

**Health Claims on food products in South East Asia:
a comparative study of the regulatory framework
and consumer understanding**

School of Agriculture, Food and Rural Development

Newcastle University

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April 2017

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consumer understanding**

Dissertation submitted in partial fulfilment of the degree of Doctor of
Philosophy

School of Agriculture, Food and Rural Development

Newcastle University

Karin Yu Mian Tan

April 2017

Declaration

I confirm that the contents of this thesis are my own and have not been presented or accepted in any previous application for a degree and all sources are fully referenced and acknowledged.

Karin Tan

Date: April 2017

Publications

Some of this thesis such as Chapter 2 and Chapter 4 has been published with full references. Chapter 2 titled ‘Health Claims on food products: the regulatory frameworks, barriers and opportunities in Southeast Asia’ has been published in *Nutrition Reviews*, and Chapter 4 titled ‘Perception and understanding of health claims on milk powder for children: A focus group study among mothers in Indonesia, Singapore and Thailand’ has been published in *Appetite*. The printed versions of these two papers are available in Appendix 3 and 4 at the end of this thesis.

Acknowledgements

First of all, I would like to express my appreciation to my sponsors, Singapore Economic Development Board and Danone Asia Pacific Holdings Pte Ltd. This research was funded through a studentship award by the Singapore Economic Development Board (EDB) and an unrestricted research grant from Singapore EDB and Danone Asia Pacific Holdings Pte Ltd.

I would like to thank the participants who participated in this research. This thesis would not have been possible without their participation. My sincere thanks go to all those who offered their comments and thoughts on this work at various stages.

I enjoyed the invaluable exchanges and advice from my supervisory team: Prof Eline Van Der Beek, Prof Chris Seal, Dr Xue Jun Zhao and Dr Iain Brownlee. Many thanks to friends and colleagues at Danone and Newcastle University in UK and Singapore for their assistance.

I am blessed to have the encouragement and support from my family and friends.

Finally, love to Alvin and Joanne. Got there in the end; and beginning of a new journey.

Abbreviations

ACCSQ	ASEAN Consultative Committee on Standards and Quality
AEC	ASEAN Economic Community
AHA	Alpha hydroxyl acids
ANZ	Australia and New Zealand
APEC	Asia Pacific Economic Co-operation
ARA	Arachidonic acid
AROFIIN	Asia Roundtable on Food Innovation for Improved Nutrition
ASEAN	Association of Southeast Asian Nations
ATIGA	ASEAN Trade in Goods Agreement
AVA	Agri-Food Veterinary Authority
BPOM	Badan Pengawas Obat Dan Makanan also known as National Agency of Drug and Food Control of the Republic of Indonesia (NA-DFC)
CAA	Consumer Affairs Agency
CODEX	Codex Alimentarius
DHA	Docosahexanoic acid
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FDA	Food and Drug Administration
FFC	Food with Functional Claims
FIA	Food Industry Asia
FNFC	Food for Nutrient Function Claims
FOSHU	Foods for Specified Health Uses
FSANZ	Food Standards Australia and New Zealand
FUFOSE	Functional Food Science in Europe
GHLC	General Level Health Claims
HLHC	High Level Health Claims
ILSI	International Life Science Institute
ISEAS	Institute of Southeast Asian Studies
ISRCTN	International Standard Randomised Controlled Trial Number
MOH	Ministry of Health
NA-DFC	National Agency of Drug and Food Control of the Republic of Indonesia
NDA Panel	Panel of Dietetics products, Nutrition and Allergies
NGO	Non-governmental organisation
NLEA	Nutrition Labelling and Education Act
NPSC	Nutrient Profiling Score Criterion
OECD	Organisation of Economic Co-operation and Development
PASSCLAIM	Process for the Assessment of Scientific Support for Claims on Foods
RCT	Randomised Controlled Trials
RDI	Recommended Dietary Intakes
SEA	Southeast Asia
SPS Agreement	Agreement of sanitary and phytosanitary measure
SSA	Significant Scientific Agreement
TPP	Trans-Pacific Partnership
UK	United Kingdom
US	United States
USFDA	United States Food and Drug Administration
WHO	World Health Organisation
WTO	World Trade Organisation

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Abstract

Health claims on food products facilitate communication of nutritional benefit of food products for the food industry and require regulatory approval. The Association of Southeast Asian Nations (ASEAN) aims to achieve free movement of goods under the formation of ASEAN Economic Community in 2015. Little is published about the structure and processes underpinning the regulatory frameworks for health claims on food in Southeast Asia (SEA) and the Asian consumers' understanding of health claims. The research topic of this thesis is on the health claims on food products in SEA. The aim of the thesis is to develop clear situation awareness of how the information flow through the existing regulatory frameworks in SEA effectively communicates understanding to the consumers. The objectives were, firstly, to review the existing regulations/ guidelines on health claims in SEA and major jurisdictions; secondly, to investigate the current practices and perspectives and the understanding of health claims in SEA through (a) semi-structured interviews with 15 key stakeholders and (b) focus groups among 48 Asian mothers in three SEA countries. There were inconsistencies in the regulations and the types of evidence required for health claims application among the five SEA countries which currently have health claims regulations/ guidelines in place. An analysis of the interviews among the key stakeholders yielded similar thinking and distinct perspectives on the challenges they faced. The mothers recalled and trusted health claims on products but lacked full understanding of the functions of the nutrients. The factors affecting the understanding on health claims among the mothers were identified. The findings suggest that in order to ensure consumer confidence and understanding of health claims, active engagement with all key stakeholders together with consumer education efforts via public-private partnerships will be required in the future. A conceptual harmonised regulatory framework was proposed to bridge the gaps between the regulatory frameworks for health claims in SEA. This research provides clear direction for food industry and the regulatory community to better support innovation to increase trade in SEA region and insights to develop effective consumer communication.

Chapter 1 Introduction

Our understanding of the role of food has evolved from providing nutrients for normal body function in the past to promoting and maintaining health (Roberfroid, 2002; European Food Information Council, n.d.). The advancement in nutritional science and technology is progressing very rapidly. There are more discoveries and development of food constituents and/ or new ingredients in foods which could have beneficial effects on physiological functions towards health. Health claims on food products provide a valuable form of communication between the food industry, regulatory agencies and the consumers on the potential beneficial effects of a food constituent or food product. Effective communication through health claims can help consumers make informed food choices in order to achieve a healthy diet.

1.1 Definition of health claims

Codex Alimentarius 'Codex' (1997, last amended in 2013) defines a health claim as 'a representation that states, suggests, or implies a relationship exists between a food and health'. Health claims are categorised into three groups: 'nutrient function claims', 'other function claims' and 'reduction of disease risk claims'. According to Codex, the definitions of the three types of health claims are as followed:

- a. 'nutrient function claim' describes the physiological role of the nutrient in growth, development and normal functions of the body
- b. 'other function claim' describes specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body
- c. 'reduction of disease risk claim' relates the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

Figure 1.1 below provides an explanation on the Codex definitions of the three types of health claims with examples of authorised health claims from the European Food Safety Authority (EFSA).

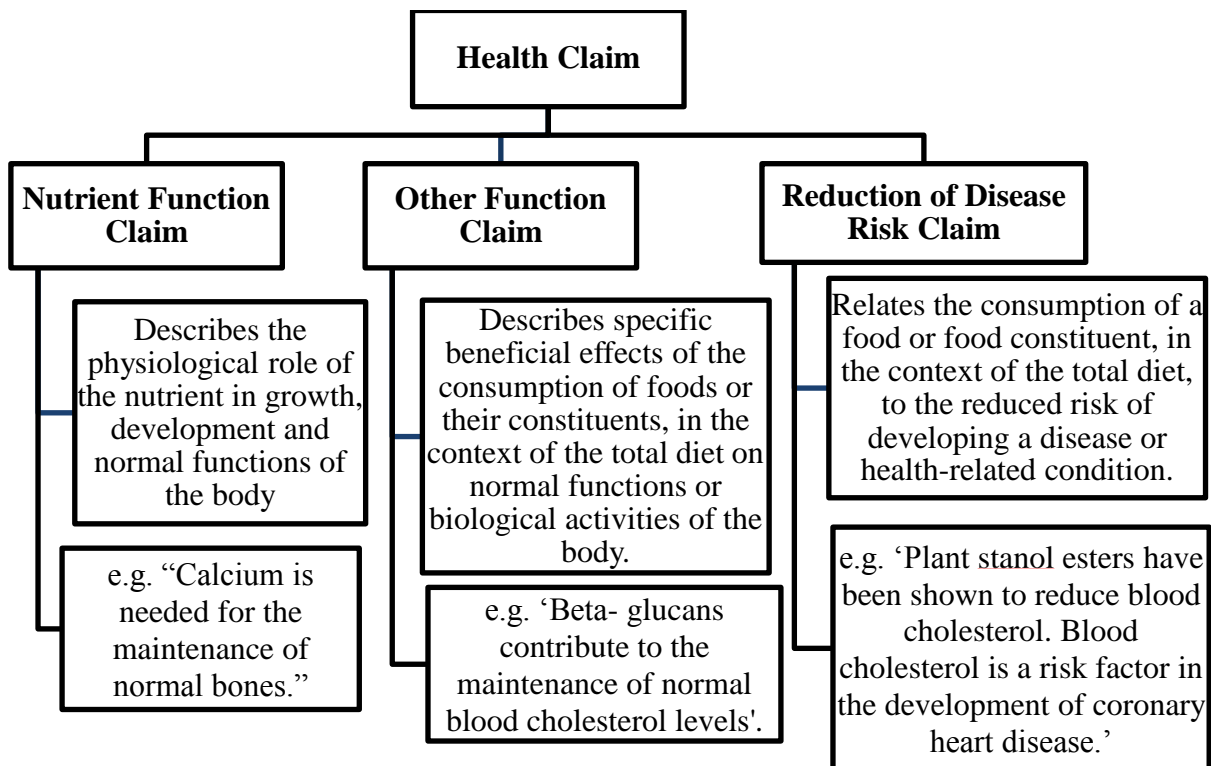


Figure 1.1: Codex definitions on the types of health claims

Source: Codex Alimentarius (1997 (last amended in 2013); European Food Safety Authority (n.d.-a)

1.2 Historical development of the health claims on food

The development of health claims has been described as the renaissance of food science and it has been linked with the development of ‘functional foods’ (Hawkes, 2004). The evolution of food science has led to a paradigm shift on the concept of food from providing ‘adequate nutrition’ to delivering ‘optimum nutrition’ among the people living in the major jurisdictions and more industrialised world in the 1980s and 1990s (Diplock *et al.*, 1999). In view of this, health authorities in many countries such as Japan and United States supported research on food components and health benefits.

Japan was the first country to establish a regulatory framework, also known as ‘Foods for Specified Health Uses (FOSHU)’ in 1991 by the Ministry of Health, Labour and Welfare (Shimizu, 2003). This Japanese system approved statements on food labels concerning the effects of food on the body based on scientific evidence and it also aimed to reduce the occurrence of lifestyle-related diseases in the rapidly aging population in Japan (Arai, 1996).

In the United States, health claims formed part of the Nutrition Labelling and Education Act (NLEA), passed by the United States Congress and President in 1990 (United States Food and

Drug Administration, 2000). The aim of the NLEA was to provide consistent and understandable food labels for the consumer to make healthy food choices and to encourage food manufacturers to produce better quality food (United States Food and Drug Administration, 2000).

The global development in functional food had also prompted the European Commission to fund a project called the European Commission Concerted Action on Functional Food Science in Europe (FUFOSE) in 1995. This 3-year project was managed by the International Life Science Institute (ILSI) Europe (Bellisle *et al.*, 1998). This initiative aimed to develop and establish a science-based approach for concepts in functional food science such as to critically assess the evidence required such as markers to support the nutrients that positively affect functions in the body. The FUFOSE project focused on six areas: 1) growth, development and differentiation; 2) substrate metabolism; 3) defence against reactive oxidative species; 4) functional foods and the cardiovascular system; 5) gastrointestinal physiology and function; and 6) the effects of foods on behaviour and psychological performance (Diplock *et al.*, 1999). The work generated by the FUFOSE project served as a basis for the Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM) project that ran between 2001 and 2005 (Aggett *et al.*, 2005). The main objective of the PASSCLAIM project was to produce a guidance tool to define the criteria for scientific substantiation of claims in food and food constituents. These criteria included that the food or food constituent should be characterised, human studies are required to substantiate a claim, use of validated markers, totality of data and weight of evidence. The work from these two European projects was instrumental in the development of a harmonised regulatory process on health claims in the European Union in 2006 and had influenced the Codex Alimentarius guidelines which include establishing a common approach for substantiation of health claims (Richardson, 2012).

The Codex Alimentarius Commission, 'Codex' first published guidelines on nutrition and health claims in 1997. Prior to that, there was no internationally agreed definition of health claims. The Codex Alimentarius Commission is an inter-governmental body founded jointly by Food and Agriculture Organisation and World Health Organisation in 1961 for the purpose of protecting public health and to ensure fair practices in food trade. The standards and guidelines established by Codex have a significant impact on global trade as these standards are recognised by World Trade Organisation under the agreement of sanitary and phytosanitary measure (SPS agreement) (World Trade Organisation). The Codex guidelines on health claims have undergone several rounds of revision over the years ranging from re-

defining the different types of health claims to adoption of the scientific substantiation on health claims in 2009 and refining the information in the guidelines (Codex Alimentarius, 1997 (last amended in 2013)).

The development of health claims on food has progressed rapidly in Europe, Japan, the United States, Australia and New Zealand since 2000. Both the United States and Japan introduced a new category of health claims known as ‘qualified health claims’ in 2003 and 2005, respectively (United States Food and Drug Administration, 2003a; Yamada *et al.*, 2008). Qualified health claims are claims that need to be accompanied by a disclaimer as the scientific evidence is considered insufficient. In 2006, the European Commission issued the regulation on nutrition and health claims (EC1924/2006) (European Food Safety Authority, 2006). All health claims on food sold in Europe need to be authorised after the implementation of this regulation. The European Food Safety Authority (EFSA) has established opinion on scientific substantiation and guidance documents to assist the applicants in preparing and submitting the health claims for scientific evaluation since 2010 (European Food Safety Authority, n.d.-b). The Food Standards Australia and New Zealand has also issued a regulation on nutrition and health claims in 2013 which came into force in 2014 (Food Standards Australia and New Zealand, 2016b).

The global development of health claims on food had some influence on the regulatory framework for health claims on food in Southeast Asia. The food authority in the Philippines issued a circular to fully adopt the Codex guidelines on nutrition and health claims in 2007 although there were no further details provided (Republic of the Philippines Food and Drug Administration). The food authorities in Malaysia and Singapore each published a guide on food labelling and advertisement, including health claims on food in 2010 (Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016)). In 2011, the Indonesian food authority issued the claims monitoring regulations (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; National Agency of Drug and Food Control of the Republic of Indonesia, 2011b). The Thai food authority also issued the application on probiotics on food component which includes a definition of health claims and requirements for health claim applications for probiotics as food constituents in the same year (Ministry of Public Health Thailand, 2011). The Vietnamese Food Authority has published a regulation on functional food that includes health claims on food and health supplements in late 2014 (Ministry of Health Vietnam, 2014).

Figure 1.2 illustrates the chronological order on the development of health claims in Codex Alimentarius and major jurisdictions such as Europe, the United States, Australia and New Zealand, Japan and in the Southeast Asia countries which have established health claims regulations and/ or guidelines. The information on SEA is listed in bold in Figure 1.2.

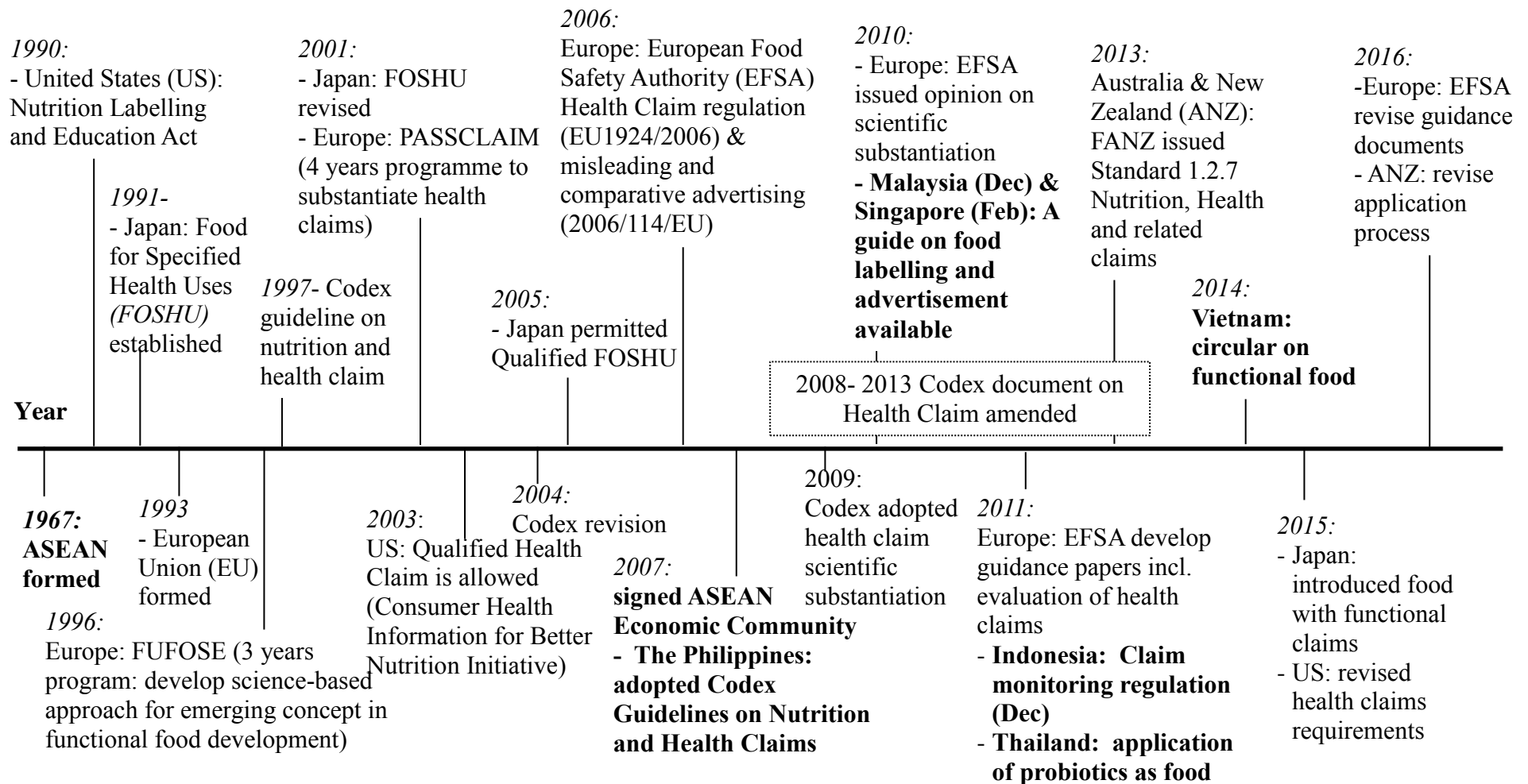


Figure 1.2: Chronological order on the development of health claims on food

Source: Author constructed (Codex Alimentarius, 1997 (last amended in 2013; Diplock *et al.*, 1999; United States Food and Drug Administration, 2000; Shimizu, 2002; European Food Safety Authority, 2006; Republic of the Philippines Food and Drug Administration, 2007; Yamada *et al.*, 2008; Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); European Food Safety Authority, 2011b; Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Food Standards Australia and New Zealand, 2013; Ministry of Health Vietnam, 2014; Association of Southeast Asian Nations (ASEAN) Secretariat, 2015b)

1.3 Existing systems in major jurisdictions for regulating health claims

The changes in regulatory frameworks for health claims in major jurisdictions and the establishment of Codex guidelines on nutrition and health claims in 1997 led to the development of the regulatory systems for health claims on food products worldwide. Health claims on food are subjected to pre-market approval from food regulatory agencies in major jurisdictions such as Europe, the United States, Japan, Australia and New Zealand (United States Food and Drug Administration, 1994 (revised January 2013); European Food Safety Authority, 2006; Consumer Affairs Agency, 2011; Food Standards Australia and New Zealand, as of 18 January 2016). Each food authority has their scientific regulatory framework to administer and evaluate health claims. The following paragraphs will briefly describe the systems in Europe, the United States (US), Japan and Australia and New Zealand. These systems have a longer history of health claims and have been discussed among the scientific and regulatory community previously (Aggett *et al.*, 2005; Asp and Bryngelsson, 2008; Yamada *et al.*, 2008; Ellwood *et al.*, 2010; Gilsenan, 2011; Lalor and Wall, 2011).

1.3.1 European Union

The regulation on nutrition and health claims on food products (EC 1924/ 2006) was issued on 20 December 2006 and was implemented on 1 July 2007 in Europe (European Food Safety Authority, 2006). Under this regulation, health claims in Europe are classified into three categories: 1) Function health claims that describe the role of nutrient/ other substances in growth, development and function of the body, psychological functions, weight-control based on general accepted scientific evidence and well-understood by consumers (Article 13.1) and claims based on newly developed scientific evidence (Article 13.5); 2) Reduction of disease risk claims (Article 14.1a) and 3) Claims relating to children's development and health (Article 14.1b). The scope of this regulation applies to the use of claims in labelling, presentation and advertising of food.

