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Evaluation of commercial probiotic supplements in Malaysia for registration status, labelling compliance, and probiotic contents

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ABSTRACT

Introduction: The global probiotics market is growing rapidly due to increasing consumer demands for functional foods and increased awareness of the importance of gut health. However, previous studies have raised concerns about the labelling, quality, and safety of commercial probiotic products available worldwide. There are limited studies focusing on probiotic supplements sold in Malaysia. Therefore, this study aimed to determine if these probiotic supplements are registered and labelled according to the guidelines by the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia, and to identify common probiotic strains found in these products. **Methods:** A total of 103 probiotic products sold at pharmacies in Klang Valley, Malaysia and online shopping platforms were included in this study. Product labels were examined for the presence of holographic security labels and other labelling requirements set by NPRA. Data were collected between January and March 2022. **Results:** 81.6% of probiotic supplements sold in Malaysia were registered with NPRA; 70% were fully labelled according to NPRA guidelines, while the rest lacked one or more standard labelling criteria. Mislabelling of probiotic contents was found in 44.7% of probiotic supplements sold in Malaysia, whereby errors were detected in the probiotic nomenclature. The most common probiotic species in these supplements were *Lactobacillus acidophilus* (61.2%), followed by *Bifidobacterium animalis* subsp. *lactis* (50.5%), and *Lactobacillus rhamnosus* (46.6%). **Conclusion:** While most probiotic supplements sold in Malaysia were registered under NPRA and properly labelled, the availability of unregistered products warrants consumers to make more informed choices about the selection of their purchases.

Keywords: labelling compliance, National Pharmaceutical Regulatory Agency (NPRA), probiotics, probiotic supplements, registration

INTRODUCTION

Probiotics are defined as 'live microorganisms that, when administered in adequate amounts, confer a health benefit on the host' (Hill *et al.*, 2014). In recent years, the global probiotics market has been growing rapidly as probiotics have been associated with a diversity of health benefits such as improving gut and skin health. The probiotics market can be divided into three major segments, including dietary supplements, animal feeds, and functional foods and beverages, where

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the latter generated the highest revenue in the global probiotics market (Mordor Intelligence, 2019).

Despite a huge demand for probiotics, there is currently no globally agreed framework for the regulation of probiotic products. Among the Southeast Asian countries, only Malaysia, Indonesia, the Philippines, and Thailand have enacted specific regulations for probiotics in foods and health supplements. Only Malaysia, Thailand, and the Philippines have published a list of microorganisms approved to be used as probiotics in foods. For use of probiotics in supplements, there are no standardised criteria across these countries in terms of the approved microbial species, application requirements for candidate probiotic species, and labelling requirements for probiotic products (Tee, Hardinsyah & Au, 2021). In Malaysia, probiotic supplements are considered health supplements, hence should be registered with the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health (MOH) Malaysia. These products should also adhere to the standard labelling requirements for health products sold in Malaysia. However, the regulatory body has not provided a list of probiotics approved for use in health supplements.

Probiotic supplements are present in different forms, including capsules, tablets, powders, and liquids. While many probiotic products are available in the market, consumers may find it challenging to determine their quality, safety, and authenticity (Jackson *et al.*, 2019). The diversification and lack of stringent regulations for probiotic products have led to the misuse of the term 'probiotic' in commercial products that do not meet the required criteria (de Simone, 2019). Previous research has highlighted issues such as mislabelling of probiotic strains, incorrect counts of viable cells, and the presence of pathogens in commercial probiotic products (Weese, 2003; Ullah *et al.*, 2019; Mazzantini *et al.*, 2021; Dioso *et al.*, 2020). Additionally, probiotic formulations in some products do not always correspond to the label claims (Mazzantini *et al.*, 2021). It is important to note that these studies were conducted in other countries and there are limited studies on probiotics sold in Malaysia.

