determining whether a particular ingredient falls within the relevant categories requires specialist knowledge, it is recommend that this is checked and confirmed at an early stage of raw-material selection. Claims of efficacy and effects will be discussed in detail in Part II.
[3] Examples of the Treatment of Ingredients (Raw Materials) under the Food-Drug Classification" (Notice No. 0331-9 of March 31, 2020, issued by the Director of the Compliance and Narcotics Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW). Because the ingredient (raw material) lists provided as examples in the notice are amended from time to time, the latest version should be checked on the MHLW's website.

over the location of customs clearance.[4] The notification may be submitted up to seven days before the cargo arrives. Food sanitation inspectors at the quarantine station will review the country of production, manufacturer, raw materials, use of additives and other matters, and may conduct monitoring inspections, administrative inspections or ordered inspections as necessary. If the review confirms compliance with applicable specifications and standards, the quarantine station will issue a "Certificate of Notification of Importation of Foods, etc." The importer must submit the certificate to Customs for confirmation and cannot obtain import clearance until that confirmation has been completed.

Key Point | Personal Imports and Commercial Imports Are Governed by Different Rules

A notification for importation of foods, etc. is not required for imports recognized as being for personal use, testing, or research. However, a small import volume or the description "sample for internal evaluation" does not automatically eliminate the notification requirement. Whether samples used for exhibitions, tastings, sales activities or evaluating commercial potential fall within the exemption may depend on the surrounding circumstances. Consulting with the quarantine station before the cargo arrives is therefore advisable. It would be a mistake to assume, as E did, that the simplified treatment available for sample import could also be used for full-scale imports for commercial sale. As a rule, commercial imports require the formal import-notification procedure for each shipment.

During the import review, importers are commonly asked to submit documents describing the raw materials and manufacturing process, together with information on the use of additives. To avoid delays in customs clearance, it is important to obtain raw-material specifications, manufacturing process flowcharts, and certificates of analysis and similar documents from the overseas contract manufacturer at an early stage. In particular, where a raw material is being imported for the first time or with little history of use in Japan, the importer should use the pre-arrival consultation service offered by the relevant quarantine station to obtain an early indication of whether testing of the material will be required.

Where the same importer repeatedly imports the same food or related product, it may be possible to use procedures that simplify the notification process, including (A) the "Item Registration System," under which certain notification details and related information are registered in advance so that portions of subsequent notification forms may be omitted;[5] and (B) the "Planned Import System," under which an import plan and import records are filed so that a separate notification is not required for each import.[6] Businesses that plan ongoing import transactions should consider whether these and other simplified procedures should be utilised.

Under the Food Sanitation Act, food business operators, including importers, must endeavor to take necessary measures to ensure the safety of the foods and related products they handle, and this remains their own responsibility (Article 3). Such operators and importers must not import unsafe foods or

[4] MHLW, "Procedures for Importing Foods, etc." Notifications are submitted to the Quarantine-Station Office responsible for the location where the imported cargo will clear customs. In addition to paper filings, electronic notification is available through the Food Automated Import Notification and Inspection Network System (FAINS).
[5] MHLW, "Procedures for Importing Foods, etc." Registration must be completed in advance at the Quarantine-Station Office, and the assigned registration number must be entered on the notification form. Registrations have a limited period of validity.
[6] MHLW, "Procedures for Importing Foods, etc." The types of food eligible for the Planned Import System are limited. Depending on the food, the importer must submit a one-year or three-year import plan together with import records for the three years preceding the filing date, and the application must be found acceptable upon review. After the application is approved, the importer must continue to report import results to the applicable Quarantine Station each fiscal year.

additives, including those containing harmful substances, or foods or additives that do not comply with Japanese specifications and standards (Articles 6 and 13(1) and (2)). Japan's Food Safety Basic Act likewise places primary responsibility on importers for ensuring the safety of imported foods (Article 8).[7] The fact that a product is lawfully marketed in Singapore is not, by itself, sufficient to discharge the importer's responsibilities under the Food Sanitation Act.

3. Problem with Measure ④: Safety Management Regulations Specific to Foods in Supplement Form

Finally, we consider Measure ④: E's assumption that it was not necessary to carry out procedures relating to Japan's GMP requirements for the capsule manufacturing process.

(1) System for Foods Containing Designated Ingredients, etc.