All health claims on food products sold in Europe are required to be authorised by the European Commission (EC) before health claims can be communicated to the consumer. The European Food Safety Authority (EFSA) is responsible for evaluating the scientific evidence supporting each health claim. The health claim applications were submitted (preferably in English) to EFSA via the food authority of each member state in the European Union. EFSA would conduct a completeness check on the application dossier within 30 working days upon

receiving the application before they decided whether the dossier can proceed to scientific assessment by the Panel of Dietetics products, Nutrition and Allergies (NDA Panel) (European Food Safety Authority, 2016a). This completeness check of the application dossier aims to look out for administrative compliance and the information required for scientific assessment. Firstly, a dossier is required to be completed based on the EFSA application form for health claims. Secondly, the critical information required for scientific assessment of health claims needs to be present in the application. This information includes clear identification of the food/ constituent about which the claim is made, clear definition of the claimed effect, identification of risk factors for disease risk reduction claims, and definition of the conditions of use (European Food Safety Authority, 2016b). The key criteria for EFSA health claims evaluation include (i) the food/constituent is defined and characterised; (ii) the claimed effect is based on the essentiality of a nutrient; or the claimed effect is defined and is a beneficial physiological effect for the target population, and can be measured in humans; (iii) a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use) (European Food Safety Authority, 2016b). The opinion of the NDA panel on the health claims should be issued within 5 months from the start of the scientific assessment (excluding the time required for the applicants to provide answers to questions from EFSA, if needed). The opinions on the health claims are published on the EFSA website within 15 working days and all submitted health claims (authorised and unauthorised) are published in the public EU register of claims (European Food Safety Authority, 2016b). Figure 1.3 depicts the application process for health claims in Europe.

European Food Safety Authority

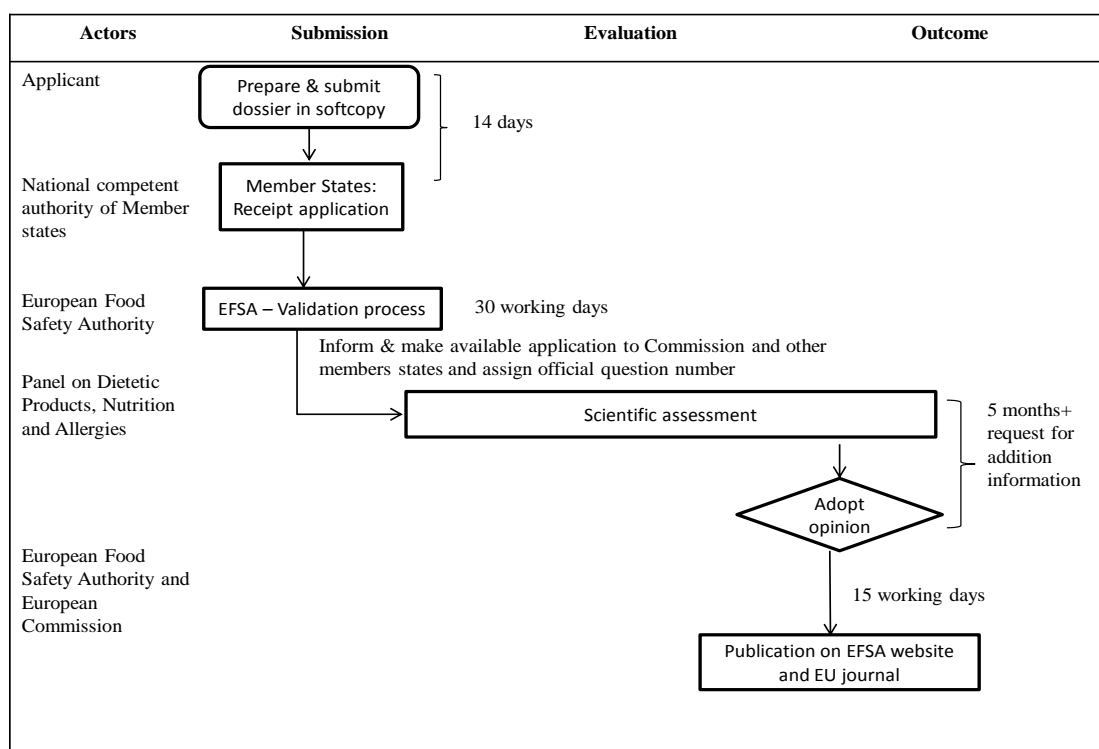


Figure 1.3: Application process for health claims in Europe

Source: adapted from EFSA website (European Food Safety Authority, 2016a)

1.3.2 United States

In the United States (US), there are two different types of health claims; 1) health claims based on significant scientific agreement (SSA) and 2) qualified health claims. Health claims in the US need to contain two elements; 1. a substance and 2. a disease or health-related conditions (United States Food and Drug Administration, 1994 (revised January 2013)). Health claims are limited to disease risk reduction and cannot treat, prevent or cure disease. The scope of the US regulation of health claims applies to conventional food labels and dietary supplement labels (United States Food and Drug Administration, 1994 (revised January 2013)). Any claims made in advertising are under the purview of another federal agency, the Federal Trade Commission (Federal Trade Commission, 1994). Any food product with health claim should not exceed the disqualifying nutrient levels of 13g of fat, 4g of saturated fat, 60 mg of cholesterol or 480 mg of sodium per serving size (United States Food and Drug Administration, Revised as of 1 April 2015a). All health claims need to be

submitted to the US Food and Drug Administration (US FDA) for evaluation before communicating to the consumers.

The health claim needs to meet the significant scientific agreement (SSA) standards under the Nutrition Labelling and Education Act of 1990. That means that the qualified experts in the field agreed that there is strong scientific evidence to support the relationship between a substance and a disease for the health claim (United States Food and Drug Administration, 2009). The food company can also submit health claims based on an authoritative statement by a US government scientific body such as ‘diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers’ (United States Food and Drug Administration, 1994 (revised January 2013)). In contrast, qualified health claims are based on scientific evidence that is credible but that does not meet the SSA standards. Qualified Health Claim must be accompanied by a disclaimer to indicate that the scientific evidence for the claim is not conclusive and the US FDA does not endorse the claim.

Qualified health claims were allowed in 2003 under the Consumer Health Information for Better Nutrition Initiative. This initiative aimed to improve availability and consumer understanding of up-to-date scientific information to aid their purchases. This also came about after the US FDA was challenged in a series of lawsuits on violating commercial speech doctrine (United States Food and Drug Administration, 2003a). In the case of qualified health claims, the US FDA will not take enforcement action against a manufacturer that has labelled its product with a qualified health claim as the agency has issued an enforcement discretion letter (United States Food and Drug Administration, 1994 (revised January 2013)).

The application process and requirements for health claims based on SSA and qualified health claims are quite similar except for the duration of the application process (Ellwood *et al.*, 2010). The health claims based on SSA applications take 540 days to complete while the qualified health claims applications take 270 days (United States Food and Drug Administration, 1994 (revised January 2013)). Figure 1.4 and Figure 1.5 illustrate the processes involved in applying for health claims in the US (United States Food and Drug Administration, Revised as of 1 April 2015a; United States Food and Drug Administration, Revised as of 1 April 2015b).

United States: Health Claims

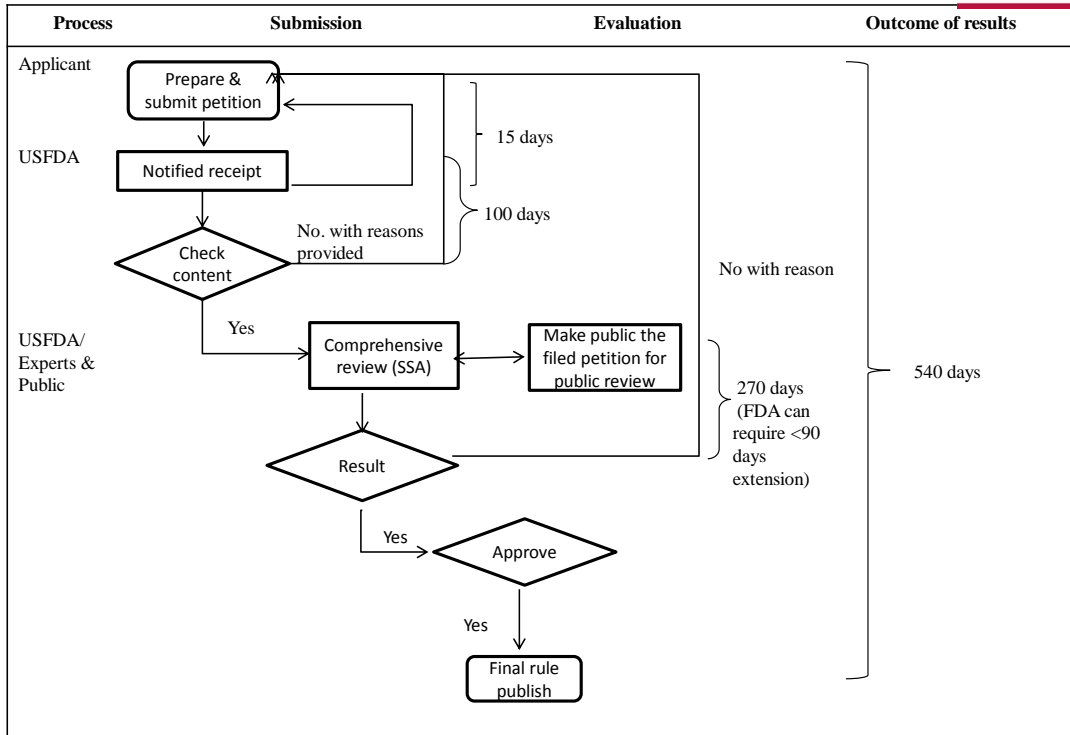


Figure 1.4: Application process for health claims based on SSA in the United States

Source: Author's construction drawing based on information from US FDA United States Food and Drug Administration (Revised as of 1 April 2015a); United States Food and Drug Administration (Revised as of 1 April 2015b)

United States: Qualified Health Claims

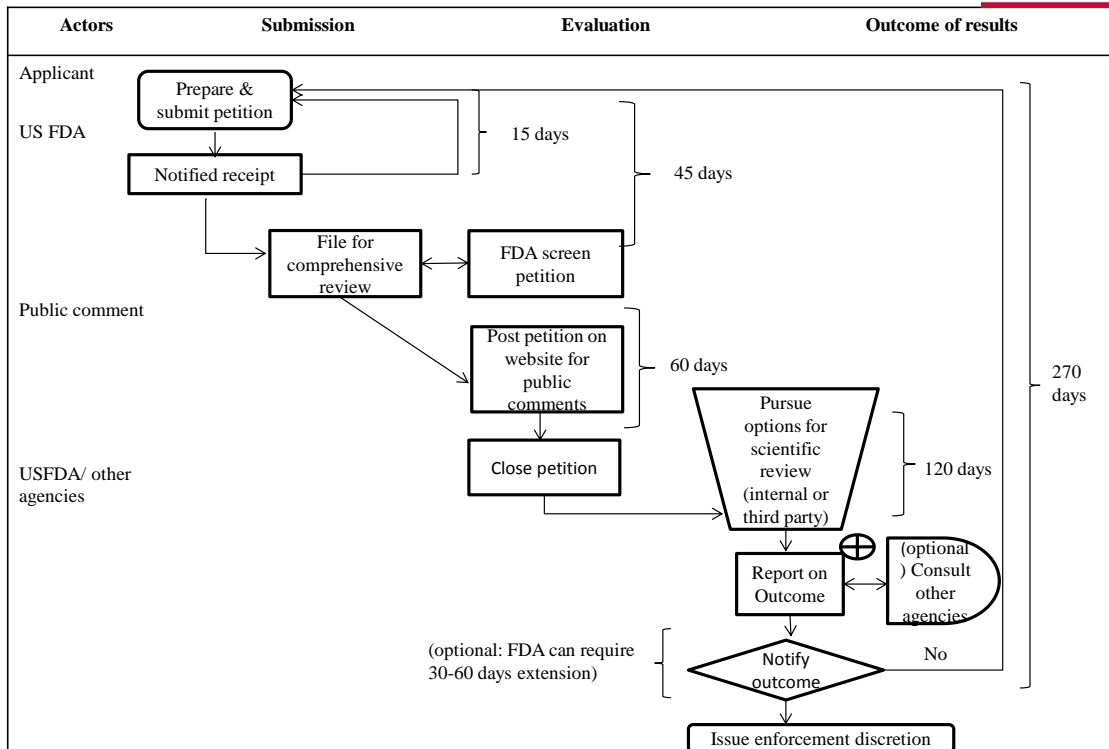


Figure 1.5: Application process for Qualified Health Claims in the United States

Source: Author’s construction drawing based on information from US FDA United States Food and Drug Administration (Revised as of 1 April 2015a); United States Food and Drug Administration (Revised as of 1 April 2015b)

The health claim applications in the US need to justify the benefit of health claims based on a clear definition of the relationship between the substance and disease using relevant human studies, reliable and recognised surrogate endpoints, totality of publicly available scientific evidence, claim supported by significant scientific agreement among recognised body of qualified experts and the prevalence of the disease or health-related condition relevant to the US population (Ellwood *et al.*, 2010; United States Food and Drug Administration, Revised as of 1 April 2015b). Due to limited resources, the FDA can prioritise petitions based on several factors such as a significant impact to the US population, strength of evidence and consumer research to show that the claim is not misleading (United States Food and Drug Administration, 2003b).

One point to note, a structure function claim that refers to a function of the body and does not make reference to a disease, is not considered as a health claim. Hence the structure function claim on food does not need to be authorised by the US FDA (United States Food and Drug Administration, 1994 (revised January 2013)). Examples of structure function claims in the

US are ‘calcium builds strong bones’ or ‘antioxidants maintain cell integrity’ (United States Food and Drug Administration, 2016). This varies from the definition of Codex Alimentarius when nutrition function claims and other function claims are classified as health claims.

1.3.3 Japan

The Japanese regulatory system of health claims comprises two categories of health claims: 1) Food for Nutrient Function Claims (FNFC) and 2) Food for Specified Health Uses (FOSHU) (Masuda, 2014). The FNFC is similar to the Codex nutrient function claims. These claims do not require regulatory approval based on the nutrition labelling standards values (Hayashi, 2015). This is currently limited to 12 vitamins and 5 minerals that are widely accepted by experts (Masuda, 2015). FOSHU are food containing ingredients that provide beneficial effects on physiological functions on the body and are intended to maintain and promote health for healthy people who wish to control their health conditions (Ministry of Health Labour Welfare Japan, n.d.). The health claims were classified into 8 groups; gastro-intestinal conditions, mineral absorption, blood pressure, blood glucose, blood fat, blood cholesterol, bone health and dental health (Yamada *et al.*, 2008).

There have been several changes in the FOSHU programme since 2001. The FOSHU programme accepted different forms of health food such as capsules and tablets, in addition to conventional foods in 2001 (Shimizu, 2002). Since 2005, there are three new groups of FOSHU such as the Standardised FOSHU, Reduction of disease risk FOSHU and Qualified FOSHU based on the strength of evidence (Yamada *et al.*, 2008). The expansion of the FOSHU categories was to align with the Codex guidelines pertaining to the ‘disease risk reduction claims’ and to meet the request from the manufacturers (Shimizu, 2014). Figure 1.6 below provides the explanation on the categories of FOSHU and is from the Consumer Affairs Agency (CAA) website (Consumer Affairs Agency, 2011).





Categories of Food for Specified Health Uses (FOSHU)	
<p>FOSHU</p> <ul style="list-style-type: none"> - Requires detailed review process with scientific evidence for each application. 	
<p>Standardized FOSHU</p> <ul style="list-style-type: none"> - No requirement of detailed review process for food products meeting the established standards and specifications. - Must be accompanied by sufficient accumulation of scientific evidence. - For efficiency: short cut process for products whose safety of use already approved. 	
<p>Reduction of disease risk FOSHU</p> <ul style="list-style-type: none"> - Requires detailed review process with scientific evidence for each application. - Permitted for products whose ingredients clinically and nutritionally established to reduce a risk of certain disease (i.e. calcium for osteoporosis and folic acid for neural tube defects) 	
<p>Qualified FOSHU</p> <ul style="list-style-type: none"> - Requires detailed review process with scientific evidence for each application. - Permitted for products with ingredients showing certain health effects but not reaching the established standards for FOSHU approval. - Labelled as ‘Qualified Food for Specified Health Uses’. 	

Figure 1.6: Categories of Food for Specified Health Uses (FOSHU) in Japan

Source: Consumer Affairs Agency (2011)

Food labels with health claims need to declare notice and warning on adverse effects due to overdosing and should not imply prevention, treatment and diagnosis of diseases. In addition, the products with Qualified FOSHU need to indicate that the scientific evidence of the health claim is inconclusive on the labels (Yamada *et al.*, 2008). To help consumers differentiate the different categories of FOSHU, the Qualified FOSHU logo is different compared with the other FOSHU logo.

Each FOSHU application is evaluated by expert panels in the government and it is approved individually by the CAA which was set up in 2009 to protect the interest of consumers (Masuda, 2014). The approvals of FOSHU are based on demanding requirements such as the effectiveness of the product based on scientific evidence, the safety of the product with safety studies and history of use, the analytical determination of the effective substance, compatibility with product specification and reasonable duration of consumption (Shimizu, 2014). This approval process for each FOSHU application takes 6 months to 3 years as they have to undergo rigorous review on safety and efficacy (Hayashi, 2015). Figure 1.7

illustrates the application flow for FOSHU application in Japan (Consumer Affairs Agency, 2011).

Japan: Food for Specified Health Uses (FOSHU)

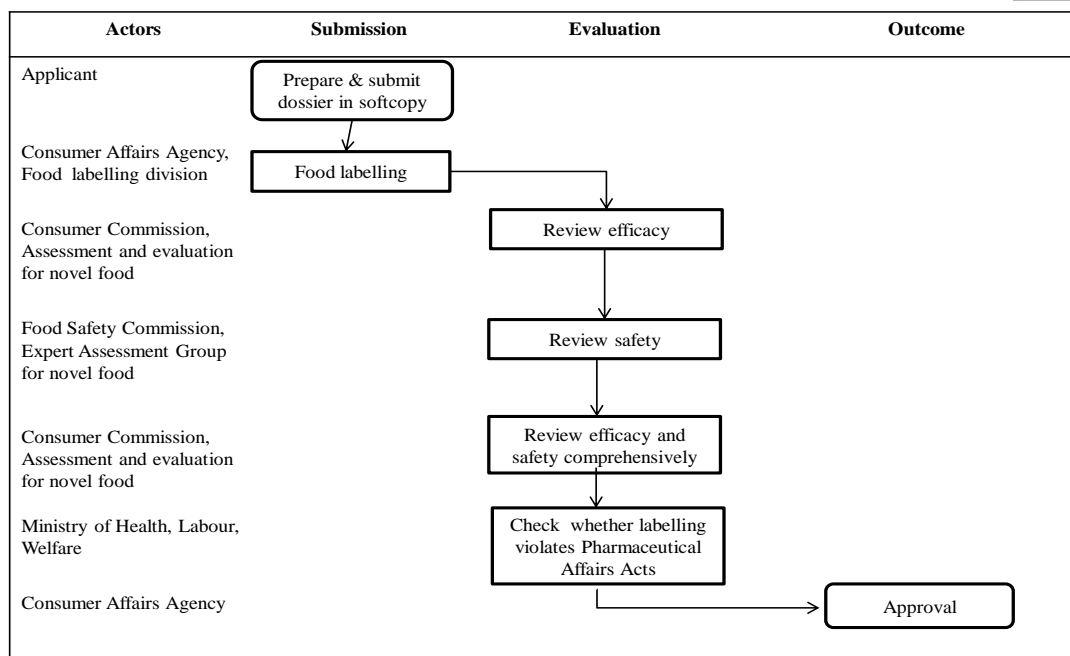


Figure 1.7: Procedure flow for Food with Specified Health Uses (FOSHU)

Source: Consumer Affairs Agency (2011)

In April 2015, the CAA established a new category of health claim labelling known as the food with functional claims (FFC). This new category aims to increase the number of foods with functional claims and to promote healthy, longer lived population and it was part of the Japan Revitalisation Strategy (also as known as ‘Abenomics’). The new FFC registration process is faster and more affordable for food manufacturers. These claims are not individually approved by the CAA and the manufacturers are required to provide CAA with the required information 60 days prior to the launch of the FFC-labelled product. The manufacturers bear the responsibilities on the scientific accuracy of the health claims under the FFC. The guidelines on labelling such as the amount of the effective food constituent required, warning and disclaimer statement must be strictly followed (Hayashi, 2015).

1.3.4 Australia and New Zealand

The Food Standards Australia New Zealand (FSANZ) issued the regulation on nutrition, health and related claims on 18 January 2013 (Standard 1.2.7) after 10 years of work (Food

Standards Australia and New Zealand, 2013). Food businesses were provided with a 3-year transition period to comply with the regulation by 18 January 2016 (Food Standards Australia and New Zealand, as of 18 January 2016). The scope of this regulation includes claims made on labels and advertisements made on food. There are two types of health claims in Australia and New Zealand (ANZ), namely; 1) general level health claims (GLHC) and 2) high level health claims (HLHC) (Food Standards Australia and New Zealand, as of 18 January 2016). The main difference between these two health claims in ANZ is that HLHC refer to a disease or biomarker of a disease and GLHC do not. The definition of HLHC and GLHC are listed below:

1. HLHC refers to a nutrient/ substance in food and its relationship to a serious disease or to a biomarker of a serious disease such as ‘Diets high in calcium may reduce the risk of osteoporosis in people 65 years and over’.
2. GLHC refers to a nutrient/ substance in a food and its effect on health such as ‘calcium is necessary for normal teeth and bone structure’.