In this study, we aimed to evaluate the registration status and labelling compliance of probiotic supplements sold in Malaysia. In addition, we also aimed to compare the characteristics of probiotic supplements sold in Malaysia in terms of their probiotic contents, storage conditions, and dosage methods.

MATERIALS AND METHODS

Data collection

Data collection was performed between January and March 2022. A total of 103 probiotic supplements were included in this study. Probiotic supplements sold at pharmacies in Selangor and Kuala Lumpur (n=74), as well as online shopping platforms (n=29) were included in this study. Simple random sampling method was used to select the products. For each product, its registration status was determined using the QUEST3plus System from the NPRA website. Labels on the products were checked for labelling compliance based on NPRA requirements (Figure 1). For probiotic supplements sold online, labels were obtained through the product showcase images provided by the official website of the company or other shopping platforms.

Data analysis

All data were tabulated and analysed using Microsoft Excel (Version 2205, Redmond, Washington, United States). Descriptive analysis on the labelling accuracy of probiotic supplements sold

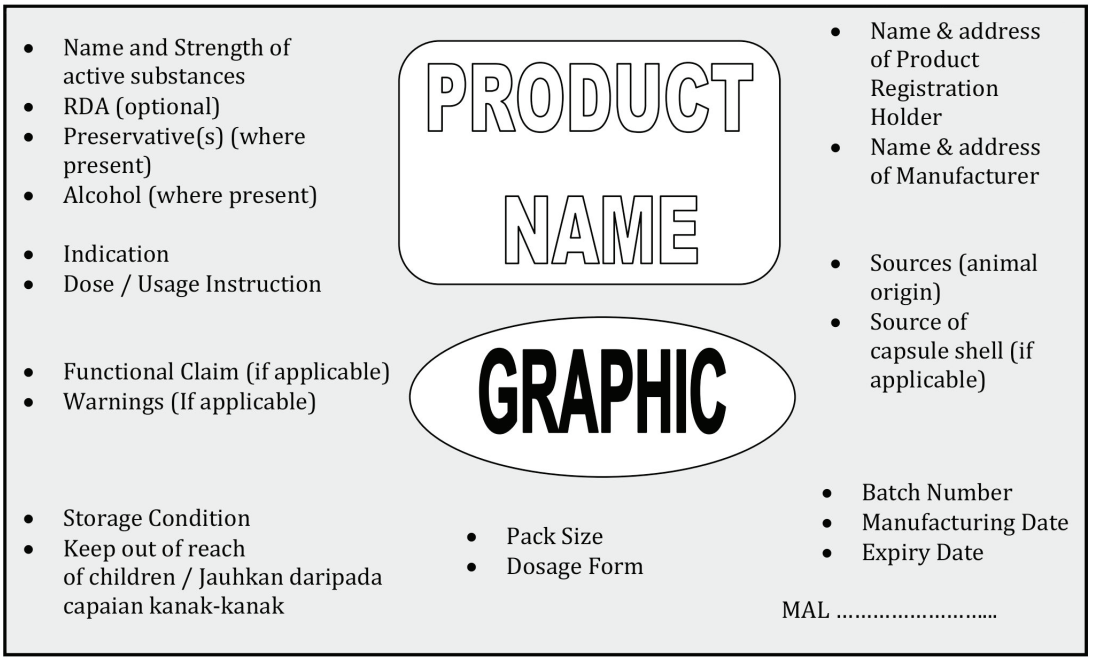

Figure 1. Standard labelling criteria for outer carton of health supplements (NPRA, 2023)

in Malaysia was performed in reference to the NPRA guidelines. This analysis included evaluation of the registration status of probiotic supplements and their compliance with the standard labelling criteria. Data on probiotic content, nomenclature, concentration, number and type of probiotic strains, dosage form, and storage condition were also tabulated.