Following amendments to the Food Sanitation Act that took effect in 2020, foods containing ingredients or substances that require special attention to prevent food-sanitation hazards ("designated ingredients, etc.")[8] are designated as "foods containing designated ingredients, etc." A business operator handling such foods, including importers, must report information on adverse health effects (including information obtained before any causal relationship has been established) to the relevant Prefectural Governor or other authority without delay.[9] Manufacturers and processors of foods containing designated ingredients, etc. are also required to comply with manufacturing and processing standards (GMP) requirements.[10] Although importers are not directly responsible for implementing GMP, they are expected to share relevant GMP information with overseas manufacturers and confirm that the imported products are manufactured in compliance with the applicable standards. Prescribed information must also be stated on the container or packaging. Among other things, statements that the product is a "food containing designated ingredients, etc." and that it contains an "ingredient or substance requiring special attention" must be displayed at size 14 font or larger.[11] In our scenario, at the time the raw materials are finalized, it needs to be checked whether the functional ingredient in "Vita Blossom" is a designated ingredient, etc. .

(2) GMP for Foods in Tablet, Capsule and Similar Forms

There are two distinct frameworks when considering GMP for foods in tablet, capsule and similar forms. The first framework is the Consumer Affairs Agency's "Guidelines on Manufacturing and Quality Control (GMP) for Foods in Tablet, Capsule and Similar Forms." These guidelines encourage businesses to implement voluntary manufacturing and quality control measures for processed foods in forms such as tablets, capsules, powders and liquids that use natural extracts, etc. (hereinafter "natural extracts") as raw materials. "Natural extracts" means natural substances or extracts derived from natural sources

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[7] Article 8 of the Food Safety Basic Act sets out the responsibilities for food-related business operators at each stage of the food supply process. Importers are subject to these responsibilities as persons engaged in collecting, manufacturing, importing, processing, cooking, storing, transporting or selling food.
[8] As of the end of July 2026, four items have been designated: Coleus forskohlii, greater celandine, Pueraria mirifica and black cohosh (MHLW Notification No. 119 of March 27, 2020).
[9] Article 8(1) of the Food Sanitation Act. The designated ingredients, etc. are specified by MHLW Notification No. 119 of 2020. As a general reporting benchmark, serious cases, including deaths, should be reported within approximately 15 days, and other cases within approximately 30 days.
[10] Notice of the Director of the Food Inspection and Safety Division, Health and Welfare Bureau, MHLW, and the Director of the Food Sanitation Standards Examination Division, Consumer Affairs Agency, "Points to Note concerning Foods Containing Designated Ingredients, etc." (August 23, 2024, Notice Nos. 0823-5 and 190, as last amended January 5, 2026). The manufacturing and processing standards themselves are set out in the Standards for the Manufacture or Processing of Foods Containing Designated Ingredients, etc. (MHLW Notification No. 121 of 2020).
[11] Schedule 20 to the Food Labeling Standards (Cabinet Office Order No. 10 of 2015) requires statements to be included that the product is a "food containing designated ingredients, etc." and that it contains an "ingredient or substance requiring special attention to prevent food-sanitation hazards" to be displayed in uniform type at least 14 points in size, as specified in JIS Z 8305.

whose composition differs from the natural form as a result of fractionation, purification, concentration, drying, chemical reaction or similar processing, as well as chemically synthesized substances. The second framework is Cabinet Office Notification No. 108 (the "GMP Notification"). This makes GMP compliance a labeling requirement for foods in tablet, capsule and similar forms that use natural extracts as raw materials and are notified under the Foods with Function Claims system. Because the two frameworks differ in both scope and legal character, they should not be confused.

Following a 2024 incident involving adverse health effects linked to red yeast rice (beni-koji) products, the importance of GMP-based manufacturing and quality control systems for foods in tablet, capsule and similar forms made from natural extracts was brought into renewed focus. Under the GMP Notification dated August 30, 2024, compliance with GMP is now a labeling requirement for Foods with Function Claims in tablet, capsule and similar forms that use natural extracts as raw materials. The notifying business must ensure that the food is manufactured and processed in accordance with the GMP Notification. Transitional measures apply until August 31, 2026, and the notification requirement becomes fully applicable on September 1, 2026.[12] A framework has also been established for self-inspection and reporting using a self-inspection checklist for certain aspects of implementation.

For the purposes of this scenario, assume that the Luna Berry-derived polyphenol ingredient is a natural extract because extraction, purification and concentration have altered its composition from that found in its natural state. If a capsule product such as "Vita Blossom" is notified under the Foods with Function Claims system, the notifying business is responsible for ensuring that the manufacturing process at the Singapore factory complies with the GMP Notification. Even if the factory has its own quality standards or certifications - such as certification under local GMP rules or international standards - those measures do not necessarily mean that the factory satisfies the requirements of Japan's GMP Notification. The process may therefore need to be revised or subjected to additional verification.