The food carrying a general or high level health claim must meet the nutrient profiling score criterion (NPSC) and the health claims are not allowed for foods high in saturated fat, sugar or salt (Food Standards Australia and New Zealand, as of 18 January 2016). The health claims must include the statements on the form of the food and dietary context statement as indicated in the regulation (Food Standards Australia and New Zealand, as of 18 January 2016).

All health claims must be supported by an established food and health relationship that is substantiated using systematic review. The systematic review needs to include the search strategy (include the inclusion and exclusion criteria), a table with key information of each included study, assessment of the quality of each included study, demonstrate a consistent association between the food and health effect based on high quality studies, show the amount of food to achieve the health effect can be consumed based on a normal diet of Australian and New Zealand populations (Food Standards Australia and New Zealand, as of 18 January 2016).

Food businesses are required to notify FSANZ before making GLHC (Food Standards Australia and New Zealand, 2015c). However, these GLHC do not require the approval of the Food Standard Australia and New Zealand. The records of the systematic review should be provided to the enforcement authority in Australia and New Zealand, if requested by the

authority to check for compliance. Figure 1.8 illustrated the process involved in notifying FSANZ on the use of GLHC (Food Standards Australia and New Zealand, 2015c) .



ANZ: General Level Health Claims (via notification)

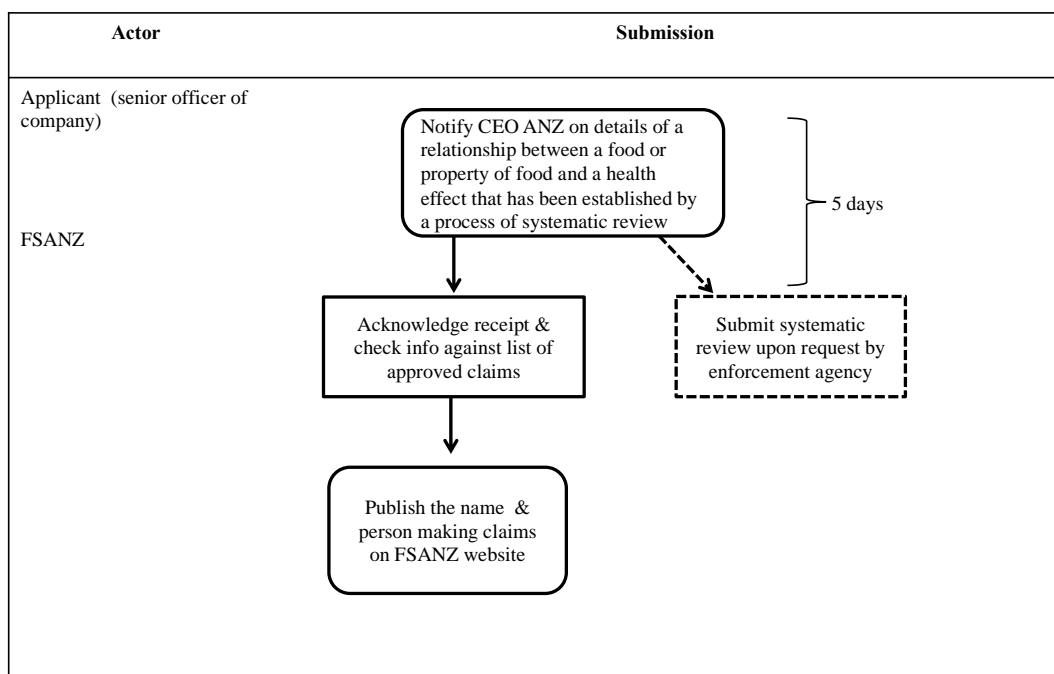


Figure 1.8: Notification process on the use of General Level of Health Claims

Source: Author’s construction drawing based on information from FSANZ website (Food Standards Australia and New Zealand, 2015c)

New high level health claims or variations in the pre-approved health claims are subjected to ‘High Level Claims Variation Procedure’ which takes 9 months from the start of the assessment (refer to Figure 1.9 below) (Food Standards Australia and New Zealand, 2016a). The health claims scientific advisory group provides advice to FSANZ on technical and scientific matters to assess the food health –relationship underpinning general or high level claims (Food Standards Australia and New Zealand, 2015a). In March 2016, FSANZ has started to charge the applicant a fee of AUD50k – 125K for a high-level claim variation procedure to recover their costs. The amount varies depending on the number of hours FSANZ spend to evaluate the application. The applicant can also opt to pay more to expedite the assessment process instead of the application being put in the ‘queue’ for assessment (Food Standards Australia and New Zealand, 2016a).

ANZ: High Level Health Claims

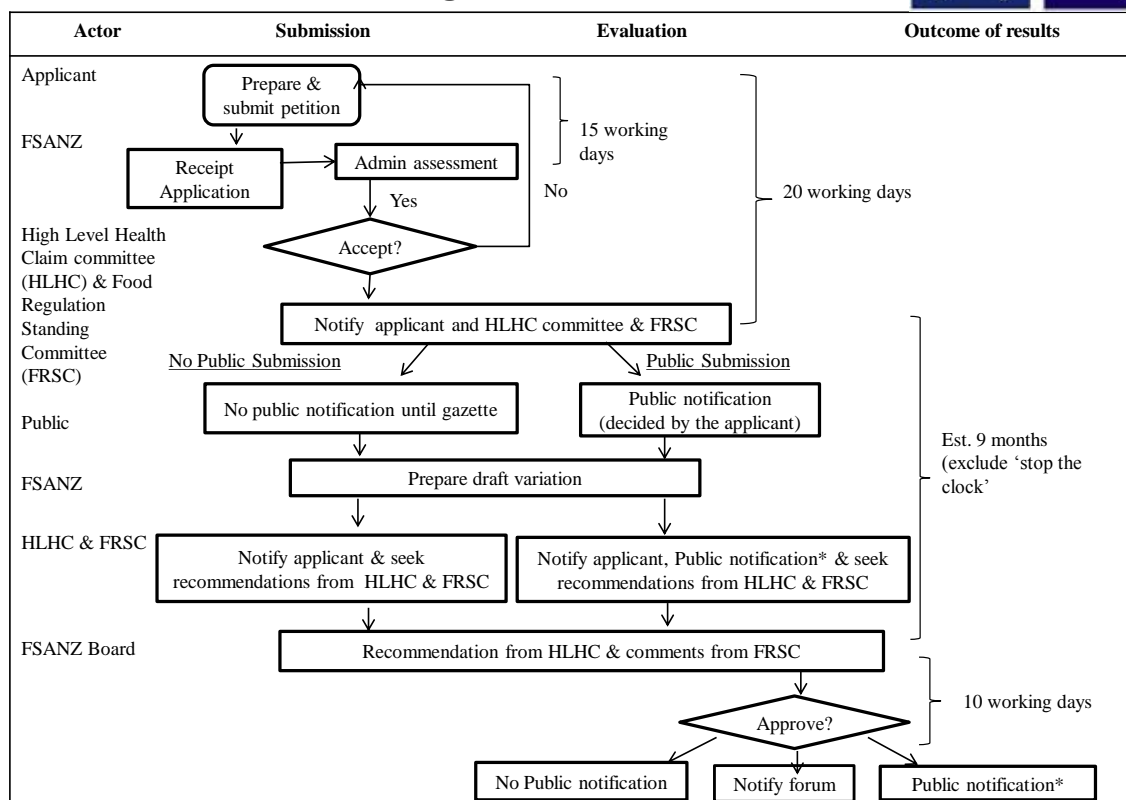


Figure 1.9: High Level Claim Variation Procedure

Source: Food Standards Australia and New Zealand (2016a)

1.4 Issues with the existing systems of frameworks in major jurisdictions

Clearly, there are differences in the regulatory frameworks among the major jurisdictions such as Europe, the United States, Japan, Australia and New Zealand (United States Food and Drug Administration, 1994 (revised January 2013); European Food Safety Authority, 2006; Consumer Affairs Agency, 2011; Food Standards Australia and New Zealand, as of 18 January 2016). These differences include the scope, the procedures on applying for new health claims and the evidence required to substantiate the health claims. Both the frameworks from the United States and Japan are deemed to be more industry- friendly as qualifying statements are allowed. This has helped the food industry in these countries to introduce food products with health claims faster to consumers (Lalor and Wall, 2011).

The scientific substantiation and evaluation of health claims have been subjected to debates between the food industry and EFSA. The food industry in Europe raised concerns about the lack of certainty, transparency and clarity on the criteria for health claims substantiation and the lexicality of the claims (Gallagher, 2011; Richardson, 2012). The food industry has spent large amounts of money conducting research and development to generate evidence to

substantiate health claims, only to have their submissions rejected by EFSA. To date, the EU register of nutrition and health claims (last checked on 11 Jun 2016) showed that 8 of 100 new health claim applications submitted to EFSA have been rejected (European Food Safety Authority, n.d.-a). The health claims based on newly developed scientific evidence (Art 13.5) have the least number of claims authorised by EFSA and only two out of 95 submitted claims on this category were approved. In contrast, the nutrient claims based on generally accepted scientific evidence (Article 13.1) have the most number of claims being authorised. This could potentially stifle innovation.

1.5 Consumer understanding about health claims

Knowledge of the consumers' understanding about health claims is limited, though the health claim is aimed at benefitting the consumers' decision-making process to achieve a healthy diet. Most of the studies which have investigated this are conducted in Western countries and are focused on consumers' responses to and perceptions of nutrition and health claims. It is challenging to measure understanding about health claims as processing of information by consumers is complex. There is a constant interaction between externally obtained information and internal knowledge present in the memory (Leathwood *et al.*, 2007). Many consumer studies (Nocella and Kennedy, 2012; Lähteenmäki, 2013; Wills *et al.*, 2012) have suggested that the understanding of health claims is multi-factorial.

Several review papers have reported that the factors influencing the perception of health claims are personal characteristics such as gender, age, education, personal relevance, attitudes towards health and nutrition, socio-economic status, familiarity with the ingredient, knowledge on nutrition issues, wording of the claims, length of exposure of health claims and the difference in country and cultures (Nocella and Kennedy, 2012; Lähteenmäki, 2013). Previous studies suggested that consumers in Belgium understood and preferred more context-specific health claims (Verbeke *et al.*, 2009) while a study among Irish consumers suggested that they preferred simpler nutrition and health claims such as structure-function and content claims (Lynam *et al.*, 2011). Studies have shown that more females read food label more frequently and were more favourable towards health claims due to general interest in health and for the health of their family (Lalor *et al.*, 2011; Lynam *et al.*, 2011; Nocella and Kennedy, 2012; Wills *et al.*, 2012). Sverderberg and Wendin (2011) showed that concerns for family health among a group of Swedish consumers influenced their decision to read and understand health claims. The effectiveness of communication of health claims could be improved by the use of visual aids such as graphics and concise messaging in prominent

locations on the packaging (Geiger, 1998; Hooker and Teratanavat, 2008). The carrier product used to test health claims has an influence on the understanding of the health claims and health claims were accepted and perceived positively on food products with healthier image such as bread, yoghurt, and breakfast cereal instead of meat replacers, biscuits and ice-cream (Dean *et al.*, 2011; Wills *et al.*, 2012; Lähteenmäki, 2013).

Consumer understanding of nutrition and health claims and perception of benefits differed substantially by country in a large- scale cross national study in Italy, Germany, the UK and the US (van Trijp and van der Lans, 2007). The study found that the UK consumers could not understand the claims on stress but the US consumers could understand the claim on stress. The German consumers could easily understand the claims on infection whereas the rest of other countries did not find these claims to be easily understood. The study also found that the US was the only country where the credibility of nutrition and health claims was slightly lower than the credibility of a taste claim. Another study conducted in Germany measured the understanding of health claims on yoghurt using open answers (Grunert *et al.*, 2011). The team found that respondents with positive attitudes to functional foods had a scientifically inaccurate understanding about health claims compared to respondents with neutral or negative attitudes. This would suggest that higher motivation leads to deeper processing of message and inferences beyond what is being said in the claims (Grunert *et al.*, 2011). Many studies have reported that attitudes to functional food and health vary in different countries (Bech-Larsen and Grunert, 2003; van Trijp and van der Lans, 2007).

1.6 Research focus on Southeast Asia (SEA)

The Association of South East Asian Nations (ASEAN) aims to be a single market to allow free movement of goods, services and manpower under the formal establishment of the ASEAN Economic Community in 2015 (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015b). ASEAN consists of ten countries in Southeast Asia, namely, Brunei Darussalam, Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam, and with a combined population of over 622 million with a multitude of cultures and languages (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015b; Association of Southeast Asian Nations (ASEAN) Secretariat, n.d.). The existing regulatory frameworks for health claims on food in SEA are unclear as it is difficult to have access to the regulations of some SEA countries. This is due to the different languages used in SEA. In addition, there is limited knowledge on the regulatory frameworks for substantiating and approving health claims in this region. The

regulations or guidelines on health claims in some SEA countries are issued without further details or guidance documents to help the applicants to prepare the health claim application. The current thinking and practices on the regulations and/ guidelines on health claims are unknown to the food industry and the scientific community. This lack of information, could potentially create challenges for the food industry and scientific community to generate evidence to support health claims application, and could restrict the food industry from selling the products with health claims in SEA. This issue contradicts the aim of AEC which is to have free movement of goods and trade across Southeast Asia. Eventually, the consumers in the SEA region could be deprived of the opportunities to have access to foods of better nutritional quality, supported by the use of relevant health claims on packaging.

Due to the recent advent of health claims in the region, there is also a knowledge gap on the Asian consumers' understanding of health claims. There is a need for research in this area as it has the potential to discover the current status on the understanding on health claim and regulatory frameworks in SEA region. This knowledge could assist the food industry to better communicate the benefits of food and the constituents effectively to the SEA consumers. In due course, health claims should benefit the consumers and help to ensure they are able to make informed food choices.

Both the regulatory frameworks and the understanding about health claims on food affect the availability and intended purpose of health claims in SEA. Currently, there is a lack of information on how health claims are regulated and approved in Southeast Asia and whether the Asian consumers understand health claims. The Asian mothers were selected for this research as the earlier studies have reported that more females esp. those with families tended to read food labels as compared to males (Williams, 2005; Lalor *et al.*, 2011; Svederberg and Wendin, 2011). In SEA, the milk powder for children display health claims on their food labels. Thereby it is more relevant to find out the understanding on health claims among the major purchasing demographic. These 'gaps' in knowledge have implications for the consumers, for the regulatory community, food industry and researchers as it impacts trade in the Southeast Asia region, limits the communication on nutritional benefits of food, and also potentially discourages innovation to develop specialised food products with potential health benefits for the Southeast Asian consumers. It is currently uncertain whether the existing regulatory frameworks on health claims in SEA are either industry-friendly, consumer-friendly, neither or both.

1.7 Research aims and objectives

The research topic is on the health claims on food products in SEA. This research, funded by the Singapore Economic Development Board and Danone Asia Pacific Holding Pte Ltd, aims to answer the following two research questions:

‘How are health claims on food products in SEA substantiated and evaluated in SEA?’ and

‘Do the Asian consumers understand health claims on food?’

The research questions guided the formulation of the aims and objectives of this research which are as follows:

Overall aim: To have a better understanding on how the information flow through the existing regulatory frameworks in SEA effectively communicates understanding to the consumers.

Aim 1: To review the health claim regulations in SEA and from major jurisdiction such as European Union, United States, Australia and New Zealand, Japan.

Objectives:

- a) Understand how health claims are administered in various countries, including substantiation and evaluation
- b) Identify the convergences and divergences between the regulatory frameworks for health claims in SEA, Codex and major jurisdictions

Aim 2: Investigate the current practices and perspectives of the regulatory frameworks for new health claim applications in SEA.

Objectives:

- a) Understand the processes of health claim substantiation and evaluation in various SEA countries;
- b) Identify the factors affecting the approval of health claims; and
- c) Understand the challenges faced by the clusters of stakeholders such as food regulators, key opinion leaders, policy makers and representatives from food associations and scientific organisations

Aim 3: Investigate Asian mothers’ understanding of health claims and the settings of local regulatory frameworks

Objectives:

- a) Understand the current status of the knowledge, perception and attitudes towards health claims
- b) Identify the mothers' current knowledge and trust of the regulatory process and framework;
- c) Identify factors affecting the understanding of health claims

Aim 4: Propose a conceptual harmonised regulatory framework on health claims for foods in SEA

Objectives:

- a) Provide a clear and transparent structure which provides confidence for the food consumers in health claims
- b) Encourage innovation in the food industry in the development of healthy food choices
- c) Provide a common basis for the regulatory community in SEA to discuss on a harmonised approach to administer health claims which could facilitate free trade in the SEA region

1.8 Introduction to methodological approach

This research consists of three methods namely review, semi- structured interviews and focus groups. First, a review of the literature, available regulations and guidelines on health claims in major jurisdictions and SEA countries, was conducted to better understand the existing regulatory frameworks and identify the barriers that impact the health claim applications such as different processes, requirements of the scientific evidence and evaluation criteria (Chapter 2). The convergences and divergences between the regulatory frameworks on health claims in SEA and the frameworks from the developed countries were compared using the collected information. Lalor and Wall (2011) applied the above method to review and compare the scientific and regulatory environments for nutrition and health claims on foodstuffs in the USA, Japan and the European Union.

Second, semi- structured interviews on scientific substantiation of health claims and their evaluation were conducted among the different clusters of key stakeholders who have experience with health claim application and evaluation in the SEA region based on the flow of health claim applications (Chapter 3). Stakeholders ranged from representatives from the food association filling in the application, to the regulators involved in the administration, to

the key opinion leaders, policy makers, and representatives from scientific organisations involved in the evaluation of health claims in the country. Detailed information was gathered from these key stakeholders to understand the practices and perspectives on health claim evaluation (Chapter 3). Interviews are commonly applied by sociology and/ policy studies to understand the current situation and gather perspectives from different stakeholders (Massa and Testa, 2008; Miguel *et al.*, 2014). For instance, Massa and Testa (2008) interviewed stakeholders such as entrepreneurs, academics, and policy makers in Italy to investigate their perspectives on innovation to provide new insight into an issue while Miguel *et al.* (2014) interviewed pharmacists from five European countries to compare policies and practices on how prescription-only medicine was dispensed across Europe.

Third, focus group discussions were conducted among Asian mothers to assess their understanding about health claims and factors affecting the understanding of health claims (Chapter 5). The Asian mothers were selected based on two reasons. Firstly, there is currently no or limited data on this research topic amongst Asian populations. Hence this research focused on a specific group of consumers, Asian mothers, using qualitative method (focus groups) to provide an in-depth understanding of this topic. Secondly, health claims are commonly found on milk powder for children in SEA. These mothers were selected based on the fact that they bought milk powder for their child aged 3 years and above¹ and claimed to read food labels. It was important to find out whether these Asian mothers who claimed to read food labels, could understand health claims. This could help understanding whether health claims on food aid consumers to make informed food choices for their children. The understanding of the health claim statement was measured based on how the mothers would explain a claim to their friends via open- ended questions. This approach to measuring the understanding on health claims was adapted from the Consumer Understanding Test method that was developed by Danone, based on principles recommended by the International Life Science Institute (Grunert *et al.*, 2011).

Both qualitative methods such as the semi-structured interviews and focus group discussions, provided in-depth and rich insights on the regulatory frameworks for health claims in SEA and the Asian mothers understanding on health claims which are currently understudied. Figure 1.10 describes the details of this research.

¹ (to satisfy the Indonesian regulation on health claims where health claims are not permitted on food for children aged less than 3 years).

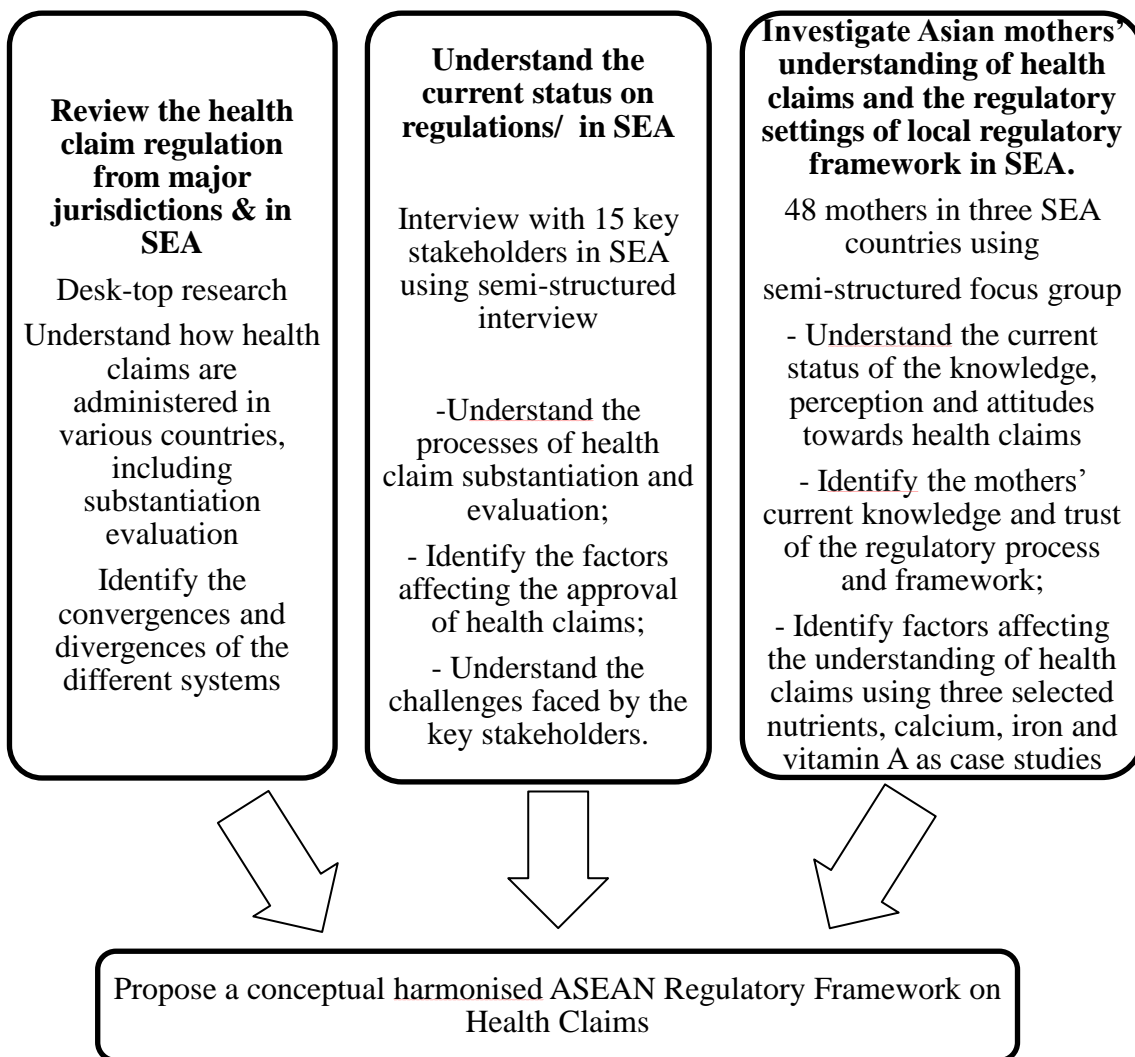


Figure 1.10: Schematic representation of this study

1.9 Outline of this thesis

The thesis begins with the landscape analysis of the existing regulatory frameworks on health claims in SEA (**Chapter 2**). The barriers and opportunities in the various frameworks in SEA are highlighted in the same chapter. **Chapter 3** reports the findings on the current practices and perspectives on health claims substantiation and evaluation in SEA from the interviews with the key stakeholders in SEA. **Chapter 4** focuses on the Asian mothers' understanding about health claims. **Chapter 5** is concerned with the proposed conceptual framework on the regulatory framework on health claims for SEA region. The final chapter summarises the main findings of this research project, anticipates the future of health claims, discusses the implications of the findings and makes recommendations for future research.