RESULTS

Registration status of probiotic products in Malaysia

81.6% (*n*=84) of probiotic supplements sold in Malaysia were registered under the NPRA. Similarly, the holographic security label, which must be displayed on all registered pharmaceutical products in Malaysia was present in 81.6% of the products. One of the probiotic supplements displayed the old Meditag™ hologram security label instead of the FarmaTag label, which was newly introduced on 1st September 2019. Of the 19 unregistered products, only four were sold online, while the rest were sold in pharmacies.

Labelling compliance of probiotic supplements sold in Malaysia

70% (*n*=72) of probiotic supplements were fully labelled according to the NPRA requirements. There is a total of 16 labelling criteria for the outer carton of probiotic supplements (Table 1); 13 labelling criteria are compulsory, while the remaining three labelling criteria are optional (functional claims, warnings, and source of capsule shell). All products displayed five out of the 13 compulsory labelling criteria on their labels, which included dosage form and pack size, storage condition, recommended dosage, batch number, and expiry date. For the other eight compulsory labelling criteria on probiotic products, compliance ranged from 79.6% to 97.1%. For the three optional labelling criteria, 36.9% of products included functional claims and

Table 1. Labelling compliance for probiotic products sold in Malaysia

Standard labelling criteria	*Presence on label n (%)*
Compulsory labelling criteria	
Registration number	84 (81.6)
Ministry of Health of Malaysia (MOH) security label	84 (81.6)
Name and strength of active substances (milligrams and/or CFUs)	93 (90.3)
Indication	82 (79.6)
Dose/usage instruction	103 (100.0)
Storage condition	103 (100.0)
Pack size and dosage form	103 (100.0)
Drug Control Authority labelling requirement	87 (84.5)
Name and address of product registration holder	94 (91.3)
Name and address of manufacturer	100 (97.1)
Batch number	103 (100.0)
Manufacturing date	96 (93.2)
Expiry date	103 (100.0)
Optional labelling criteria	
Functional claim	38 (36.9)
Warnings	50 (48.5)
Source of capsule shell	48 (46.6)

48.5% included warnings. Additionally, 46.6% (*n*=48) of probiotic products were in capsule form and all indicated the source of capsule shell on their labels. Of these, 45 products used vegetable capsules, while two products had capsule shells made from animal origin (bovine). One product did not report the origin of its gelatine capsule, whether it was made from bovine or porcine.

Characterisation of probiotic supplements sold in Malaysia

Probiotic concentrations

Probiotic concentrations in colony-forming units (CFUs) were found on the packaging of 57.3% (*n*=59) of probiotic supplements. One probiotic supplement was labelled as 'cell/g' and another was labelled as 'organisms' instead of CFUs or milligrams to describe the strength of the probiotic strains. For the remaining 44 probiotic supplements, the probiotic concentrations of 27 products were found on the companies' official websites. The probiotic concentrations for all products ranged from 0.01 billion to 100 billion CFU.

Number and type of probiotic strains

Most probiotic supplements contained one or two strains of probiotics (Figure 2), while one product did not list the probiotic strain used. In terms of the types of probiotic strains in products, 22 different probiotic species were found in these supplements (Figure 3), with *Lactobacillus acidophilus* and *Bifidobacterium animalis* subsp. *lactis* being the most common strains.

Dosage and storage conditions

Five of the probiotic supplements were sold in liquid form, while the rest were sold in dry form, either in capsules or powder sachets. Most of the probiotic products (56.3%) recommended the use of one dose (either one packet or one capsule) daily (Table 2). For product storage conditions, most products (97%)