Key Point | Lessons to learn from the Red Yeast Rice Incident

The incident involving adverse health effects associated with red yeast rice (beni-koji) products came to light in March 2024, with reports of kidney dysfunction and deaths. It prompted a series of regulatory reforms, including requirements for businesses that have notified Foods with Function Claims to collect specified information on adverse health effects and provide that information to the authorities (effective September 1, 2024),[13] and the introduction of GMP-based manufacturing control as a labeling requirement for Foods with Function Claims in tablet, capsule and similar forms that use natural extracts If adverse health effects occur, inadequate safety assessments of raw materials or insufficient control of manufacturing processes may lead not only to withdrawal of a

[12] "Standards for the Manufacture or Processing of Foods in Tablet, Capsule and Similar Forms Made from Natural Extracts, etc. among Foods with Function Claims" (Cabinet Office Notification No. 108 of August 30, 2024; effective September 1, 2024). The underlying amendment to the Food Labeling Standards was made by Cabinet Office Order No. 71 of August 23, 2024, amending the Food Labeling Standards.

[13] Ordinance Partially Amending the Ordinance for Enforcement of the Food Sanitation Act (MHLW Ordinance No. 115 of 2024; promulgated August 23, 2024 and effective September 1, 2024); and Notice of the Director-General of the Health and Welfare Bureau, MHLW, "Promulgation of the Ordinance Partially Amending the Ordinance for Enforcement of the Food Sanitation Act" (Notice No. 0823-8 of August 23, 2024). Operational details are set out in the Notice of the Director of the Food Inspection and Safety Division, Health and Welfare Bureau, MHLW, "Provision of Information on Adverse Health Effects Relating to Foods with Function Claims, etc." (Notice No. 0823-3 of August 23, 2024, as last amended January 5, 2026). The notice requires businesses that have submitted notifications for Foods with Function Claims and holders of permits for Foods for Specified Health Uses to collect information on adverse health effects where a physician has diagnosed that the symptoms were or may have been caused by the relevant food or additive, and to promptly provide the information to the relevant prefectural governor or other authority when they learn that adverse health effects may occur or spread. By contrast, the requirement to report adverse-health-effects information "including where causation has not yet been established" applies under the system for foods containing designated ingredients, etc.; the scope of adverse-health-effects information for Foods with Function Claims, etc. is different.

notification and regulatory action, but also to serious consequences for consumers' lives and health. The lesson is equally important for importers handling products manufactured overseas.

(3) Latest Developments: Considering Cross-Cutting "Supplement" Regulation for Health Foods

To date, businesses have been encouraged to adopt GMP voluntarily for foods in tablet, capsule and similar forms that use natural extracts. Mandatory GMP requirements have instead only applied to limited categories, such as certain tablet-form and capsule-form Foods with Function Claims and Foods for Specified Health Uses, and foods containing designated ingredients, etc. Following the red yeast rice incident, the Newly Developed Food Subcommittee of the Consumer Affairs Agency's Food Sanitation Standards Council has considered defining "supplements" as a cross-cutting category of foods - including Foods with Health Claims - regardless of whether function claims are made, and also to establish an appropriate framework for controlling their manufacture.[14] On June 19, 2026, the Subcommittee formally published its "Interim Report on the Approach to Supplement Regulation" (“Interim Report”).[15] The Interim Report continues to treat "supplements" as foods, and presents the following working definition: foods intended to supplement nutritional intake from a normal diet or to support the regulation of physiological functions ordinarily achieved through a normal diet, where some or all ingredients are concentrated during manufacturing, the product is in an easily consumable form such as a tablet, capsule, liquid or powder, or the product otherwise presents a risk of excessive intake. Not every health food necessarily falls within this definition. A product must first satisfy the purpose requirement: supplementing nutritional intake from a normal diet or supporting the regulation of physiological functions ordinarily achieved through a normal diet. After satisfying this requirement, the product must then fall within at least one of the following three categories: (1) products containing concentrated ingredients; (2) products in an easily consumable form, such as tablets, capsules, liquids or powders; or (3) other products presenting a risk of excessive intake.