Chapter 2 Health Claims on food products: the regulatory frameworks, barriers and opportunities in Southeast Asia²

2.1 Abstract

The Association of South East Asian Nations (ASEAN) aims to act as a single market and allow free movement of goods, services and manpower by Year 2015. The purpose of this paper is to present an overview of the current regulatory framework on health claims in Southeast Asia (SEA) and to highlight the current barriers and opportunities in the regulatory frameworks in the ASEAN. To date, six countries in SEA, i.e. Indonesia, Malaysia, the Philippines, Singapore, Thailand and Vietnam have regulations and guidelines to permit the use of health claims on food products. There are inconsistencies in the regulations and the types of evidence required for health claim application in these countries. A clear understanding of the regulatory frameworks in these countries may help to increase trade in this fast-growing region, and to provide directions for food industry and the regulatory community to develop and market food products with better nutritional quality tailored to needs of the Southeast Asian consumers.

Key words: Health claims, regulatory frameworks, Southeast Asia, food trade, food industry

² This chapter has been published in *Nutrition Reviews*. The content in this chapter is expanded from the paper to include discussion on Vietnam which was not available when the paper was published.

2.2 Introduction

The Association of South East Asian Nations (ASEAN), made up of a collective population of 622 million, consists of ten countries in Southeast Asia (SEA) namely Brunei Darussalam, Cambodia, Indonesia, Laos PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015b). The ASEAN has an overarching integration objective to be a single market to allow free movement of goods, services and manpower by the Year 2015 (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015b). The ASEAN Trade in Goods Agreement (ATIGA) was signed by the 10 SEA countries since 2009. The agreement which aims to achieve free flow of goods in ASEAN, includes tariff liberalisation, removal of non-tariff barriers, trade facilitation, customs under the agreement (Association of Southeast Asian Nations (ASEAN) Secretariat, 2009b).

All the 10 SEA countries are members of the World Trade Organisation (World Trade Organisation, n.d.-a). The World Trade Organisation under the Sanitary and Phytosanitary Measures Agreement recognised the Codex Alimentarius Commission as the relevant standard-setting organization for international food safety (World Trade Organisation, n.d.-b). The Codex Alimentarius Commission (the “Codex”) is an inter-government body established by the Food and Agriculture Organisation and the World Health Organisation in 1961. The Codex Alimentarius is a collection of international food safety standards, guidelines and code of practices adopted by the Codex Alimentarius Commission to protect the health of consumers and ensure fair practices in the international food trade (Codex Alimentarius, n.d.). To facilitate international trade and a freer movement of goods among the countries, it is important for the countries to harmonise food regulation and adopt internationally agreed standards such as those developed by the Codex Alimentarius. Codex guidelines on Nutrition and Health claims have been adopted in 1997 and the recent revision updated in 2013 (Codex Alimentarius, 1997 (last amended in 2013)).

The regulatory frameworks on health claims encompass several different aspects of food regulations such as the procedures to apply for new health claim, the types of scientific evidence required for health claims substantiation, the process for evaluating the scientific evidence which lead to approval or rejection of the new health claims, and the enforcement actions in place to ensure that the health claims on food comply with local food regulations. To date, there is limited or no knowledge of the regulatory frameworks in SEA and the process for implementing food regulations. This lack of information could potentially restrict the free movement of goods across SEA, thereby restricting access of consumers in this

region to foods of better nutritional quality. The purpose of this chapter is to provide an overview of the regulatory frameworks on health claims on food products in SEA and to highlight the current barriers and opportunities in the various regulatory frameworks in the ASEAN setting.

2.3 Existing regulatory frameworks for the health claims for food products in SEA

To date, six countries in SEA namely Indonesia, Malaysia, the Philippines, Singapore, Thailand and Vietnam each permit the use of some forms of health claims on food products today (Ministry of Health Vietnam, 2014; Tee, 2014). Regulations and guidelines on health claims have been published for each of these five countries except the Philippines which, as indicated on the official website of the Philippines Food and Drug Administration, have adopted the full standards on nutrition and health claims issued by the Codex Alimentarius Commission (Republic of the Philippines Food and Drug Administration, 2007). Three SEA countries, Indonesia, Malaysia and Singapore have published application forms for new health claims (Ministry of Health Malaysia, 2010; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Agri-Food and Veterinary Authority of Singapore (n.d-b)). The application forms apply to all types of health claims applications such as nutrient function claims, other function claims etc. The health claim application forms for Indonesia, Malaysia and Singapore are available in Appendix 1. There is no official guideline on health claims issued in the rest of the four SEA countries belonging to ASEAN. Hence the procedures for approval and regulation of health claims on food products in these countries are unclear. This lack of information could lead to different approaches and practices (Aggett *et al.*, 2012).

2.4 Differences among the existing frameworks in SEA

There are several areas of divergences within the existing regulation and guidelines governing health claims in the six SEA countries that have them. This could affect food trade among the countries in the SEA region as different food regulations potentially create barriers for the food products to be sold across the different markets because of differing labelling requirement, permitted health claims etc.

2.4.1 Different definitions, scopes and objectives

Codex Alimentarius (1997) defines a health claim as ‘a representation that states, suggests, or implies a relationship exists between a food and health’ (Codex Alimentarius, 1997 (last amended in 2013)). Health claims are categorised into three groups: (1) nutrient function claims, (2) other function claims and (3) reduction of disease risk claims. The Codex Alimentarius also states that ‘health claims must be consistent with national health policy,

including nutrition policy, as well as support for such policies'(Codex Alimentarius, 1997 (last amended in 2013). In general, health claims on food products aim to help consumers make informed food choices to achieve a healthy diet.

Table 2.1 and Table 2.2 show some of the inconsistencies in the definitions of health claim as well as the scope and objectives of the regulations and guidelines for health claims in the six SEA countries that have them.

Standard/ country	Definition of health claim	Types of health claims	Others	References
Codex standard	Any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health	Nutrient function Other function Reduction of disease risk	Nil	(Codex Alimentarius, 1997 (last amended in 2013; Republic of the Philippines Food and Drug Administration, 2007)
Indonesia	Claim state the relationship of food or substances contained in food to health	Nutrient function Other function Reduction of disease risk	Nil	(National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; National Agency of Drug and Food Control of the Republic of Indonesia, 2011b)
Malaysia	No definition	Nil	“Nutrient function” claims and “other function” claims classified under “Nutrition” claims	(Ministry of Health Malaysia, 2010)
The Philippines, Singapore	Any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health	Nutrient function Other function Reduction of disease risk	Nil	(Republic of the Philippines Food and Drug Administration, 2007; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016))

Thailand	Image illustration, picture, artificial mark, mark, trademark, or any statements appeared on the label in connection with food, food component, or nutrient that are associated directly and indirectly with health	Nutrient function Other function Reduction of disease risk	Nil	(Ministry of Public Health Thailand, 2011)
Vietnam	No definition	Not listed	Nil	(Ministry of Health Vietnam, 2014)

Table 2.1 Summary of health claim definitions in Southeast Asia countries

Standard/ country	Scope	Objectives	References
Codex	All foods Food labels Advertisement (if required by local authorities)	To provide truthful and non-misleading information to aid consumers in choosing healthful diets	(Codex Alimentarius, 1997 (last amended in 2013))
Indonesia	Processed foods with claim declaration Includes labels and advertisements	To protect the public from misleading claims on labels and advertising of processed foods	(National Agency of Drug and Food Control of the Republic of Indonesia, 2011a)
Malaysia	Unavailable	Unclear	(Ministry of Health Malaysia, 2010)

Standard/ country	Scope	Objectives	References
Singapore	Food labels and advertisements	Provide food importers, manufacturers and retailers with a better understanding of the labelling requirements of the Food Regulations, as well as the permitted and prohibited claims for use in food labels and advertisements	(Agri-Food & Veterinary Authority, 2010 (with amendments to 2016))
Thailand	Unavailable	Unavailable	(Ministry of Public Health Thailand, 2011)
Vietnam	Functional foods consisting of supplemented food, health supplement, medical food and food for special dietary uses	Regulate activities of manufacture, trade, product announcement, labelling and instruction for use	(Ministry of Health Vietnam, 2014)

Table 2.2 Scope and objectives of health claim regulations and guidelines in Southeast Asia countries

The Vietnam regulation on functional food does not have the definitions or types of health claims (Ministry of Health Vietnam, 2014). Malaysia does not have a health claim definition and the ‘nutrient function claim’ and ‘other function claims’ are classified under ‘nutrition claims’. The reduction of the disease risk claim is not permitted in Malaysia (Ministry of Health Malaysia, 2010). This classification of the ‘nutrient function’ and ‘other function’ claims as nutrition claims in Malaysia differs from the classification of health claims in the Codex standards. Indonesia is the only country among the six SEA countries with regulation on health claims that stated the scope and objectives of the regulation. The objective of the Indonesian regulation is mainly to protect consumers from misleading claims (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a). These ambiguities in the regulations and guidelines could potentially affect how the regulations are enforced in practice.

The Codex Alimentarius Commission and food authorities from the major jurisdictions such as the European Food Safety Authority (EFSA), the United States Food and Drug Administration (USFDA), the Food Standards Australia & New Zealand and the Japanese Consumer Affairs Agency each have their established regulatory frameworks through which to approve health claims (United States Food and Drug Administration, 1994 (revised January 2013); Codex Alimentarius, 1997 (last amended in 2013); European Food Safety Authority, 2006; Food Standards Australia and New Zealand, as of 18 January 2016). These regulatory frameworks are well-recognised as these frameworks have been widely discussed within the scientific community as well as within the regulatory community (Asp and Bryngelsson, 2008; Hasler, 2008; Gallagher, 2011; Gilsenan, 2011; Lalor and Wall, 2011; Flynn, 2012).

The definitions, scopes and objectives in the major jurisdictions where health claims are more established, are clearly stated within the regulations. The scope of the health claim regulations in these major jurisdictions cover food labels and advertisement. The objectives of their regulations are to protect the consumers and to facilitate informed food choices and encourage food innovation within the food industry and to permit free movement of foods across countries. Nevertheless, there are differences among the definitions of the health claims issued by regulatory agencies in these countries.

The European Union (EU) which currently consists of 27 countries, implemented a framework on nutrition and health claims in January 2007. Developed by the EFSA (European Food Safety Authority, 2006), the framework aims to provide a high degree of protection for consumers to ensure clear and accurate information on food products and to

facilitate free movement of goods within the European Union. All health claims used or to be used on food products have to be submitted for scientific evaluation by EFSA. Since 2006, health claims are classified into three categories; Type 1, which include claims based on generally accepted scientific evidence well understood by consumers (covered by Article 13.1), and claims based on newly developed scientific evidence (covered by Article 13.5); Type 2, which include claims on reduction of disease risk (covered by Article 14.1a) and Type 3, which include claims on children's development and health (covered by Article 14.1b) (European Food Safety Authority, 2006).

The United States (US) Food and Drug Administration has authorized health claims for labels of food products since 1993. Health Claims characterise the relationship between a substance (food or food component) and a disease or health-related condition. Most health claims are scientifically reviewed and must meet the significant scientific agreement standards (SSA) (e.g., strong evidence) before such a claim can be used on a food product. Qualified Health Claims are based on scientific evidence that does not meet the SSA standard, and therefore qualifying language is included as part of the claim to reflect the level of scientific evidence. Qualified health claims also undergo premarket scientific review (United States Food and Drug Administration, 1994 (revised January 2013)).

Food Standards Australia and New Zealand (FSANZ) published Standard 1.2.7, Nutrition, Health and Related claims, in January 2013. The new standard has classified health claims into two categories such as general level health claim and high level health claims. High level health claims refer to a nutrient or substance in a food and its relationship to a serious disease or to a biomarker of a serious disease. High level health claim require pre-market approval from FSANZ (Food Standards Australia and New Zealand, as of 18 January 2016).

Putting things in a wider perspective, the differences between the definitions, the scopes and the objectives of health claim regulations could affect the free movement of the food product within the Southeast Asia or the export of foods to other countries if such claims violate World Trade Organisation Agreement (Aggett *et al.*, 2012).

2.4.2 Principles of health claims and the languages used on health claims

Details on the principles of health claim in Indonesia, Malaysia, Singapore, Thailand and Vietnam are listed in Table 2.3 (Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Ministry of Health Vietnam, 2014). The principles of health claims vary among the five SEA countries

compared with Codex Alimentarius. There were also differences in the principles of health claims in SEA when compared with those recommended by EFSA as shown in Table 2.4. It could be challenging to align every stakeholders involved if there is no clear, common principles for the health claims. Indonesia and the Philippines have adopted most of the health claim principles from Codex Alimentarius which states that health claims need to be consistent with national health policy including nutrition policy and the claims should contribute to the consumption of a balanced diet (Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Ministry of Health Vietnam, 2014).

Codex Principles*	Consistent with national health policy	Supported by a sound and sufficient body of scientific evidence to substantiate the claim	Provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education	Not associated with treatment and prevention of diseases	Do not lead to wrong consumption patterns	Contribute to the consumption of a balanced diet	References (Codex Alimentarius, 1997 (last amended in 2013))
Indonesia	✓	✓	✓^	✓	✓	✓	(National Agency of Drug and Food Control of the Republic of Indonesia, 2011a)
Malaysia	X	✓	X	✓	X	X	(Ministry of Health Malaysia, 2010)
Singapore	X	✓	✓^	✓	X	✓^	(Agri-Food & Veterinary Authority, 2010 (with amendments to 2016))`
Thailand	X	✓	X	✓	X	X	(Ministry of Public Health Thailand, 2011)

Codex Principles*	Consistent with national health policy	Supported by a sound and sufficient body of scientific evidence to substantiate the claim	Provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education	Not associated with treatment and prevention of diseases	Do not lead to wrong consumption patterns	Contribute to the consumption of a balanced diet	References (Codex Alimentarius, 1997 (last amended in 2013))
Vietnam	X	✓^	X	X	X	X	(Ministry of Health Vietnam, 2014)

Table 2.3 Comparison between principles of health claims in 6 Southeast Asian countries and Codex Alimentarius

EFSA Principles*	A nutrient or other constituent has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;	False, ambiguous or misleading;	Average consumer can be expected to understand the beneficial effects as expressed in the claim	Do not give rise to doubt or fear about the safety and/or the nutritional adequacy of other foods, either textually or through pictorial, graphic or symbolic representations	Do not encourage or condone excess consumption of a food; or state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general	References (European Food Safety Authority, 2006)
Indonesia	✓	✓^	X	✓	✓	(National Agency of Drug and Food Control of the Republic of Indonesia, 2011a)
Malaysia	✓	X	X	X	X	(Ministry of Health Malaysia, 2010)
Singapore	✓	✓^	X	X	✓^	(Agri-Food & Veterinary Authority, 2010)

EFSA Principles*	A nutrient or other constituent has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;	False, ambiguous or misleading;	Average consumer can be expected to understand the beneficial effects as expressed in the claim	Do not give rise to doubt or fear about the safety and/or the nutritional adequacy of other foods, either textually or through pictorial, graphic or symbolic representations	Do not encourage or condone excess consumption of a food; or state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general	References (European Food Safety Authority, 2006)
						(with amendments to 2016))`
Thailand	✓	X	X	X	X	(Ministry of Public Health Thailand, 2011)
Vietnam	✓^	X	X	X	X	(Ministry of Health Vietnam, 2014)

Table 2.4 Comparison between principles of health claims in 6 Southeast Asian countries and European Food Safety Authority

The health claims displayed on food products in these countries are required to be stated in the national languages in Indonesia, Malaysia, Thailand, Vietnam and the business language (English) in Singapore which is outlined in Table 2.5 (Ministry of Health Malaysia, 2010; Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a). This could help the consumers in the local markets to utilise the health claims and make informed food choices.

Country	Language	References
Indonesia	Bahasa Indonesian	(National Agency of Drug and Food Control of the Republic of Indonesia, 2011a)
Malaysia	Bahasa Malaysia Imported products in Bahasa Malaysia/ English	(Ministry of Health Malaysia, 2010)
Singapore	English	(Agri-Food & Veterinary Authority, 2010 (with amendments to 2016))
Thailand	Thai	(Ministry of Public Health Thailand, 2011)
Vietnam	Vietnamese	(Ministry of Health Vietnam, 2014)

Table 2.5 Language of health claims used by the 5 Southeast Asian countries with independent guidelines or regulations

2.4.3 Scientific substantiation and evaluation of health claims

The inclusion of data from human intervention studies is the most common requirement for health claims applications in the SEA countries that permits health claims (Ministry of Health Malaysia, 2010; Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Agri-Food and Veterinary Authority of Singapore, n.d.-b). Clear inconsistencies are reported in the types and the amount of evidence required for health claim substantiation in these countries such as requirements that the evaluation be conducted by independent institutions or that the claim be substantiated by at least five independent peer-reviewed reports. The inconsistencies in the types of scientific evidence required make it difficult and costly for the food industry to apply for health claims. Table 2.6 summarizes the scientific data required for a health claim application in these SEA countries (Ministry of Health Malaysia, 2010; Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Agri-Food and Veterinary Authority of Singapore, n.d.-b).

Country	Types of data			Supporting knowledge	References
Indonesia	Human studies such as randomized controlled trials (RCT) or observational studies if experimental research is not possible.	Published in scientific journals.	Research conducted by independent researchers or institutions are preferred.	In vitro and animal studies can be submitted to support the petition.	(National Agency of Drug and Food Control of the Republic of Indonesia, 2011a)
Malaysia	Human intervention trials	Published in refereed journals.	Studies should include those conducted by other organizations or institution.	Epidemiological and experimental studies and reviewed papers may be included as supportive evidence.	(Ministry of Health Malaysia, 2010)
Singapore	Well-designed human intervention studies	At least five independent peer-reviewed reports of studies, preferably published in the last 10 years.	Nil	Human observation studies, animal model studies, ex-vivo and in-vitro studies can be submitted.	(Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Agri-Food and Veterinary Authority of Singapore, n.d.-b)
Thailand	At least two appropriate-designed human intervention studies with adequate samples for the consideration of probiotic efficiency	Nil	Nil	Data unavailable	(Ministry of Public Health Thailand, 2011)

Country	Types of data			Supporting knowledge	References
Vietnam	Human studies on efficacy	Conducted by authorised local institutions	For overseas studies: conducted by institutions accepted by local authorities or published in scientific journals	Data unavailable	(Ministry of Health Vietnam, 2014)

Table 2.6 Types of scientific data required for health claim application in the 4 Southeast Asian countries with independent guidelines or regulations

The Indonesian regulatory agency has published a list of principles for the assessment of new health claims and require six months to evaluate a new claim (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a). The criteria for the evaluation of health claims and the timelines for approving new health claims in most of the five SEA countries are also not sufficiently clear. The lack of clear guidance and criteria in the different countries makes it challenging for the food industry and the research community to develop and launch innovative products for the consumers in this region. At the same time, the consumers in SEA find it difficult to understand how the health claims are approved in the various SEA countries.