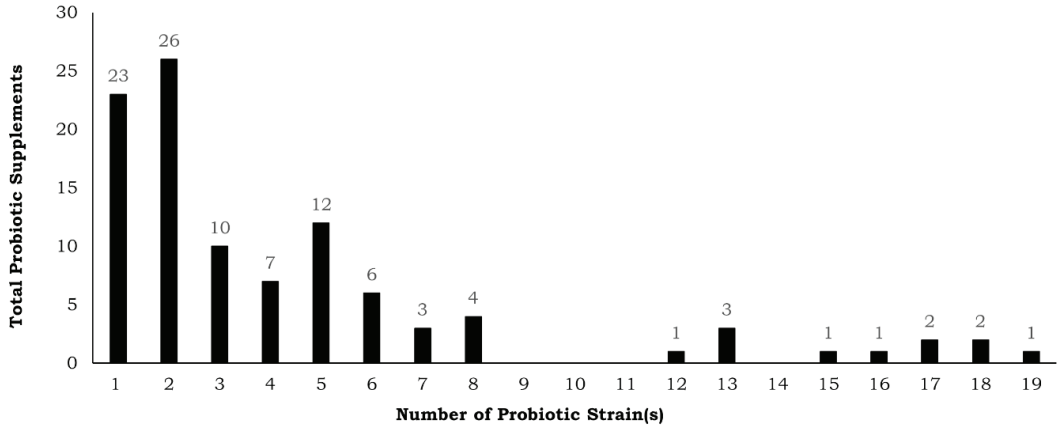

Figure 2. The number of probiotic strain(s) found in each probiotic supplement sold in Malaysia

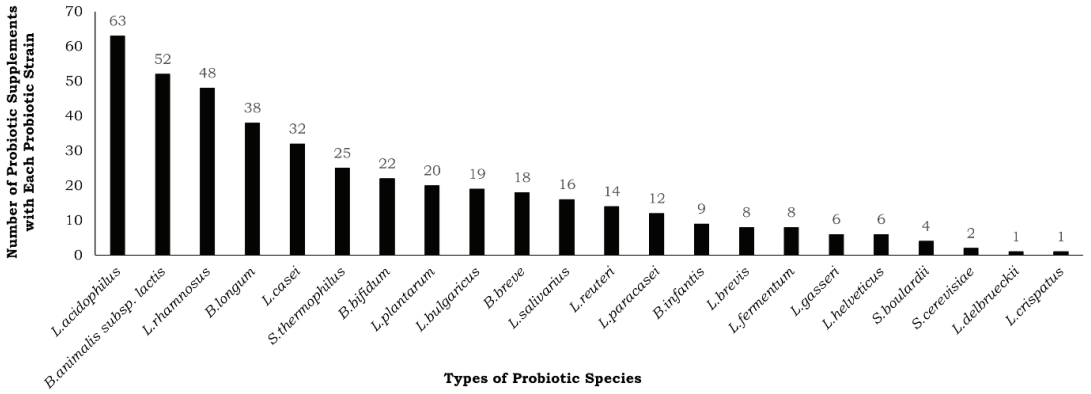

Figure 3. The types of probiotic species found in each probiotic supplement sold in Malaysia

Table 2. The different dosages for probiotic supplements sold in Malaysia

Dosages	*Probiotic supplements, n (%)*
1 dose once daily	58 (56.31)
1-2 dose(s) once daily	22 (21.36)
1-2 dose(s) twice daily	4 (3.88)
1-3 dose(s) once daily	1 (0.97)
1 dose twice daily	4 (3.88)
1 dose thrice daily	1 (0.97)
2 doses once daily	10 (9.70)
2 doses twice daily	2 (1.94)
5 drops	1 (0.97)

should be stored at room temperature, while three products needed to be kept refrigerated between 2°C to 8°C.

Probiotic supplements with mislabelling issues

Forty-six probiotic supplements sold in Malaysia had mislabelling issues, where most of them involved the use of the old nomenclature for *Bifidobacterium animalis* subsp. *lactis,* which was previously known as *Bifidobacterium lactis* (*n*=29). In addition, the terms 'spp.'

and 'ssp.' instead of 'subsp.' were used for this probiotic strain in 12 probiotic supplements. For the remaining products, species names of the probiotics were incorrectly capitalised. For example, *Lactobacillus acidophilus*' was written as '*Lactobacillus Acidophilus*'.