A particularly noteworthy aspect of the Interim Report's approach to manufacturing control is its conclusion that GMP compliance should be mandatory for tablet-form and capsule-form foods falling within the proposed "supplement" category.[16] For products such as gummies that have the same form as ordinary processed foods, however, the Interim Report states that exclusion from mandatory GMP compliance may be unavoidable for the time being, taking into account the lower risk of confusion with drugs, existing manufacturing practices (including production on confectionery lines) and regulatory effectiveness. The exclusion is not intended to be permanent; the path toward eventual mandatory compliance should be clarified. Even if a capsule product such as "Vita Blossom" is marketed as an ordinary food rather than being notified under the Foods with Function Claims system, it may eventually be required to comply with GMP as a "supplement". The Interim Report does not expressly state that the GMP obligation would also apply to imported products. Materials prepared for the April 23, 2026

[14] Consumer Affairs Agency, Food Sanitation Standards Examination Division, "Approach to the Regulation of Supplements" (materials of the Newly Developed Food Subcommittee of the Food Sanitation Standards Council, March 30 and April 23, 2026). The materials proposed a cross-cutting definition encompassing "other so-called health foods," including Foods with Health Claims: foods intended to supplement nutritional intake or regulate physiological functions through a normal diet, where concentrated ingredients, an easily consumable form or similar characteristics create a risk of excessive intake.

[15] Newly Developed Food Subcommittee of the Food Sanitation Standards Council, "Interim Report of the Newly Developed Food Subcommittee on the Approach to Supplement Regulation" (June 19, 2026). The Interim Report continues to classify supplements as foods, while indicating that foods containing concentrated ingredients, foods in easily consumable forms such as tablets and capsules, and other foods presenting a risk of excessive intake should fall within the scope of "supplements."

[16] See footnote 15 above, Part II, 2(2)(a).

deliberations, however, indicated that imported products were intended to be covered, making the treatment of imported products an important issue for the detailed design of the future framework.[17]

Separately, the Health Science Council of the MHLW has, from the outset, been tasked with considering the reporting of adverse health effects and the framework for business licenses and notifications. That work is proceeding in parallel with the Consumer Affairs Agency's Food Sanitation Standards Council, which is considering the definition of "supplements" and manufacturing controls. Hovever, the two matters are being considered by different deliberative bodies. Details - including the products covered, the implementation date and the treatment of imports - will depend on future legislation and related rules. Nevertheless, businesses importing health foods should now consider preparing internal systems not only to comply with the current GMP framework and the rules for foods containing designated ingredients, etc., but also for a possible expansion of the regulated scope.

Conclusion (Part I)

Part I used the fictitious launch of "Vita Blossom" in Japan as an introduction to survey the threshold issues that arise when a foreign company imports and sells health foods in Japan: food-drug classification, import procedures under the Food Sanitation Act, and the overall framework of safety management regulations for foods in supplement form.

Unlike cosmetics, importing and selling health foods does not, as a general rule, require a blanket license to import and sell the products merely because they are imported as food. Nevertheless, importers must independently verify and assume responsibility for numerous matters, including the threshold question of whether the product may be imported as a food, the notification to the quarantine station generally required for each shipment, and safety management requirements relating to designated ingredients, etc. and GMP. Depending on the nature of any manufacturing, processing, storage or sales activities conducted in Japan, separate business permits or notifications may also be required under the Food Sanitation Act. Of particular importance, the Interim Report on "supplement" regulation published on June 19, 2026 presents a working definition covering foods intended to supplement nutritional intake from a normal diet or support the regulation of physiological functions, where the ingredients are concentrated, the product is in an easily consumable form such as a tablet or capsule, or there is otherwise a risk of excessive intake. It further concludes that GMP compliance should be mandatory for tablet-form and capsule-form foods within that category. The details of the future framework, including the treatment of imported products, remain to be developed through legislation and related rules. This is a development that may materially affect the import and sale of health foods by foreign businesses in practice and should be monitored closely.

Part II will use Measures ② and ③ to examine in detail the regulations governing advertising and package labeling of health foods - including the PMD Act, the Health Promotion Act, the Act against Unjustifiable Premiums and Misleading Representations, and the Food Labeling Act - and the proper use of the Foods with Function Claims system, including the prohibition on using such labeling without filing the required notification, the steps required for notification, and considerations specific to products manufactured overseas.

[17] The Consumer Affairs Agency's materials dated April 23, 2026 asked whether GMP compliance should be made mandatory for supplements, including imported products.
The final Interim Report published on June 19, 2026 omits the phrase "including imported products" and states only that GMP compliance should be mandatory for foods in tablet, capsule and similar forms within the proposed "supplement" category. As the final Interim Report does not expressly address imports, the position will need to be confirmed via future legislation, notices, Q&As and other guidance.

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