The scientific substantiation and evaluation of health claims has been a subject of debate between the food industry and the EFSA. This is worth noting that the Codex Guidelines on Nutrition and Health Claims is derived from the two previous projects conducted in Europe namely, the ‘Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)’ carried out from 1 April 2001 – 1 April 2005 and the project ‘Functional Food Science in Europe (FUFOSE)’ which was the basis for PASSCLAIM (Cummings *et al.*, 2003). The main aims of these two European Union projects were to develop a guidance tool to assess scientific support for claims on foods and food components and the common criteria for assessment of the scientific substantiation (Aggett *et al.*, 2005). To date, eight out of 10 health claim applications on newly developed scientific evidence, child development and reduction of disease risk submitted to EFSA have been rejected. Misreporting of the studies and the quality of the human studies were two of the main issues that arose during the review of the scientific evidence (Martin, 2013). The food industry in Europe has raised concerns about the lack of clarity on the criteria for substantiating health claims and the wording of the claims (Gallagher, 2011; Richardson, 2012). Binns (2009) criticised the regulation for stifling

innovation. EFSA adopted the pharmaceutically accepted evidence-based medicine approach to evaluate health claims on foods.

The frameworks from the United States and Japan are considered to be more industry friendly than that in Europe, since qualifying statements under the Qualified Health Claims are allowed (Lalor and Wall, 2011). Qualified Health Claims were introduced in US in 2003 and were defined as claims that have passed a premarket scientific review but which emerging evidence does not meet the Significant Scientific Agreement standards. For such claims, a qualifying statement must be included when evidence is limited (Lalor and Wall, 2011). In 2005, the Japanese Food for Special Health Uses (FOSHU) system introduced the qualified FOSHU. Food in the qualified FOSHU scheme can be sold in the market with a qualifying statement stating ‘evidence has not necessarily been established’ and/ or with words like ‘possibly’ as part of the approved health claim (Shimizu, 2003; Ohama *et al.*, 2006; Yamada *et al.*, 2008). This use of qualified statements has helped the food industry expedite the introduction of specific food products to consumers in both the US and Japan.

Results from the randomised placebo- controlled double-blind studies, rather than results from epidemiological and observational studies, are considered as the strongest form of evidence in EU, US and ANZ. Data from epidemiological and observational studies, however, are usually used for nutrition research for some obvious reasons (Binns, 2009). Well- designed controlled nutrition studies may be used to show the cause-effect relationship of the food but the placebo controlled studies are often not possible because the control product should also be nutritious. This rigorous, more pharmaceutical approach poses difficulty, impracticality, and very high cost for the food industry to achieve the level of evidence required, that is if possible at all since nutrition research, in which complex foods or nutrient combinations are investigated, is very different from pharmaceutical research (Tapsell, 2008; Richardson, 2012). Food and medicine are also essentially different because medicine is given to treat medical conditions while food is consumed to support general well-being. This could potentially influence the availability of food products with better nutritional quality for consumers since the difficulties in meeting the requirements for health claims might discourage innovation in the food industry. The lack of approved health claims will not make it easier for the consumers to make informed choices as not all foods are the same.

2.5 Opportunities to harmonise health claims regulations in SEA

Despite the differences, there are some convergences among these five SEA countries such as Indonesia, Malaysia, Singapore, Thailand and Vietnam since there are existing regulatory

frameworks in these countries (see Table 2.7 (Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Agri-Food and Veterinary Authority of Singapore, n.d.-b; Agri-Food and Veterinary Authority of Singapore, n.d.-a). The Philippines is excluded in this context, since no further information on health claim in Philippines can be found on the available English literature. Indonesia, Malaysia, Singapore and Thailand state that health claims should not be associated with treatment and prevention of disease (Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a). This clearly indicates that the role of food is to promote and maintain health. In these countries, all claims needs to be scientifically substantiated with sound and sufficient evidence (preferable human intervention studies) and the regulatory status and/ or approval by national or international regulatory body is required as part of the health claim application (Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Ministry of Public Health Thailand, 2011; Agri-Food and Veterinary Authority of Singapore, n.d.-b).

Country	List of approved Nutrient Function Claims	List of approved Other Function Claims	List of approved Reduction of Disease Risk Claims	An example of the approved Nutrient Function Claims in four countries: - Vitamin C	Require regulatory status of Health Claim by other countries	Expert committee to evaluate Health Claims	References
Indonesia	✓ 12 nutrients	✓ 2 food components	✓ 7 nutrients/ food components	Vitamin C plays a role in the formation and maintenance of collagen tissues.	✓	✓	(National Agency of Drug and Food Control of the Republic of Indonesia, 2011a)
Malaysia	✓ 16 nutrients	✓ 14 food components	X	Vitamin C enhances absorption of iron from non-meat source.	✓	✓	(Ministry of Health Malaysia, 2010)
Singapore	✓ 22 nutrients	✓ 4 food components	✓ 1 food component	Vitamin C enhances absorption of iron from non- meat products.	✓	✓	(Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Agri-Food and Veterinary Authority of Singapore, n.d.-b; Agri-Food and Veterinary Authority of Singapore, n.d.-a)
Thailand	✓ 29 nutrients	X	X	To regenerate collagen and cartilage tissues.	Unavailable	Unavailable	(Ministry of Public Health Thailand, 2011)
Vietnam	Unavailable	Unavailable	Unavailable	Unavailable	✓	✓	(Ministry of Health Vietnam, 2014)

✓ - refers to 'have'

X - refers to 'do not have'

(Note: Some nutrients have a few approved claim statements which can be used.)

Table 2.7: Areas of convergence among health claims in Southeast Asian countries

2.5.1 List of approved health claims and expert committees in Southeast Asia

All these countries, with the exception of the Philippines and Vietnam have a positive list of permitted nutrient function claims, other function claims and reduction of disease risk claims (Tee, 2014). Expert committees have also been established in Indonesia, Malaysia and Singapore (Ministry of Health Malaysia, 2010; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Agri-Food and Veterinary Authority of Singapore, n.d.-a). The committees have been tasked with evaluating the health claim applications on the basis of the scientific data submitted and providing recommendations to the local food authorities (Ministry of Health Malaysia, 2010; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Agri-Food and Veterinary Authority of Singapore, n.d.-a).

2.5.2 Other considerations on the regulatory frameworks in SEA

The regulatory agencies and the food industry play equally important roles with an aim to benefit food consumers. The regulatory agencies aim to protect consumers from misleading information, while the food industry aims to communicate the proposed benefits to consumers to help them make informed food choices.

During the literature search, however, no published review paper or discussion on the regulatory framework for health claims in SEA was identified. The emerging issues are the difficulties and high cost for food industry to register new health claims throughout SEA and to meet the different regulatory requirements and approaches across these countries, as there is not a single approach for the approval of health claims (Itkor., 2014). This could create major barriers for new product development and food trade within this region and dampen the interest of investors to invest in new markets. There is a need for collaboration among the stakeholders to address the lack of transparency surrounding the evaluation of health claims.

Inconsistent communication about the health benefits of specific food could cause confusion about the beneficial effects of the food components. Consumers in SEA are not able to find the beneficial effects of the food constituent on the relevant food products sold in their countries, even though sources of information such as health authorities, scientific journals, health magazines, health-related websites etc. have been educating on the effects of the food constituent. These Asian consumers might not know that health claim on food products in SEA requires regulatory approval, unlike the health information available on mass media.

The regulations on health claims have an important role in facilitating the free movement of goods including food among ASEAN nations. Several fundamental issues that need to be addressed by all the stakeholders affected by health claims, including members of the food

industry, the regulators and the consumers. These issues include: 1) What are the principles, the scope and the objectives of health claims?; 2) How should the ten SEA countries work together when the regulatory status and development differs among the ten member states in SEA? ; 3) What should be the best approach for SEA since the SEA region has diverse cultures and languages?; and 4) How can the balance between consumer-friendly health claims and industry-friendly processes for developing health claims be achieved to benefit consumers in ASEAN countries?

2.6 Conclusion

In the light of the goal to be an integrated ASEAN Economic Community by end of 2015, it is timely to understand the regulatory framework for health claims in SEA, since there is currently no unified approach. Clear guidance could provide directions for the food industry and the regulatory community to support food innovation, and to make food products available with better nutritional quality for the Southeast Asian market. In addition, a clear, consistent regulatory framework has the potential to increase trade in this fast-growing region and it will provide directions for the food industry and the regulatory community to make food products with better nutritional quality to the Southeast Asian consumers.

Chapter 3 Health claim approval in Southeast Asia: Current practices and perspectives from food regulators, key opinion leaders, policy makers and representatives from the scientific organisations and food associations

3.1 Executive Summary

All new health claims need to be approved by the local food authority in each country before such claims can be stated on the product labels and sold in Indonesia, Malaysia, Singapore, the Philippines and Thailand. We aimed to investigate the current practices and perspectives of the regulatory frameworks for new health claims applications in Southeast Asia (SEA). The objectives seek to understand the following three points: 1) the processes of health claim substantiation and evaluation; 2) factors affecting the approval of health claims; and 3) the challenges faced by the key stakeholders engaged in health claims regulation. The objectives were achieved by gathering detailed information from the regulators, key opinion leaders from the scientific community, public health policymakers and representatives from scientific organisations and food associations. Semi-structured one-to-one interviews were conducted with 15 key stakeholders who have direct influence on the approval and use of health claims on food in several SEA countries. Practices and perspectives in the substantiation and evaluation of health claims were comparable among stakeholders who participated in this study. More specifically, the health claim application dossiers need to explain the rationale to consume the food constituent clearly and demonstrate the cause-effect relationship between the constituent and a specific health outcome. In general, the guidelines on nutrition and health claims established by Codex Alimentarius served as a basis to evaluate health claims by all the countries surveyed in this study. The quality of the supporting evidence from (human) studies in particular (i.e. evidence from well-designed human intervention studies), wording of the proposed health claim, condition of use (realistic amount of the constituent to be consumed in the diet and how it would fit into food matrix), were key considerations for any application. More regular and open communications and collaboration among different stakeholders can make the process of development of relevant food product with understandable health claims more efficient.

3.2 Introduction

The establishment of the Association of Southeast Asian Nations (ASEAN) Economic Community (AEC) in 2015 envisions the free movement of goods (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015a). The ASEAN consists of ten countries in Southeast Asia; Brunei Darussalam, Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam with a total population of over 622 million people (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015b). To date, only six out of these 10 Southeast Asia countries (SEA) namely Indonesia, Malaysia, Singapore, Thailand, the Philippines and Vietnam have health claim regulations and guidelines (Republic of the Philippines Food and Drug Administration; Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Ministry of Health Vietnam, 2014). All new health claims need to be approved by the food regulators in each individual SEA country before they can be stated on a product label sold in these SEA countries. A recent review showed there were inconsistencies in the regulations and the types of evidence required for health claim applications as reported in Chapter 2 (Tan *et al.*, 2015). This could potentially hinder the free trade of goods under the ASEAN Economic Community.

In Indonesia, the regulation of health claims published by the National Agency of Drug and Food Control of the Republic of Indonesia (NA-DFC) in 2011. The regulation has the most comprehensive information on health claims application in a single document in SEA (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a). The regulations include the application process, the information required in health claim applications and a list of principles on assessing new claims, similar with Codex guidelines for use of nutrition and health claims. Indonesia is also the only SEA country to establish the principles on assessing new health claims such as clear characterization of food constituents, design of human intervention studies, appropriate statistical analysis, relevant to country populations, and totality of relevant available studies (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a). All health claim applications in Indonesia will be screened by an official in the Indonesian food authority to check for comprehensiveness of data before the application is accepted for evaluation. Each application takes a maximum of 6 months (excluding time involved for receipt of additional data requested) to be evaluated by the expert committee and approved by the head of NA-DFC (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a). The expert committee consist of

professionals with different backgrounds such as nutritionists, chemists, paediatricians, food technologists, pharmacologists etc. (Maemunah, 2015). Figure 3.1 indicates the health claims procedure in Indonesia with key actors indicated.

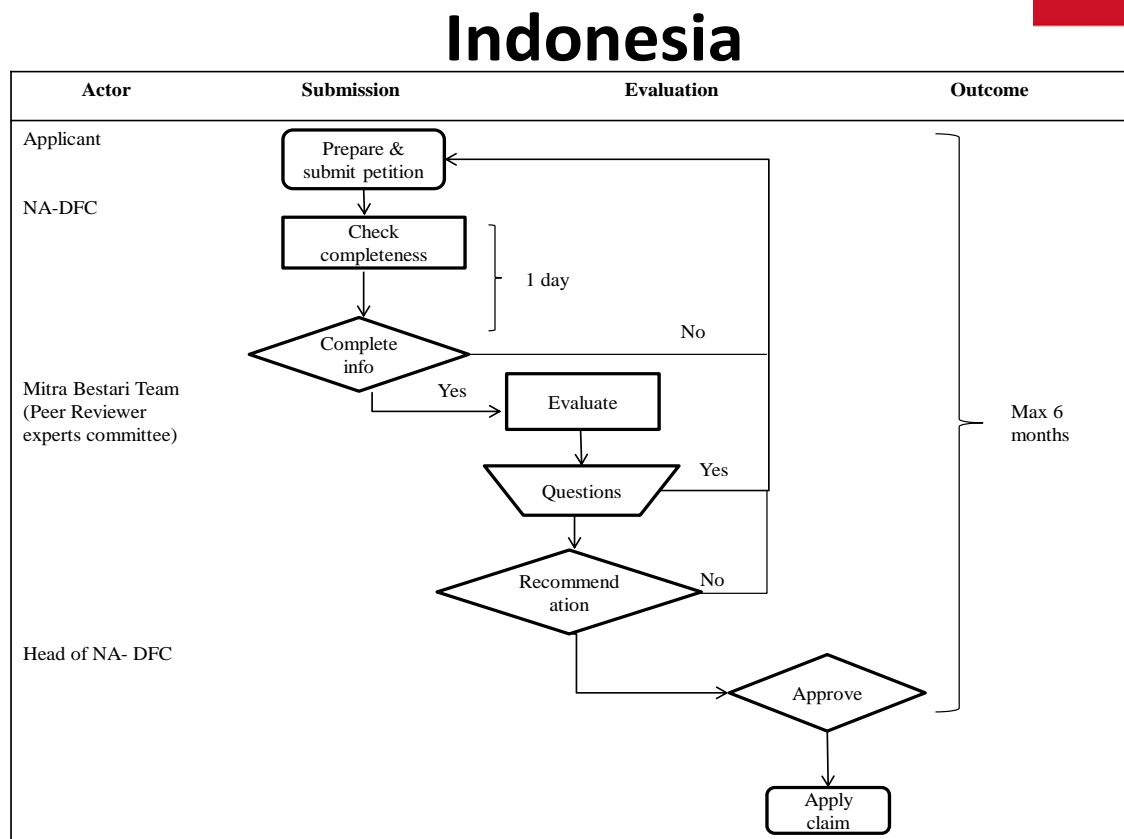


Figure 3.1: Health Claim application procedure in Indonesia

Source: adapted from National Agency of Drug and Food Control of the Republic of Indonesia (2011a)

To date, Malaysia has the most number of approved ‘other function’ claims among the SEA countries with health claims regulations or guidelines. The Malaysian guide to nutrition labelling and claims was published in December 2010 (Ministry of Health Malaysia, 2010). The health claim application in Malaysia has to include published data from at least 5 clinical trials to substantiate the relationship of the nutrient/ food constituent with health. In addition, the chemical structure, analytical method and daily intake of the constituent and any evidence of the approval of the claim from other countries are required as part of the application (Ministry of Health Malaysia, 2010; Eksan, 2015). The duration of the application process for each application is not stated in the Malaysian guidelines. The gazettment for new nutrition claims involves several key actors such as an expert committee, an advisory committee, public comments, a legal department and a health minister (Sulong and Tee, 2012;

Eksan, 2015). The expert committee consists of representatives from academic, government officers from the Ministry of Health (MOH), research institutes, the Malaysian palm oil board and health professionals from multi-disciplinary backgrounds such as Paediatrics, dietetics, nutrition and pharmacy (Ministry of Health Malaysia, 2010). Figure 3.2 illustrates the health claim application process in Malaysia.

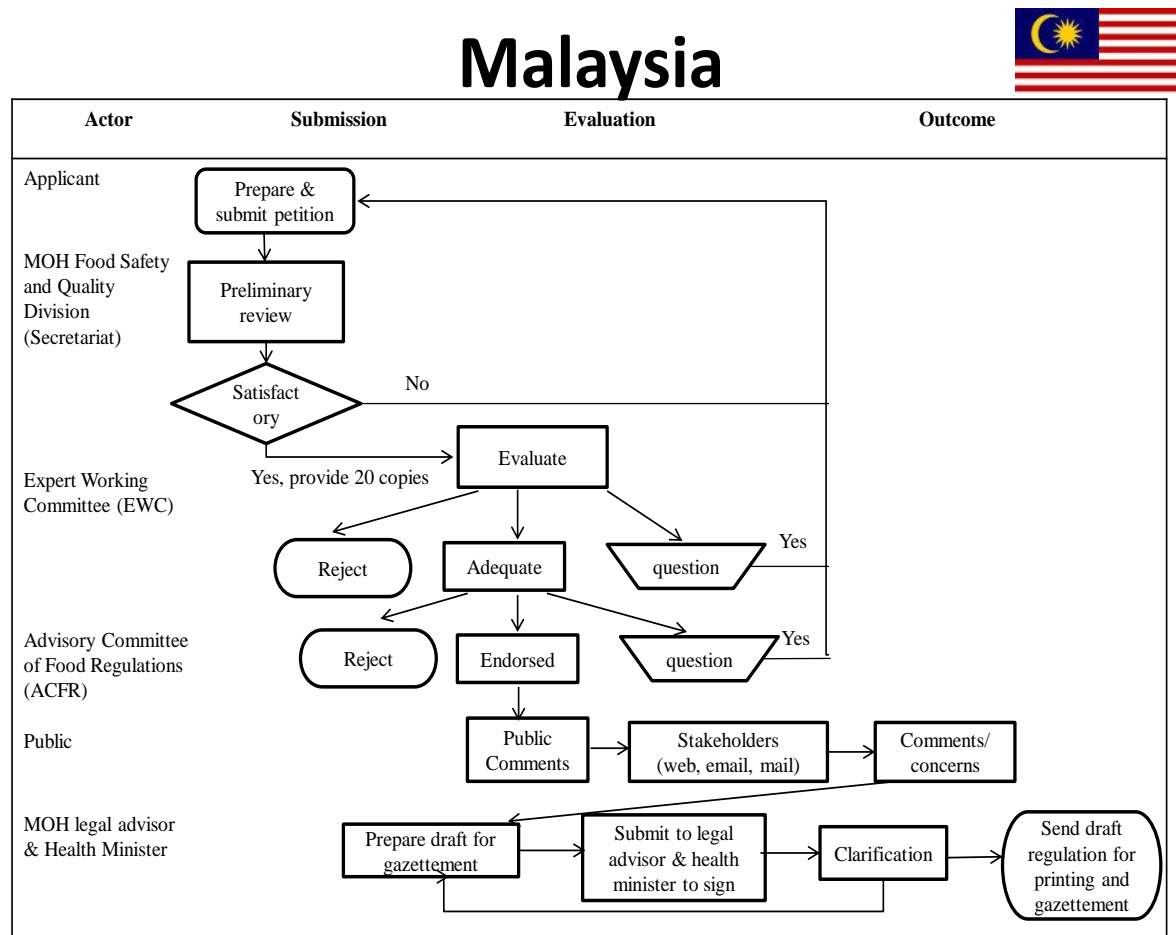


Figure 3.2: Health Claim application process in Malaysia

Source: Author’s construction drawing based on Eksan (2015); Sulong and Tee (2012)

In Singapore, the Agri-Food Veterinary Authority (AVA) established the guide to food labelling and advertisements (including health claims) in 2010 to provide food businesses with a better understanding of the food labelling requirements and approved claims for use in food labels and advertisements (Agri-Food & Veterinary Authority, 2010 (with amendments to 2016)). This guide has undergone several revisions over the years and it includes the positive list of health claims permitted in Singapore and the requirements on how to apply for new health claims. The requirements include the characteristics of the nutrient/ food constituent, the proposed wording of the claims, and that the claim has to be supported by >5 independent peer-reviewed human intervention studies published in the last 10 years. The

applicant is required to use the AVA health claim application form for new applications (Agri-Food and Veterinary Authority of Singapore, n.d.-b). As described in Figure 3.3, each application will be screened for relevant evidence by the AVA secretariat based on the Codex Guidelines on Scientific Substantiation of health claims before forwarding to the Advisory Committee for evaluation (Neo, 2015). The Advisory Committee comprises of the scientific experts with relevant professional training and experience. The members are mainly from the government bodies, tertiary institutions, consumer associations and industry associations (Agri-Food and Veterinary Authority of Singapore, n.d.-a). Other than making recommendation to AVA on health claim applications, one of the main tasks of this committee is to establish the framework and the principles for evaluation of health claims in Singapore (Agri-Food and Veterinary Authority of Singapore, n.d.-a). The applicant will be informed of the result before all approved health claims are published on the AVA website or food regulations gazette. The estimated time for the whole cycle is 9 months depending on the complexity of the claims and turnaround time by the advisory committee (Neo, 2015). To date, the AVA has received 28 new health claim applications over 6 years and only 6 claims were approved (Neo, 2015).