DISCUSSION

Our results showed that the majority of probiotic supplements sold in Malaysia were registered and conformed to the labelling requirements by NPRA. There was one probiotic product that was registered but did not display the security label. Under Regulation 8(1) of the Control of Drugs and Cosmetics Regulations 1984, all registered pharmaceutical products and health supplements without security labelling will be considered unregistered products (NPRA, 2021). Each product registered under NPRA must affix a hologram security label onto the outer carton of the packaging, which may otherwise incur a penalty.

In Malaysia, some probiotic-containing products may fall within the food-drug interphase (FDI) category, which is defined as products with both food and active ingredients for oral consumption. When in doubt, companies can verify the classification of their products with NPRA. FDI products that are subsequently classified as drugs will be under NPRA's purview and require registration, while those classified as food will be under the Food Safety and Quality Division (FSQD)'s purview. However, for consumers, they may not know which classification the product belongs to and whether or not registration of the product is required. For example, an unregistered probiotic product that should be classified as a "drug" might mistakenly be considered a food product that does not require regulation by NPRA.

There are differences in terms of labelling requirements by regulatory agencies worldwide. NPRA does not have any specifications on the unit that should be used to label the strength of probiotic strains. However, the United States Food and Drug Administration (FDA) specifies that the Supplement Facts label of dietary supplements containing live microorganisms must be listed in milligrams (US FDA, 2018). In this study, 51.5% of probiotic supplements expressed the quantity of each probiotic strain in milligrams. A guideline issued by the Joint Food and Agriculture Organisation of the United Nations and World Health Organisation in 2002 stated that probiotic labels should include the minimum viable quantity of each probiotic strain at the end of shelf life, expressed in CFU or mg (FAO/WHO, 2002). About 4% of probiotic supplements in this study had stated the probiotic concentrations at the time of manufacture. Consumers should be educated that probiotic counts at the time of manufacture may not represent the quantity of active ingredients at the end of their shelf lives, as their amount may decline over time. The FDA also specifies that on the Supplement Facts label of dietary supplements, live microbial dietary ingredients in a proprietary blend must be listed in descending order of predominance by weight (US FDA, 2018). However, this was not a requirement by NPRA and 29% of probiotic supplement labels in this study did not follow the order of predominance by weight.

There are three other labelling criteria in Figure 1 that were not listed in Table 1, namely the recommended dietary allowance (RDA), alcohol, and preservatives. RDA labelling is optional and was not displayed on the labels of any products in this study. This is because probiotics, unlike vitamins or minerals, do not have a standardised

RDA. They are live microorganisms that vary significantly in species, strains, and their impact on health, making it difficult to establish a universal dosage recommendation. Moreover, probiotics are typically consumed for specific health benefits, such as improving gut health or supporting the immune system, which further complicates the creation of a one-size-fits-all guideline for intake. Consequently, none of the products included in the analysis displayed the RDA on their labels. Alcohol and preservatives were also not listed on any of the product labels, as these substances were absent in all products.

Most probiotic supplements in this study were labelled as 'health supplements' or 'dietary supplements' to indicate their intended usage. This signifies their roles in supporting general well-being rather than treating specific medical conditions. Hence, it is essential that all probiotic supplements include indications on their labels to prevent misuse of the product. For probiotic supplements that included functional claims on their labels, these claims were mostly related to gut health, with statements such as 'helps improve beneficial intestinal microflora', 'supports immune health and intestinal health', and 'improves intestinal and gut function'. These are general health claims that are typically permissible on health supplement labels. The warnings on labels of probiotic supplements included advice to consult a pharmacist or doctor before use, instructions not to use if the tamper-evident seal is broken or missing, a caution against consumption if immunocompromised or having a central venous catheter, and guidance to avoid taking the supplement with hot or warm liquids or foods. These warnings are important because probiotics are products containing live microorganisms, which may cause allergic reactions, side effects, and potentially sepsis in at-risk individuals. Clearly labelling the source of capsules allows consumers to make informed choices that align with their religious beliefs and dietary requirements. In this study, all capsule-based probiotic supplements listed their capsule sources as either vegetable or animal; however, one product did not specify whether its gelatine was derived from bovine or porcine sources. This highlights the need for consumers to carefully examine product labels before purchasing their chosen probiotic supplements.