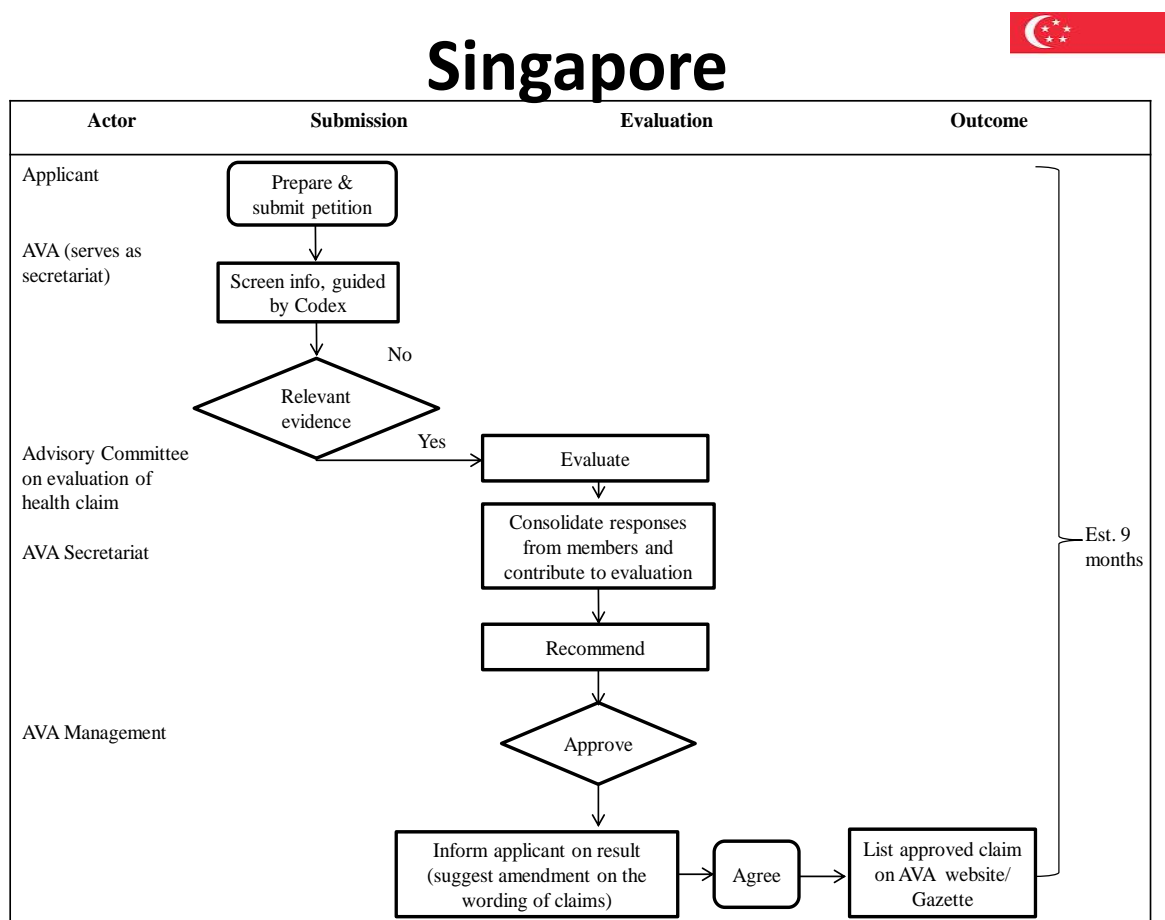


Figure 3.3: Health Claim application in Singapore

Source: Author's construction drawing based on Neo (2015)

The Ministry of Public Health in Thailand issued a notification specifically on probiotics as food constituent in 2011 (Ministry of Public Health Thailand, 2011). The notification states the definition of health claims and the requirements for submitting health claim applications on probiotics. Each application needs to be supported by at least two well-designed, appropriate human intervention studies to demonstrate the efficacy of the probiotics. The details of the studies such as study group, control group, adequate duration of exposure, the amount of food constituent to be consumed to have the intended effect, the influence of the food matrix, and the statistical power to test the hypothesis should be included. The health claim application in Thailand has only one process which described for probiotics, and no further information was provided on the evaluation of the applications. Separately, the Thai Ministry of Public Health has also published a list of approved nutrient function claims for 29 nutrients.

The Philippines food and drug administration (FDA) announced in a circular in 2007 the full adoption of the Codex guidelines on nutrition and health claims in evaluating the use of the health claims in labelling and advertisement of food products (Republic of the Philippines Food and Drug Administration). There is no further information on the regulatory framework on health claims and how the claims are administrated or evaluated in the Philippines.

Vietnam is the latest country among the SEA countries to release regulations on functional foods in late 2014 which took effect from 15 January 2015 (Ministry of Health Vietnam, 2014). The scope includes labelling, manufacturing and commercial activities on ordinary food with additional ingredients beneficial to health which are termed as 'supplemented food', health supplements in different forms of presentation, medical foods and foods for special dietary uses. The regulation defines scientific evidence as the information and documents obtained from 'research accepted by state institutions or published by national or international scientific journals; or documentation of traditional medicine, medicinal herb and traditional remedy published in scientific printed materials' (Ministry of Health Vietnam, 2014).

Evidence from human studies is required in new health claim applications to support the safety and beneficial effects of the food/ constituent on health. In addition, the target audience of the products and recommended intake has to be exactly as the amount and subjects stated in the scientific supporting documents. Studies that are conducted outside of Vietnam will be accepted, provided the institutions conducting the studies are recognised by the Vietnamese local authorities or the studies are published in scientific journals. A

Scientific Council consisting of experts from relevant fields has been established to assess the scientific evidence in the application. The beneficial food constituent needs to be analysed for the content in the product by the testing institutions in Vietnam. For food constituent which the testing method is unavailable in Vietnam, the content of the ingredient needs to be justified in the application dossier (Ministry of Health Vietnam, 2014). There is no further information on the regulatory process as this Vietnamese system is relatively new.

To date, there is limited or no information on how the health claim applications are evaluated and the key factors affecting the approval of the health claims in the SEA countries. The lack of this information results in uncertainty for the applicant when applying for health claims, and the investment involved in generating evidence to support the health claim application might not justify the return of investment for the applicant. This could negatively affect the motivation for the food industry to support innovation, if most health claims applications have been rejected. In addition, the Asian consumers could have restricted access to food products of better nutritional quality.

This chapter aims to investigate the current practices and perspectives of the regulatory frameworks of new health claims applications in Southeast Asia (SEA). The objectives were to understand the following three points: 1) the processes of health claim substantiation and evaluation; 2) factors affecting the approval of health claims; and 3) the challenges faced by the key stakeholders. The objectives were achieved by gathering detailed information from the different clusters of stakeholders in SEA such as food regulators, key opinion leaders, policy makers, and representatives from scientific organisations and food associations.

3.3 Materials and methods

3.3.1 Participants

The aim was to gather information from individuals regarded as key stakeholders involved in health claims are residing in SEA. The chosen stakeholders were grouped into different clusters based on the flow of health claim application to understand the current situation on how health claim applications are applied and processed in the different SEA countries. The participants included representatives from the food associations filing the applications, regulators involved in the administration process, policy makers, key opinion leaders from the scientific community, and representatives from scientific organisations involved in the evaluation of health claims in the country. All participants had direct influence on the availability of health claims on food in the various SEA countries when interviewed and were science-trained. Most participants held high-ranking positions in their institutions, and/or

were independent, well-respected experts. The different clusters of participants identified, were selected to capture a broader comprehension into the opinion and insight of this research topic.

3.3.2 Recruitment of participants

Purposive sampling was applied in the selection of the participants for this study. To gain a deeper understanding of the research topic being studied, it was more important to target the selected participants with a range of backgrounds and job responsibilities, and avoid repetition of information by reaching out to people with similar backgrounds and responsibilities. They were considered as the spokesperson for the respective cluster as they could have the authority to influence the health claim regulations/ guidelines in their respective countries. The targeted participants across the 10 ASEAN countries were identified after performing an exhaustive web search, and via networking through the researcher's contacts and with key informants to ensure the potential participants had direct influence on health claims policies in their countries in terms of drafting the health claims regulations/ guidelines in the country, evaluating health claim applications or having a voice in the relevant committees. Participants were invited to participate in this study via email and/or were approached face-to-face. More background and information about the study and the interview questions were sent to the potential participants, prior to any interviews. Reminder emails were sent to increase participation in the study. Food regulators from all of the ten Southeast Asia countries were invited to participate in this study initially. The research invitations were extended to the representatives from the other backgrounds and clusters, in order to broaden the understanding and to provide different insights on the research topic (Massa and Testa, 2008; Miguel *et al.*, 2014).

3.3.3 Interview guide development

An interview guide with a set of specific questions was developed, based on the research objectives and the identified gaps in the existing local regulations and guidelines on health claims issued by the local food regulatory agencies in SEA as identified in chapter 2. The interviews involved four key sections: 1) to identify and confirm their roles in the country; 2) to gather information on the details of health claims regulations/ guidelines processes of applying for health claims, and the criteria in selecting the expert committee, 3) to gather information on how health claim applications are reviewed and to identify the factors affecting the approval of health claims application and 4) to gather information on the challenges faced and explore potential suggestions to mitigate the challenges. The questions were tailored for each interview depending on the available time and the job responsibilities

of the interviewee. All questions were pre-tested among experts such as former and current food regulators who are familiar with this research topic to check if the questions were clearly worded and to minimise the risk of cross-cultural misunderstanding. The interview guide is available in Appendix 2.

3.3.4 Data collection

Semi-structured interviews were conducted among participants, who accepted the invitation to participate in the study. Most interviews were conducted in English by a single designated researcher in a face-to-face manner at the participants' workplaces in the various SEA countries. Each interview session was estimated to last for about one hour. Four participants completed the questions electronically via email, due to their busy schedule.

3.3.5 Ethical approval

Ethical approval for this study was obtained from Newcastle University Faculty of Science, Agriculture and Engineering Research Ethics Committee. Prior to data collection, the participants were briefed on the purpose of the study, their rights as participants and the assurance of confidentiality. Each participant gave their written informed consent to take part in this study. All interviews were audiotaped with the permission from the participants and then destroyed after transcription.

3.3.6 Data analysis

All the interviews were transcribed verbatim using qualitative software programme NVivo version 10 (QSR International Pty Ltd, Australia). The completed questionnaires from the participants sent via email, were also input into NVivo for analysis. Each participant was allocated a number such as P1, P2 to ensure participant anonymity. Thematic analysis was applied to analyse the data. The transcripts were read thoroughly several times so that the researchers were familiar with the data before coding (Braun and Clarke, 2006). The data were analysed in an inductive process which began with open coding, based on the specific research questions and extended to the emerging issues presented in the data. The patterns or 'themes' were generated and identified from the data. The themes in a transcript were constantly compared and contrasted with other transcripts to look for similarities, differences and relationship between the themes before further coding (Glaser, 1965). For example, the perspectives on the objectives of health claims and the challenges faced by the different clusters of stakeholders were compared between the different transcripts to provide an accurate reflection of the content in the dataset.

3.4 Results

The findings of this study were gathered from a total of 15 participants who are known within the regulatory community and food associations to be the key stakeholders involved with health claims in SEA. The participants were from the different clusters; namely the regulators (5 participants), key opinion leaders from scientific community (3 participants), public health policymakers (2 participants), representatives from the scientific organisations (2 participants) and food industry associations (3 participants). Responses were obtained from six out of ten SEA countries, with the exception of Brunei Darussalam, Cambodia, Lao People's Democratic Republic and Myanmar. Despite repeated attempts, representatives from the four countries were unavailable for interview. The four countries omitted, did not have health claims regulations/ guidelines during the study. The demographics of the participants are presented in Table 3.1.

Country	Position/ Role
Indonesia	Food Regulator
Indonesia	Key Opinion Leader (Academic)
Malaysia	Key Opinion Leader (Regulatory/ Scientific)
The Philippines	Food Regulator
Singapore	Food Regulator
Singapore	Director, Scientific Organisation
Singapore	Representative of Local Food Industry Association
Singapore	Representative of Regional Industry Association
Thailand	Food Regulator
Thailand	Public Health Policymaker
Thailand	Key Opinion Leader (Regulatory)
Thailand	Representative of Local Food Association
Vietnam	Food Regulator

Country	Position/ Role
Vietnam	Public Health Policymaker
Vietnam	Chairman, Scientific Organisation (Medical)

Table 3.1: Background information on interviewees

The results are divided into sub-topics to create clarity on the current practices on health claims applications in SEA, e.g. claim substantiation and evaluation, and factors affecting health claim approval or challenges faced by the different stakeholders in that process. The term ‘food constituent’ will be used throughout this chapter for consistency. The term is used to refer to a whole food or a constituent of that food such as energy, specific nutrients, related substances, ingredients, and any other feature of a food, a whole food, or a category of foods that has the potential to have beneficial effects to health and on which a health claim could be based. The perspectives gathered from the different stakeholders were incorporated to provide insights on potential issues and opportunities. Based on the interview feedback, practices and perspectives in the substantiation and evaluation of health claims were comparable between the SEA countries evaluated.

Key actors relevant for health claims evaluation were the regulatory setting including the organisation of food regulatory agencies such as the NA-DFC, AVA, in the SEA countries and the involvement of expert committees. In each country, the role of expert committees is to provide scientific expertise to evaluate the scientific evidence for new health claims applications, and to provide recommendations to the food regulatory agency on application approval or rejection. Table 3.2 summarises the details of expert committees in the SEA countries that participated in this research. The expert committees mostly consisted of local scientific and technical experts with multi-disciplinary scientific education and experience such as nutrition, food science/ technology and medicine, and the knowledge related to the submitted claims. The experts were mainly from the government agencies, local tertiary institutions, healthcare professional organisations and research institutions. Most SEA countries had committees that consisted of a core team of experts. Depending on the nature of the claims, other experts with relevant knowledge and experience could be consulted on a case-by-case basis.

Country	Indonesia	Malaysia	Singapore	Thailand	The Philippines	Vietnam
Name of expert committee	Mitra Bestari Team (Peer Reviewer experts)	Expert Committee on Nutrition, Health Claims and Advertisement	Advisory Committee on evaluation of health claim	Expert Committee	Expert Committee	Scientific committee
Membership	Representatives from internal government departments and health professionals such as nutritionist, chemist, paediatrician, food technologist, pharmacist (Maemunah, 2015)	Experts from academia, representatives from Ministry of Health (MOH), research institutes, and health professionals such as medical doctors, dietician, nutritionist and food scientists/technologists. (Ministry of Health Malaysia, 2010)	Experts from academia, representatives from multi-government agencies, consumers association, food industry (Agri-Food and Veterinary Authority of Singapore, n.d.-a)	Experts from academia with direct experience/ research related to claims, government agencies or industrial associations (interview)	Experts who are independent from industry, and internal experts from FDA (interview)	Experts from academic, health professions, government agencies (interview)
Co-opt members	Yes, depending on the submitted claim	Yes, depending on the submitted claim	Yes, may consider	Unknown	Yes, depending on the submitted claim	Yes, depending on the submitted claim

Table 3.2: Details of the expert committees in the selected SEA countries

3.4.1 Congruent opinion on the objectives and principles of health claims

Most participants had similar opinion on the objectives and principles of health claims. Health claims were regarded as assisting the consumers in making informed food choices to achieve a well-balanced diet. Claims also serve as a form of communication between manufacturers and consumers on the relationship of the food constituent and health.

'Health claims products are aimed to communicate to consumers about the relevance of any benefits or properties of food or constituent of that food to consumers' health' - P4

'Consumers should have the right to know and the company should have the right to communicate to the consumers. That is the fundamental on claims.' - P15

Some of the participants commented that health claims motivated the industry to continue innovation to develop healthful products; the industry stakeholders similarly commented (in part 1 of the interview) that health claims provided competitiveness in their businesses by helping the consumers to differentiate between products of the same food group.

'Health claims help consumers to make informed food choice and encourage the industry to continue innovate new healthful products for consumers.' - P3

'One is for consumer education when consumer can understand why this nutrient is added and what is the function; and the other for the industry benefit is for them to differentiate from one another.' - P13

One participant held the view that for industry, it was less about innovation and more about using health claims as part of their marketing strategy.

'Marketing strategies is one main objective on the point of food industry on health claims.' - P2

All participants agreed that health claims had to be evidence-based and scientifically-substantiated. In addition, the regulators specifically stated that claims have to be perceived holistically in the context of a balanced diet for the general population. Above all, health claims should not treat, cure and prevent medical conditions linked to diseases. Some were wary that the consumers would perceive the food with these claims as a 'quick fix' or 'miracle food'. They reasoned that the role of food is for normal body maintenance.

'Approval of health claims should be viewed holistically to ensure that consumers continue to consume a balanced and varied diet.' - P3

'Health claim for food should be for maintaining well-being. We eat food when we are healthy. For example, iron is not for anaemia. It is required for the production of the red blood cells.' - P8

'No health claim is absolute. It should not be seen as a quick fix to your health. [...] You need to do that too, together with that.' - P8

Table 3.3 summarises the scope of the health claims regulations and guidelines in SEA countries. Most regulators were unclear on the scope of the health claims regulations/guidelines. Most responded by sharing the definitions of health claims when asked about the scope of health claims regulations and guidelines. The scopes of health claims are listed in the health claims regulations/ guidelines with the exception of Malaysia, but the objectives of the health claims were unclear in the health claims regulations/ guidelines in the six countries. For example, the scope of the Indonesian and Thailand regulation includes labels and advertisement of processed food with nutrition and health claims (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a), and Vietnamese health claims regulation regulate labelling, marketing activities and instruction for use of functional foods (Ministry of Health Vietnam, 2014).

Country	Indonesia	Malaysia	Singapore	Thailand	The Philippines	Vietnam
Scope	Processed food with claim declaration. Apply to label and advertisement of processed food and food with health claim. (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a)	Not stated/ unclear (Ministry of Health Malaysia, 2010)	Food label and advertisements (Agri-Food & Veterinary Authority, 2010 (with amendments to 2016))	Representation of pictures, photograph, invented designs, mark, trade mark or any texts on labels that states a relationship existed between a food or constituent and health (Ministry of Public Health Thailand, 2011)	Labelling and advertisement of consumer products.(Republic of the Philippines Food and Drug Administration, 2007)	Regulate labelling, marketing activities, and instruction for use of functional foods. (Ministry of Health Vietnam, 2014)

Table 3.3: Scope of health claims regulations and guidelines in the selected SEA countries

3.4.2 Health claims substantiation and evaluation

All the regulators declared that they used the Codex standard on health claims substantiation and evaluation, and their existing regulation/ guidelines of the requirements on the claims substantiation. All the regulators, as well as key opinion leaders and scientific organisations consistently emphasized that the food or food constituent had to be safe for human consumption and within the food jurisdiction. They also stated that food constituent must be characterised and quantifiable. The rationale as to why there is a need to consume the food constituent must be clear, and the effectiveness and efficacy of the food constituent and to a specific health outcome ‘also known as the cause- effect relationship’, had to be substantiated by scientific evidence in the submitted application.

‘Safety, evidence- scientific substantiation. Evidence to show the cause that has the properties or the functions. Human data to demonstrate the cause- effect relationship. They [food regulators] will always ask you to state the amount to show the effect e.g. 1gram, 3 gram or 5 gram. Hence you need to be able to measure the component. Example if you are claiming for the whole food, your studies should show based on the consumption of the whole food rather than certain component.’ - P11

All the regulators, key opinion leaders and policy makers noted that they looked for ‘comprehensiveness of data’ in the applications. The term ‘comprehensiveness of data’ refers to the required data as stated in the application forms for new claims in each country such as human intervention data, quantity to consume, target group etc. These data had to sufficiently demonstrate the effectiveness and efficacy of the food constituent and the benefits to health, also known as the cause-effect relationship.

‘It goes to what they want to want. We are not asking for information beyond to the claim they want to say.’ - P1

‘One example is that all the information for the required 18 items in the form are provided.’ - P7

3.4.2.1 Codex Alimentarius

All regulators but also key opinion leaders mentioned the Codex guidelines for the use of nutrition and health claims as the basis to evaluate new health claim applications. However, to date, only the Indonesian regulations on health claims state the principles of evaluation for approval explicitly in their guidance materials.

‘We follow other countries and Codex guidelines.’ - P1

'Evaluations are based on the Codex Guidelines on Scientific Evaluation of claims.' - P2

'Applicants should also ensure that the studies submitted best substantiate the proposed health claims. This is as recommended by Codex under the 'Guidelines for Use of Nutrition and Health Claims. The guiding principles are based on the recommendation made by Codex.' - P3

The key information required for the health claim applications are similar to the key parameters used to evaluate health claims. The key parameters to evaluate health claim applications were the presence of human intervention studies, the quality of human studies, the proposed wording of the claim and a clear scientific rationale on the condition of use such as the realistic amount of the food constituent to consume in a given food matrix that will be discussed in the subsequent paragraphs. Figure 3.4 provides an overview on the data required to substantiate the new health claim application based on the interviews and the existing regulations, guidelines or application forms published by the following SEA countries: Indonesia, Malaysia, Singapore and Thailand (with the critical information for health claim substantiation in bold).

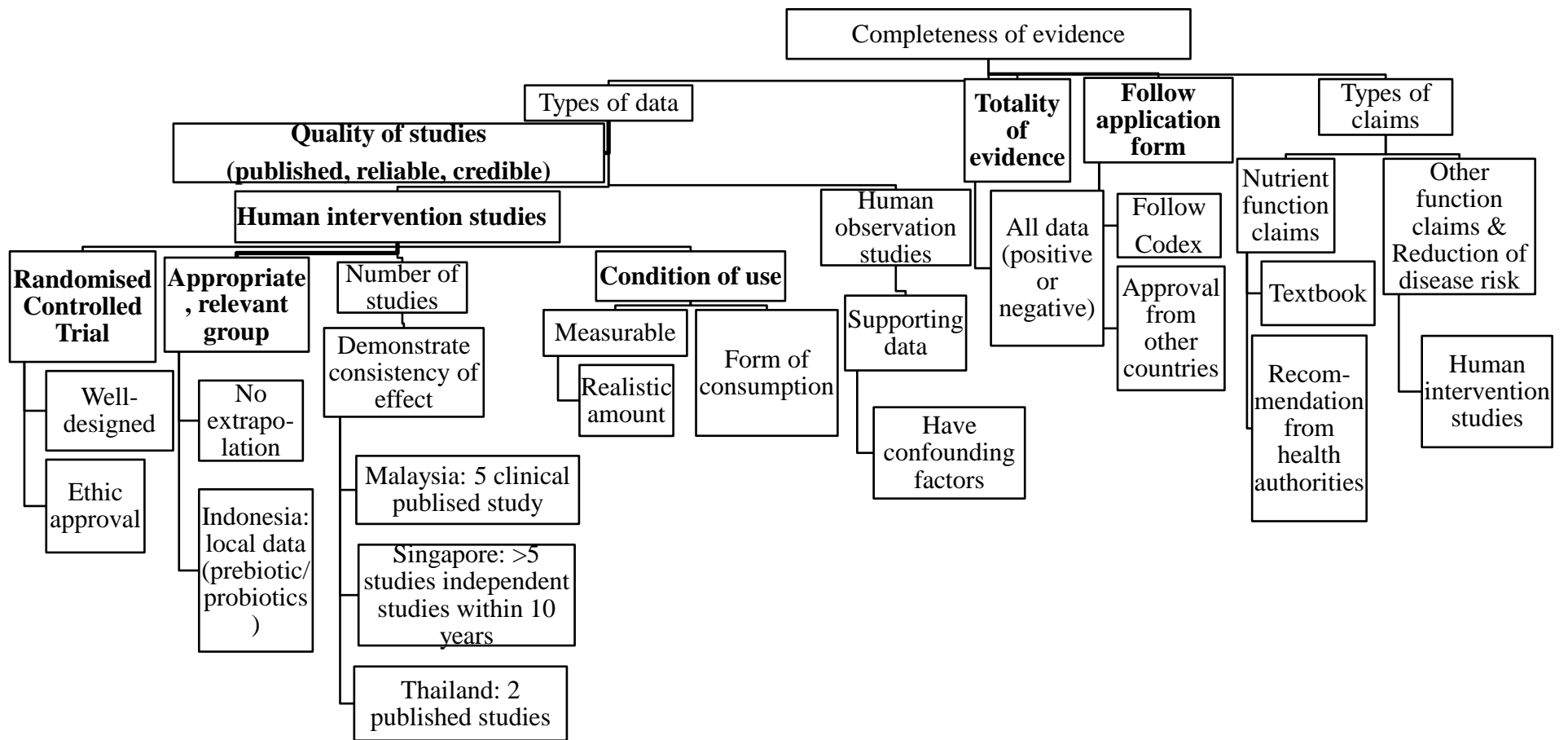


Figure 3.4: Summary of data requirements for claim substantiation

Source: Author’s construction drawing upon data from the interviews; and Ministry of Health Malaysia (2010); National Agency of Drug and Food Control of the Republic of Indonesia (2011a); Agri-Food & Veterinary Authority (2010 (with amendments to 2016)); Agri-Food and Veterinary Authority of Singapore (n.d.-b); Ministry of Public Health Thailand (2011); Ministry of Health Vietnam (2014)

3.4.2.2 Quality of the human studies

Primarily, good quality of scientific studies is a pre-requisite before any application can be considered for evaluation. Based on the feedback of a few participants, it seems that the quality of human studies was reviewed based on criteria such as the type of human studies, sample size, selection of subjects, quantity of the constituent required to consume, and the endpoints or biomarkers measured in the studies. Well-designed human intervention studies such as Randomised Controlled Trials (RCT) were repeatedly quoted as the type of high - level quality evidence that is needed by the regulators, but also by some key opinion leaders and most policy makers. These human intervention studies were expected to be included as evidence in the new applications. Finally, the subjects participating in these intervention studies should reflect the intended target audience of the product/ food constituent.

'The main principles are: the randomized placebo-control trial be of sound design (sample size, selection of subjects, how nutrient/food component is given to subjects, parameters measured); scientific data must be in line with the proposed claim wordings; clear scientific rationale of the proposed minimum amount that must be present; subjects studied must be similar to intended targets of the product' –P7

3.4.2.3 Human intervention data to demonstrate health efficacy

Human intervention data are compulsory to demonstrate the cause-effect relationship of the food constituent to health in all countries. Studies to be submitted in application dossiers were preferred to be peer-reviewed and published data from studies that were conducted within the past ten years by reliable, recognised institutions such as governments' ministries, and academia. Human intervention studies conducted in other countries and/or by the industry, were accepted by the regulators, provided that these studies were well-designed, peer-reviewed published and conducted using good research practices. Human intervention studies were also required for claims on foods with a long history of use, such as ginger or garlic in all SEA countries, not just for novel food constituents.

'They should be obtained from human studies, which may supplemented by data from non-clinical studies. Furthermore, these data should come from the reliable resources or publications that are generally recognized in academics or research fields.' – P4

'The company showed scientific results from other countries. For example, Singapore, America, Europe are good. But some developing countries are not accepted, so the result is not considered. Some studies from [Country X] can be good but must be supervised by government offices or other countries, organisations from Europe/ developed countries.' - P5

'In the current system, foods with limited scientific evidence are not likely to be accepted to make health claims, although they may have a long history of use. This is especially if long history of use is not well documented.' - P7

Non- human intervention studies may not substantially contribute to a higher likelihood of approval as the evidence was considered supporting and secondary. Human observational data which are commonly used for nutrition research, were considered as supporting evidence in most SEA countries. Animal studies, in-vitro studies, and medical textbooks were also classified as supporting evidence. Supporting evidence was a 'good- to- have' piece of information, if there were no human intervention data available.

'Human observation studies may be used to provide further support to strengthen applications. If an application has only human observation studies, it will likely not be accepted by the Committee.' - P7

'Human intervention data is a must. Human observation data is used as supporting evidence, not a primary data used to substantiate.' - P11

3.4.2.4 Proposed wording of claims

Most participants stated that the proposed wording of claims should not extend to other benefits and it must clearly explain only the benefit of the constituents. Participants from the food associations echoed similar responses with the regulators and key opinion leaders in that claims should be truthful and be evidence- based. The understanding (by consumers) of claims was not an immediate consideration by the interviewees, until they were being further asked.

'The benefits are showed and demonstrated. It is exactly the results and no extrapolation. With that, it will be easy to approve. The product for this group, the formula is the same and formula used is the same, so no extrapolation beyond the conditions of the studies.' - P8

'Industry should only claim on what they have' - P14

3.4.2.5 Condition of use

The quantity required to consume to achieve any beneficial effect should be at a realistic amount of the food constituent which does not lead to overconsumption of certain products. Most countries accepted data on the food or food constituent, provided the matrix of the food/ vehicle does not change the physical or chemical properties of the active ingredients. The

vehicle of consumption should be part of food matrix and able to fit into the local dietary pattern.

'Let's say we are talking about cheese, people in western countries eat cheese like eating crackers. Do we eat cheese in that way? That means we need to take into consideration that situation. Maybe they will take up the dosage higher or more frequent, or the consumption maybe little.' P1

3.4.2.6 Totality of the evidence

The expert committees established in Indonesia, Malaysia, Singapore, conducted holistic evaluation for the new health claims based on the totality of available evidence. Each new claim application dossier is required to include all available studies regardless of positive or negative results (Ministry of Health Malaysia, 2010; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Agri-Food and Veterinary Authority of Singapore, n.d.-b). The Philippines regulatory agency differed from the rest of the SEA countries as they conducted their own evaluation to assess the totality of evidence by searching the literature, rather than relying on the information provided in the dossier and assuming it is complete.

The rationale for some SEA countries such as Malaysia, Singapore, Thailand to request for a specific number of studies in the application dossier is to ensure that there was sufficient evidence, and that there were consistent outcomes from the studies to demonstrate the benefits of the food constituent to health as claimed. Some commented that the quality of the studies was more important than dictating a certain number of studies to be submitted.

'The number of studies is important to establish consistency on the findings to support the claims.' - P2

'This is to display consistency in the outcome of the studies. Applicants should also ensure that the studies submitted best substantiate the proposed health claims.' - P3

'But I think they just want to make sure that you have enough. If you have one and only one study or published papers from the same old story, same study, then it might not so representative. [...] To them, it is not like it must be five, it must be seven. It is basically telling you must have the evidence. If you only have one study, there is no point to apply the information.' - P11

'There is no minimum number of studies that is required. A loose guide is 5 clinical studies. What is more important is the quality of the studies.' - P7

3.4.2.7 Approval/ status of claim applications in major jurisdictions

The approval and status of a new claim in other jurisdictions such as European Union, United States, Australia and New Zealand provided a reference for the Asian regulators on how the claim could be viewed by the regulatory agencies in non- ASEAN countries. Most participants mentioned that the information coming from other jurisdictions, did not influence the approval of the claim application in their country, but that this information was required in the applications. Some participants commented that the ASEAN regulators could feel more confident about the claim, knowing that the particular claim had been screened or approved by other competent authorities from major jurisdictions such as European Food Safety Authority (EFSA), Food Standards Australia and New Zealand (FSANZ).

'We have requested for applicants to indicate if the claim has been evaluated by other national regulatory bodies (whether accepted or rejected). This is to provide a holistic view and opinion of the proposed claim and not as a deciding factor to approve or reject a claim application.' - P3

'To see how the other countries regulate health claims in their countries [..].' - P4

'It is only for reference, to determine how other countries view the intended claim. It does not necessarily follow that if another country has approved a claim, we will follow suit. It also does not mean that if no country has approved a claim applied, we will also not approve. The committee views the evidence on its own merit.' - P7

'So this has been screened or approved by another competent authorities like FSANZ or EFSA. They will feel a bit more relaxed, knowing that someone has reviewed the evidence so they can actually look at the summary reviewed by these countries and draw their own conclusion.' - P11

3.4.3 Factors affecting the approval of health claims

Two key factors affecting the approval of new health claims involved the comprehensiveness of the scientific evidence and the common errors in the application dossiers. The health claim application had to be substantiated with a comprehensive and consistent body of evidence to demonstrate the relationship between the food constituent and health, or otherwise it would be rejected during the evaluation. The common errors mentioned by the regulators and key opinion leaders were: i) inadequately and ill- prepared application dossiers, such as poor

explanation on the scientific substantiation; ii) lack of strong scientific data to substantiate the claims such as non-human data, or outdated data (more than 10 years old); iii) the food constituent was not well-characterised with no clear unique characteristics; iv) the wordings of the claims did not match with the study findings or a mismatch and/ or extrapolation of information from the human studies, e.g different target audience, studies using ‘pure’ constituent(s) consumed as a supplement, but a claim on the constituent in a food matrix; and v) proposed claims that implied treatment of medical conditions and/or diseases such as constipation, lower blood pressure, which are all outside the jurisdiction of food regulations in the countries examined.

‘the documents, sometime we ask for current documents, but maybe they prepare documents many years ago or the studies are not with the subjects they want to explore (target of the people).[..] If the way to consume the products like certain way. If it is put in biscuit, would it be useful? Sometime the consumers' way to consume, have link on the benefits that is mentioned that. Maybe the studies were conducted on the certain pill, they want to put in milk in whatever. Would it have the same benefit? If the study is only on certain groups, now they want to claim people. We cannot say that it is related. Sometime certain component cannot be generalised, depending on the metabolism.’ - P1

‘Completeness of the application is an important factor. Incomplete applications could delay the application process. In recent years, several applications have been submitted based on pure food components taken as supplement. They have not yet been incorporated in to food products/matrices. Members felt that these components should be evaluated as supplements rather than nutrients/components added to food. Wordings for claims bordering on disease reduction e.g. lowering blood pressure, constipation, diarrhoea.’ – P7

Interestingly, the response rate from the expert committees was described as a factor which delayed the approval timeline. Some participants raised concerns on the availability of experts in Asia to evaluate health claims.

‘Timeline of the health claim evaluation is dependent on several factors like the complexity of the case, response from the Committee on Evaluation of Health Claims (which is made up of mainly external experts working on a pro-bono basis) and availability of evidence.’ - P3

‘Because when a country has lot of experts, they can afford to do it fast. But unfortunately in ASEAN, I think this is a major problem faced by many countries. There are not enough experts in the countries. They have experts but not enough. They might have that few experts

which they re-used many times. And the people also have their full-time jobs. If they are experts, they are also involved in many other committees. So this is difficult. Let's say there have 100 experts just like Europe. They don't have to use the experts many times again.' - P11

'the question is very few reviewers. That's why I propose FDA limit. So we are going to have public organisation to review outside FDA under supervision of FDA. Maybe next year. Because I don't think the government can recruit experts. Company have to pay for review and we need to build more experts at universities ready to review. I think not only from Thailand, maybe recruit from everybody. We want to be International. Because limit manpower, limit knowledge.' – P9

3.4.4 Challenges faced by the SEA stakeholders

3.4.4.1 Regulators and Policymakers

Some regulators faced difficulties in differentiating between health claims and medical claims in more complex applications. There is marginal difference between food and drug/supplement in some cases, such as the creativity or innovation of adding non-food constituent into food.

'The claims that are closely to medical claim. As mentioned above no medical claims are permitted, so the challenge is how we should do to prevent consumers misunderstanding that the claimed food products have therapeutic action.' - P4

'First, we put the regulation draft. Food is not a drug; Supplement we have to say not to cure, prevent or treat the disease. I like the labelling, warning on the supplement. But the food and drug is very narrow. Now the food put Coenzyme Q10. It is very difficult for every government.' P9

The regulators found it challenging to allow more compelling health claims and to show flexibility in rewording the approved health claims for commercial viability. Some feared that rewording of claims could mislead the consumers to interpret the claims in different ways. One participant described that they were in a difficult position and they were unsure on how to achieve a balance between business-friendly and consumer protection.

'They want the claims to bombardise and catchy. That is one of the challenges. This is true, just say the study saying it is approved. If we put that to the consumer in the labelling or advertisement, we want to make sure do people understand or do they apply in the right way. Or they may exaggerate from the claims or they may expect too much from that claim.' P1

'Industrial push for more flexibility on rewording of claims for commercial viability, leading to potential truncation of approved claims.' – P3

'Not just the committee, NGO (non-governmental organisation), consumer groups, they want to challenge. I like the challenge. You (Academia), company, NGO, FDA debate and get the conclusion. Platform is at the food committee. [...] I prefer the balance. You know I like everybody come and balance. I am in the middle of [...], very difficult.' –P9

3.4.4.2 Key Opinion Leaders

The key opinion leaders from the scientific community expressed difficulty in evaluating new health claim applications. They reported that most applications were not well-prepared and lacked strong evidence to substantiate the proposed health claim. In addition, some applications were based on pure food components consumed as supplements but were intended to be made in a novel food containing the constituent. One participant commented on the difficulty on agreeing on whether there was sufficient evidence for a claim and that there was inconsistency on making a decision when the members in the committee change during the evaluation process.

'Document not well prepared, lack of quality strong evidence. The completeness of the submission documents, the quality of evidence, experts review'-P6

'One of the main challenges is agreeing on what constitute sufficient evidence for approval of an application. It is important to make consistent decisions; however this is difficult. It is not something that we can quantitate. When members in the committee change, then the decision becomes even more varied.' - P7

3.4.4.3 Representatives from food associations

The participants from the food associations consistently raised that the rigorous, pharmaceutical- like approach to substantiate health claims for food, was very challenging to achieve. They held the view that a food is not a drug, and that scientific evidence should not stringently follow the pharmaceutical standards, which are also mainly for treatment of a medical condition and not for use in an otherwise healthy population. These stringent requirements could include well-designed human intervention studies in a healthy population, or in specific subgroups in which it is preferable to use the same products but without the constituent as applied to drug standards.

'Food is not a medicine. I do not agree why just to make a claim that a food product will help support healthy condition of the consumers, would need a clinical trial. Requirement of "Well

designed Human Intervention Study” done with the product in a specific group of population.’ – P14

One participant indicated that it was unrealistic to request for independent studies and a certain (minimal) number of studies for each new application.

‘It (clinical trials) should be independent and ideally not be funded by the company. So that is ironical. [...] Of course, they [the company] need to collaborate with the company which has the ingredient that can engage a third party academic to do the trial. I think they [the regulators] should not focus so much on that, rather they should focus on the merit of the study. Not many companies can do that to submit five human intervention studies on an ingredient to make a claim. That cause a barrier for company to consider submitting new claim.’ - P13

Another participant commented that there was a need for the authority to change the mindset that does not allow nutrients without recommended dietary intakes (RDI) to carry a health claim.

‘Mindset of authority that does not allow nutrients without RDI to carry a health claim.’ - P14

The industry requested for transparency in the health claim evaluation. They found it difficult to understand some decisions on application rejections, as no clear explanations were provided. The industry suggested that it would be better to work with a list of approved health claims, and that they would appreciate it if more health claims and some flexibility in wording could be approved for communication.

‘We do not know what is going on with the evaluation. I think because it comprises of lots of academia, agencies which gives comments. [...] Unfortunately we do not know what is the reason of the rejection. So sometime the details of the comments from the committee or rationales behind it.’ – P13

3.4.5 Key country differences

3.4.5.1 Local data required in Indonesia for prebiotic and probiotic claims

Claim applications specifically for prebiotics and probiotics in Indonesia have to be supported by human intervention studies conducted in the local Indonesian population as the function is assumed to be dependent on the unique flora of the indigenous populations.

3.4.5.2 Developments in health claims regulations and guidelines

The development of regulations and guidelines for health claims are at different stages across the SEA territory. Indonesia, Malaysia and Singapore had written documents to provide reference for industry in filing of new health claim applications. These documents include application forms, the description of processes and lists of approved health claims (Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Agri-Food and Veterinary Authority of Singapore, n.d.-b). These SEA countries also expected the scientific substantiation to have more complete information than officially required. In contrast, Vietnam, which did not have any official health claim regulations at the time of interview, was more receptive to approving health claims as long as the evidence was from credible sources such as the Vietnamese National Institute of Nutrition, and/ or peer-reviewed scientific publications. The Vietnamese regulatory agency also permitted health claims on foods that had a long history of use, provided the scientific substantiation was from widely-referenced and established textbooks, such as the encyclopaedia of traditional medicines.

3.4.5.3 Expectations on the scientific substantiation depending on types of claims

Some key opinion leaders and representatives from scientific organisations expressed different expectations on the robustness and rigor of scientific evidence depending on the types of health claims submitted. According to Codex Alimentarius, health claims are categorised into three categories; nutrient function claims, other function claims and reduction of disease risk claims (Codex Alimentarius, 1997 (last amended in 2013). Reduction of disease risk claims can be considered as the highest level health claim, compared with nutrient function or other function claims. Some participants suggested that more stringent, rigorous scientific evidence such as Randomised Controlled Trials were required to substantiate these high-level claims, while nutrient function claims required only scientific information from well-established recognised textbooks. The participants also suggested that other function claims could be considered a hybrid between a nutrient function claim and a reduction of disease risk claim, and also required evidence from human intervention studies to substantiate the effectiveness of the food constituent to a health outcome.

'Need to be human intervention data. It depends on the level of health claims. Disease risk reduction claim definitely need human intervention trials. Unlike nutrient function claims that are very well-established nutrients such as the textbooks, recommendation from health authority. then you don't need to have. Example: Calcium in the strengthening of bone

functions, you don't need to conduct another study to demonstrate this effect as it is quite established. Other function claims also need human intervention trial as they are not the traditional nutrients. They could be novel ingredient and they need to demonstrate that. Observation studies do not give you strong enough data to show the effects'.- P11

'let's say they only say 'the product contains', mainly we ask for the certificate of analysis. They have the certain amount. If they say help to maintain digestive system, they have to give us a study on that issue. Behind that, we would like to understand if the study does it once, or do it on certain group of people, do it for a range of age. Deepness of the claims may go to what they want to achieve.' - P1

3.4.5.4 Time of the health claim approval process

The time notification on the outcome of health claim applications varied considerably. Only the Indonesian regulations stated a time frame of a maximum of 6 months, which was confirmed by the interviewee but this was subject to the availability of the scientific evidence (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a). In the Philippines and Singapore, the review process typically took one week to one month and 9-12 months respectively from the time of complete submission to relay of the evaluation outcome to the applicant. In Malaysia, the whole process took 'several months' without a specific time frame indicated. The Thai authority took around 1-2 years to process an application before the applications for new health claims on food in Thailand was stalled without further notice (obtained from several interviews). No information was available for Vietnam at the time of the interviews, as the Vietnamese health claim system was newly established in January 2015.

3.5 Discussion

The interviews conducted with the various stakeholders in SEA clearly indicated that all regulators and key opinion leaders used the Codex Alimentarius guideline on health claims as a basis for their scientific substantiation and evaluation of health claims. This common base will have a positive influence on trade opportunities in ASEAN region which is in line with the intention of the ASEAN Economic Community to provide more access to nutritious food for all SEA consumers by providing a level playing field for food companies which operate across SEA. The findings of this qualitative study show that the current thinking on substantiation of health claims and the evaluation criteria were quite similar among the stakeholders across the SEA countries. This includes the need for high quality well- designed human intervention studies, conducted in the target groups, using clearly characterised food constituents, indicating the conditions of use (quantity to consume and pattern of diet) to

demonstrate the ‘cause- effect relationship’ and the application could be accompanied with the approval or status of the claims in other major jurisdictions. To a large extent, the approach is in line with other major jurisdictions such as the European Food Safety Authority (EFSA), the United States Food and Drug Administration (USFDA), and the Food Standards Australia and New Zealand (FSANZ) (Codex Alimentarius, 1997 (last amended in 2013; European Food Safety Authority, 2006; Food Standards Australia and New Zealand, as of 18 January 2016; United States Food and Drug Administration, Revised as of 1 April 2015a). This common understanding also provides a base for the food industry to prepare clear application dossiers for regulatory submission and approval in multi- SEA countries.