There is no specific guideline by NPRA on the minimum number of probiotics to be included in health supplements. Similarly, no guideline has been provided by the International Scientific Association of Probiotics and Prebiotics (ISAPP) on the minimum probiotic content for health supplements. This is because higher CFU counts of probiotics do not necessarily mean more superior supplements, as the number of CFU needed by a person may vary, depending on their purposes for taking the probiotics (Ouwehand, 2016). In addition, there are other variables that can affect probiotic efficacy, such as strains of probiotics, the viability of probiotics on the shelf and upon ingestion, and the combination of probiotics in each supplement. Nonetheless, for food products, FSQD regulation states that viable probiotic counts should not be less than 10^6 CFU/g during the food's shelf life. Similarly, a previous study also suggested that probiotic supplements should contain at least 10^6 CFU/g of viable probiotic cells (Kechagia *et al.*, 2013). The concentration of probiotic strains in all 103 probiotic supplements in this study was more than or equal to 10^7 CFU/g, which surpasses the aforementioned minimum number.

A total of 76.7% of the probiotic supplements contained multi-strain

probiotics. Adding multi-strain probiotics into the formulation may appear more desirable than single-strain probiotics, as a combination of strains can potentially exert synergistic effects to improve human health (Kwoji *et al.*, 2021). However, it should be noted that strain specificity is also an important consideration in choosing probiotic supplements, as different probiotic strains may be used to target specific health concerns. The most common probiotic species found in this study were *Lactobacillus acidophilus*, *Bifidobacterium animalis* subsp. *lactis,* and *Lactobacillus rhamnosus*, which mainly target gastrointestinal health. In terms of storage conditions, most products recommended a storage temperature of below 25°C and 30°C. Accordingly, consumers may store their probiotic supplements at room temperature. However, the indoor temperature in Malaysia ranges from 24°C to 31°C (Md Kamal, Sazali & Sarnin, 2021). It remains unclear if this factor can potentially affect the viability of probiotic cells.

This study was constrained by several limitations. Firstly, the complete list of probiotic supplements sold in the Malaysian market was not available and this study had a small sample size, which only focused on products available in pharmacies within the Klang Valley. These factors limited the generalisation of findings to the broader probiotics market in Malaysia. Additionally, reliance on online research for product information introduced uncertainty regarding the accuracy of the data obtained from product official websites and online shopping platforms. For example, online sellers may not update the most recent product labels for the supplements on their websites. Furthermore, this study lacked an assessment of actual probiotic concentrations and characterisation of probiotic strains through *in vitro* studies, rendering the accuracy of label claims unverified. Future investigations employing advanced molecular techniques, such as whole genome sequencing, could address these limitations, providing a more comprehensive understanding of product composition and enhancing the validity of study outcomes.

CONCLUSION

Overall, the majority of probiotic supplements sold in Malaysia were registered under NPRA and there was high compliance with the NPRA compulsory labelling criteria for health supplements. However, the availability of unregistered supplements warrants consumers to make more informed choices about the selection of their purchases. Online sellers are also recommended to display each plane of the probiotic supplements' label on their websites to ensure transparency of product information and to assist consumers in their decision-making process.

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Authors' contributions

Lee SY, performed data collection and analysis, and prepared the draft of the manuscript; Yeo SK, assisted in drafting of the manuscript, reviewed and proofread the manuscript; Chua LLC, conceptualised and designed the study, and reviewed the manuscript.

Conflict of interest

The authors have no competing interests to declare.

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