Clearly, there are different expectations on the different types of scientific evidence required to substantiate the different types of health claims, especially human intervention studies are required for ‘other function ’ and ‘reduction in disease risk’ claims, which could have an influence on the approval of health claims. This difference in the weight of the evidence is similar to the situation at the EFSA which has established a hierarchy of studies to evaluate health claims (European Food Safety Authority, 2011b). Some research has suggested that health claims can be divided into two groups; generic and product- specific or disease-related when preparing scientific substantiation (Cummings *et al.*, 2003; Asp and Bryngelsson, 2008; Lalor and Wall, 2011). Several review papers on health claims in Europe and the United States reported that the scientific substantiation of health claims ranged from the well-established evidence accepted by scientific bodies for nutrient function claims to multiple well- designed human intervention studies with consistent results for reduction of disease risk claims (Cummings *et al.*, 2003; Binns, 2009; Richardson, 2012). In the recent scientific guidance documents established by EFSA, the evaluation panel has approved health claims on essential nutrients based on a large body of scientific evidence which includes case reports of clinical studies and animal studies (European Food Safety Authority, 2016b). This approach by EFSA is aligned with PASSCLAIM and the Codex recommendation which suggests that nutrient function claims can be substantiated by well-established information (Codex Alimentarius, 1997 (last amended in 2013; Aggett *et al.*, 2005). This explains why there are generally more approved nutrient function claims compared with other types of health claims by EFSA. This study also suggested culture could influence the acceptance of different types of scientific information such as in Vietnam. For example, the health claims on food with long history of use can be supported by the encyclopaedia of tradition medicines in Vietnam. This could be due to the fact that the consumption of traditional herbs is seen as part of the normal Vietnamese diet and culture (Nguyen and Nguyen, 2008).

The key parameters to evaluate health claims and the common errors on the application faced in SEA were similar with those faced by EFSA. In EFSA, the quality of the study is important and this is assessed by the quality of reporting in the studies (Martin, 2015). Each application was evaluated by matching the target population of the submitted claim, the condition of use such as the amount to consume to be part of balanced diet and the wording reflecting the scientific evidence. In addition, the totality of evidence is weighed to look for the cause-effect relationship between food constituent and health (Martin, 2015). Most health claims applications on children development in Europe were rejected due to the limitations of research studies in paediatric nutrition, too generic benefits such as gastrointestinal health, immune system, wide range of tests for different aspects of development and extrapolating results in different populations from diseased population to the target group (Valtueña Martínez and Agostoni, 2013). Harmonisation on the research methodology was suggested to overcome the research limitations and it can be achieved by communication and consensus among research community (Valtueña Martínez and Agostoni, 2013). Most recently, the EFSA has recognised the limitations in obtaining the biological plausibility such as mechanism and bioavailability of the essential nutrients from human randomised controlled trials due to ethical considerations and the nature of repletion human studies (European Food Safety Authority, 2016b). This suggests that the human intervention studies for health claim applications are difficult to achieve.

Well-designed human observation studies should be considered as high quality scientific information that can be used to substantiate generic health claims. This study has shown that human observation studies were viewed as only supporting evidence and was considered less credible compared with human intervention studies. This creates challenges for the research community and the food industry to generate data to support health claim applications. It is clear that the nature of food and nutrition studies in humans is different from those required for drugs. Foods provide a matrix containing multiple nutrients and the consumption in diets makes it difficult to single out the specific benefits of any particular food constituent (Aggett *et al.*, 2005; Binns, 2009; Aggett *et al.*, 2012; Richardson, 2012). Therefore, most of the nutritional research has historically been mainly through human observation studies. A more pharmaceutical- approach to investigate the benefit of any food constituent is difficult to achieve, generating high costs for the food industry (Binns, 2009; Aggett *et al.*, 2012; Richardson, 2012; Richardson and Eggersdorfer, 2015). The representatives from food associations in SEA shared similar concerns. In SEA, human observation studies are accepted for scientific substantiation of ‘other function’ claims and ‘reduction of disease risk’ claims

according to the recently-launched ASEAN Harmonisation on health claims for traditional medicine and health supplements which follows the Codex classification of health claims on food (Association of Southeast Asian Nations (ASEAN), 2015). It can be worthwhile to take reference from the disciplines related to nutrition such as health supplements to mitigate issues which exist in food and nutrition area. For instance, it could be useful to understand the rationale why the human observation studies are accepted to substantiate health claims on traditional medicine and health supplements. This could help the regulators and key opinion leaders to decide on the types of human studies acceptable for health claim substantiation in food, knowing the limitations of nutrition studies.

The phrasing and choice of words in health claims application are important because they differentiate between health claims on food and medicinal claims, and clearly influence how the health claims will be classified. The evaluation of the health claim application process clearly indicates that the appropriate wording needs to be used when formulating new health claims for regulatory approval. In Europe, it is reported that there is a risk of overlap between health and medicinal claims due to the beneficial health effects and end point measured and the wording used (Flynn, 2012). For instance in Europe, the benefit of ‘maintaining cholesterol’ is classified under Article 13.1 (General or function claims) while the claim of ‘reducing cholesterol’ is classified under Article 14 (Reduction of disease risk claims) (Binns, 2009). The wording of the health claims can also indirectly impact the scientific substantiation required. A reduction of disease risk claim requires more rigorous and stringent human intervention data compared with a nutrient function claim. However the consumer-friendly wording is not under the purview of the EFSA NDA panel (Martin, 2015). With the evolving scientific insight, some food constituents may have multiple benefits and/or even drug-like functions. A clear question to raise here is what is the balance between non-misleading and consumer-friendly wording of claims? In addition, the wording of claims can have different meaning in different cultures which influence their understanding and also the subtleties of the English language makes interpretation difficult for lay consumers. Several review papers have highlighted how the impact of the wording of claims and different cultures influences the understanding of the claims (Dean *et al.*, 2011; Nocella and Kennedy, 2012; Lähteenmäki, 2013). A recent focus group study conducted among SEA mothers (Chapter 4) demonstrates that the choice of words, phrasing, length of claims and the use of scientific terms such as haemoglobin, carotenes, antioxidants etc., were clearly barriers to the understanding of health claims (Tan *et al.*, 2016). Other studies in Europe have also shown that scientific terms on claims such as ‘connective tissues’, ‘platelet aggregation’ were not

understood (Richardson and Eggersdorfer, 2015). In a cross- country study conducted in Denmark and the United States, the Danish consumers responded more positively towards the soft framing of information while the American consumers preferred the scientific framing of information (Aschemann-Witzel and Grunert, 2015). The wording of the claim can affect both the application and understanding of health claims.

The two emerging issues of requiring human intervention data in local populations and the mindset of rejecting claims on nutrients which do not have RDI, are considered good ways to protect consumers, but may prevent consumers from having access to foods that could support their health. Both issues may also provide a hurdle for the industry to develop innovative, healthier, nutritious product due to the high cost of generating supporting scientific evidence, the time lag in developing this evidence and the legal processes associated with acquiring a claim for regulatory approval.

The establishment of experts committees from multi- disciplinary backgrounds to evaluate new health claims can be seen as a solid base. These committees work based on the key concepts and guidance provided by Codex in line with other major jurisdictions on scientific substantiation and evaluation, the availability of application processes, and the positive list of approved health claims. This use of Codex as key references and provision of processes provides robustness and transparency on how health claims are approved in the countries for the industry and consumers, and this also creates certain level of consistency that can facilitate food trade. Two key areas that could improve were unclear or outdated regulations and guidelines and irregular communication across the different clusters of stakeholders.

An opportunity for improvement lies in the clarity in the regulations/ guidelines and the availability of established guidelines documents for health claim applications. These could include further guidance on the scope, objectives and principles of the regulations/ guidelines and the required materials such as food labels, advertisements that require pre-market approval. Guidance documents can be a way to align among stakeholders. The checklists on scientific documents required and the guidance documents such as scientific and technical guidance on scientific substantiation could be included to facilitate the process. These documents can be updated, as and when the scientific insights and regulations change. For instance, food authorities from the major jurisdictions such as EFSA, USFDA, FSANZ, and Health Canada publish official guidance documents (United States Food and Drug Administration, 1994 (revised January 2013); Health Canada, 2009; European Food Safety Authority, 2016b; Food Standards Australia and New Zealand, 2016a). At present, equivalent

information is either unavailable or not as complete in SEA. This would also bring more clarity to potential applicants on the requirements for regulatory approval on new health claims.

The different perspectives and viewpoints on the challenges faced by the stakeholders within the same clusters, could have resulted from the job responsibilities, different professional training and/ or field of expertise of the stakeholders, and not competencies. All of the interviewees were science-trained. A study in Italy reported that the diverging goals among the stakeholders such as entrepreneurs, academics and policy makers, resulted in different perspectives on innovations and the perspectives deeply influenced behaviours (Massa and Testa, 2008). A cautious and consumer-protection mindset of the regulators was observed when the adoption of Codex guidelines on health claim was stalled for several years (Hawkes, 2004). This suspension on the establishment of the Codex guidelines on health claim was mainly due to the disagreement over reduction of disease risk claims among the member states and the fear that the food could imply curative, therapeutic properties (Hawkes, 2004). It is understandable that the different clusters of stakeholders have different perspectives as the key objective of the regulators is to protect consumers from being misled, while the key opinion leaders is to uphold highest scientific standards and the food industry is to provide a solution to satisfy the need and wants of the consumers. This research seems to suggest a need for reconciling different perspectives for health claim regulations to progress. This does not mean that total agreement among stakeholders is needed. If the intention of the stakeholders is to have more health claims available for consumers, it is important to have platforms for the different clusters of stakeholders to communicate and brainstorm for possible solutions to mitigate the challenges faced by each cluster of stakeholders.

A regional expert group consisting of the scientific experts from the SEA region should be established to evaluate health claims. This regional scientific expert group could facilitate the cross-fertilisation of knowledge and potentially solve the issue when the limited availability of experts to evaluate health claims in individual SEA countries. Aggett (2012) highlighted that it is critical that those who review and assess evidence for health claims to have the competency and appropriate knowledge to do so. In addition, this group could be tasked to develop a consistent decision framework to approve new applications based on scientific consensus. This framework could address inconsistency on decisions when members in the evaluation committees change. The international experts can be consulted/ invited on an ad-hoc basis, subject to the approval of local regulatory bodies. Although the ASEAN secretariat is the most ideal channel for this work, the organisation has limited resources as there are

other pressing issues to resolve in the SEA setting. ASEAN operates differently compared with the European Union. Unlike the membership of EU, each member state in ASEAN pays the same amount for the annual full membership fee of \$1 million which is affordable to all ASEAN members (Munthit, 1994; Grainger, 1995). The International Life Science Institute-Southeast Asia (ILSI-SEA) or the ASEAN Committee on Science and Technology are also potentially a good platform to facilitate the formation of an advisory group for the time being. ILSI, as an independent organisation which receives funding from industry but which has independent academic advisors has already established the connections with well-known, well-respected scientific experts in SEA and it has been organising many scientific meetings including some on health claims harmonisation in this region. In addition, the ASEAN Committee on Science and Technology which is funded by the governments in SEA, could have the resources to carry out the work to form an advisory group.

More regular communication and collaboration among and across the different clusters of stakeholders can facilitate communication and understanding of health claims by the Asian consumers. If shared, the most common mistakes identified in health claim application dossiers could help to create clarity in the research community and the industry. This communication can be conducted via public consultation, official government website publications, and through direct connections with the local food associations. A regional database with the consolidated approved health claims and country regulations and/ or guidelines on health claims can be developed for the ASEAN region. This could provide a win-win situation for all stakeholders as the consumers can visit a public website to check if health claims on specific food products are indeed approved; the regulators are perceived to protect their consumers; and the industry has more health claims to communicate with the consumers and it could facilitate cross-border trade.

3.6 Limitations and future research direction

This qualitative study provides clear insights and helps to build further understanding on the research topic. However, it does not fully represent the views on the whole ASEAN region as only six out of ten ASEAN countries participated in this study. Furthermore, feedback was restricted to selected participants representing different stakeholders involved in the regulatory process of health claim approval and each type of stakeholder was not represented in each country. It was challenging to achieve a well-balanced number of subjects with which to conduct the interviews due to busy work schedules and the different developmental stage of the health claims regulations in this SEA region. Like any qualitative study, there could be self-reported bias as the data are based on self-reporting and personal viewpoints regarding

issues. Future studies should be extended to study the factors why the potential participants declined to participate in the interview and expand to more stakeholders such as policymakers, or different disciplines related to nutrition that could obtain ideas on how to mitigate the existing challenges and issues on health claims on food.

3.7 Conclusion

This study aimed to shed new light on the current practices and perspectives on health claims in Southeast Asia. The study was not intended as an attempt to determine which practice or perspective is ‘right’ but rather aimed to find the points where practices and perspectives converge and diverge and provide some suggestions to reconcile those. In the light of the formation of Association of Southeast Asian Nations (ASEAN) Economic Community in 2015, the regulatory systems play an important role to protect consumers, promote innovation and facilitate trade within the SEA region. The availability of application processes, establishment of expert committee, and using Codex as the basis to evaluate scientific evidence for health claim application are seen as best practices. Clearly, clarity and transparency on the existing health claims systems in SEA can be improved. Nutritional science and food technology will continue to evolve and be influenced by the needs of changing demographics, lifestyle, economy, and knowledge etc. Studies have shown that health claims educate the consumers on health benefits and may support healthy food choices (Wills *et al.*, 2009; Wills *et al.*, 2012; Richardson and Eggersdorfer, 2015; Tan *et al.*, 2016). By allowing more health claims, the Southeast Asian consumers can be educated on new scientific insights on nutrition and health, and be supported in their ability to make informed food choices.

Chapter 4 Perception and understanding of health claims on milk powder for children: A focus group study among mothers in Indonesia, Singapore and Thailand³

4.1 Abstract

Health claim regulations and guidelines on food products have been established in some Southeast Asia (SEA) countries. Health claims on food products aim to help consumers make informed food choices to achieve a healthy diet. This study aimed to investigate the SEA mothers' perception and understanding of health claims and the associated regulatory frameworks using semi-structured focus groups conducted in Indonesia, Singapore and Thailand. Milk powder for children for three years and above was used as the product focus. The mothers recognised and recalled some specific nutrients by names but lacked full understanding of the function of these nutrients. The findings indicated that the mothers in all three countries trusted health claims made on the products which were, in part, explained by their trust in their governments and the international brand manufacturers. Their understanding of health claims was influenced by several factors such as the familiarity of the nutrient, previous knowledge of the nutrients, the perceived relevance of the nutrient, the use of scientific terms, the choice of words, and also the phrasing and length of the claims. Consumer education efforts via Public, Private Partnerships could be an approach to educate SEA consumers and help them to better understand health claims. The findings of this study may be relevant to different stakeholders such as local regulatory bodies, policy makers, food industry, academia and non-profit organisations that aim to effectively communicate health claims.

Keywords: Health claims, Southeast Asia, consumers, perception, understanding, regulatory affairs

³ This chapter has been published in *Appetite*.

4.2 Introduction

Health claims communicate a relationship between a food and health via i) nutrient function claims, ii) other function claims, and iii) reduction of disease risk claims (Codex Alimentarius, 1997 (last amended in 2013)). Research has suggested that health claims have an educational impact by informing consumers of previously unknown health benefits and diet-disease relations, with the potential to support healthy food choices (Wills *et al.*, 2009; Wills *et al.*, 2012; Richardson and Eggersdorfer, 2015). Health claims can also create more favourable attitudes to products (Kozup *et al.*, 2003) through potential positive framing effects (Van Kleef *et al.*, 2005) as a heuristic to indicate perceived product healthiness (Roe *et al.*, 1999) and via a ‘halo effect’ when a food is conferred with additional health benefits that were not mentioned in the claim (Roe *et al.*, 1999). Given the potential commercial benefits of products with health claims, health claims legislation typically aims to provide a regulatory framework in which consumers can confidently use health claims to make informed food choices via clear, accurate and scientifically grounded evidence to protect consumers, promote innovation and a fair, competitive environment (European Food Safety Authority, 2006).

Since 2014, the Association of South East Asian Nations (ASEAN) Economic Community (which includes the ten nations of Brunei Darussalam, Cambodia, Indonesia, Lao People’s Democratic Republic, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam) has represented the third largest trading block globally, with a combined population of 622 million. The strategic forward plans for the region outlined in the ‘*ASEAN Economic Community Blueprint 2025*’ (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015a) have espoused the need for consumer protection, including the provision of adequate information to support consumers’ informed product choices. At present, due to differences in cultures, languages and stages in economic development (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015b), health claim regulations and guidelines which would support this consumer protection remit have only been established in five countries, namely Indonesia, Malaysia, the Philippines, Singapore and Thailand (Tan *et al.*, 2015). To support both the free movement of goods and services within the ASEAN single market and the use of health claims as part of brand communications between the food industry and consumers, it is critical to understand how ASEAN consumers respond to and understand health claims.

To date, most empirical research relating to consumer understanding of health claims has been conducted in western countries such as Germany (Grunert *et al.*, 2011); Ireland (Lalor *et al.*, 2011; Lynam *et al.*, 2011), Sweden (Svederberg and Wendin, 2011), Denmark

(Aschemann-Witzel and Grunert, 2015; Orquin and Scholderer, 2015), Belgium (Verbeke *et al.*, 2009), Canada (Wong *et al.*, 2014), the United States (US) (Wills *et al.*, 2009), Italy, Germany, United Kingdom (UK) and US (van Trijp and van der Lans, 2007), including reviews of European consumers (Wills *et al.*, 2012; Lähteenmäki, 2013). This body of research has identified that consumers prefer short, succinct claim statements without scientific terminology on the front of the pack and context-specific health claims (Williams, 2005; Verbeke *et al.*, 2009). Visual aids such as graphics and concise messaging in a prominent, typically front-of-pack location have been identified as improving the communication effectiveness of health claims (Geiger, 1998; Hooker and Teratanavat, 2008). Descriptive phrasing using simple language is recommended as the regulatory process and the level of scientific evidence required to approve claims is poorly understood by the consumers (Wills *et al.*, 2009). A further dimension of the usefulness and acceptance of health claims is the trust of consumers and food manufacturers in the health claim statements and the regulatory environment (Lalor *et al.*, 2011; Svederberg and Wendin, 2011). In order to understand the awareness, understanding and preferences for health claims within their cultural context, this study aimed to investigate South East Asian consumers' perception and understanding of health claims and the regulatory settings of the local regulatory frameworks in Southeast Asia (SEA), using milk powder for children aged 3 years and above as a research focus.

Milk powder was used as an elicitation prompt because it contains key nutrients to support growth and development among children (Food and Agriculture Organisation of the United Nations, 2013) and it is commonly used in SEA countries. In SEA, this category of food can display health claims on the food labels. The objectives of this study were as follows: 1. to understand the current status of the knowledge, perception and attitudes towards health claims on milk powder for children among mothers in Indonesia, Singapore and Thailand using semi-structured focus groups; 2. to explore the mothers' current knowledge and trust of the regulatory process and framework; 3. to identify factors affecting the understanding of health claims using three selected nutrients, calcium, iron and vitamin A as case studies.

4.3 Materials and Methods

Ethical approval for the study was provided by the Newcastle University (UK), Faculty of Science, Agriculture and Engineering Research Ethics Committee. All participants gave written informed consent before taking part in focus group discussions.

4.3.1 Design and Setting

This study was conducted in three SEA countries, Indonesia, Singapore and Thailand which were selected on the basis of the presence of established regulations and/or guidelines for the use of health claims on food in each country. All three countries have a list of permitted health claims with precise wordings which must be stated exactly on the food labels and any form of consumer communication, as outlined in Table 4.1 (Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a). For example, in Indonesia, nutrient function claims are allowed on products for young children aged one to three years old and no other function claims or disease risk reduction claims are allowed on products targeted for this age group. In contrast, nutrient function claims and other function claims are allowed in Singapore and Thailand, provided they comply with requirements in the regulations and/or guidelines.

Country	Established health claims regulations and guidelines	Approved health claims to be stated exactly	List of approved health claims		
			Nutrient function Claims	Other Function Claims	Reduction of Disease Risk claims
Indonesia	√	√	√	√*	√*
Singapore	√	√	√	√	√
Thailand	√	√	√	×	×

√ - present in country indicated

× - not present in country stated

* Prohibits claims on processed food for babies, and other function claims and reduction of disease risk claims for processed food intended for young children aged 1-3 years old (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a)

Table 4.1: Summary of health claims regulations and guidelines in Indonesia, Singapore and Thailand

4.3.2 Participants

Forty-eight mothers were screened and recruited from Indonesia, Singapore and Thailand (16 in each country) by an independent market research agency through telephone interviews. The inclusion criteria for participation were mothers aged between 21-40 years old, with at least one child aged three- six years, who were current users of milk powder for their children, and claimed to read food labels (including health claims). It was assumed the mothers residing in urban areas would have greater access to information and more choices of brands compared with those residing in non-urban areas. Research participants were therefore recruited from urban areas of Jakarta, Singapore and Bangkok and were purposively sampled to be socio-economically comparable with the 'average' monthly gross household income and

education level for each country; i.e. participants in Singapore and Bangkok had a gross monthly average household income of USD 3684- USD 7370 and USD856- USD1711, respectively. For Indonesia, participants were recruited based on average household expenditure, brand of drinking water, types of fuel purchased and amount spent on food and non-food items to provide a realistic picture of status and consumption patterns of respondents due to some ambiguity with income levels. The education level of the mothers in the three countries was mainly to a tertiary level. Excluded from this study were women who worked for marketing agencies and the milk industry. Before commencing each focus group the purpose of the study was explained again to the participants and each gave written informed consent to take part. The recruitment strategy is outlined in Figure 4.1. The focus group guide can be found in Appendix 2.

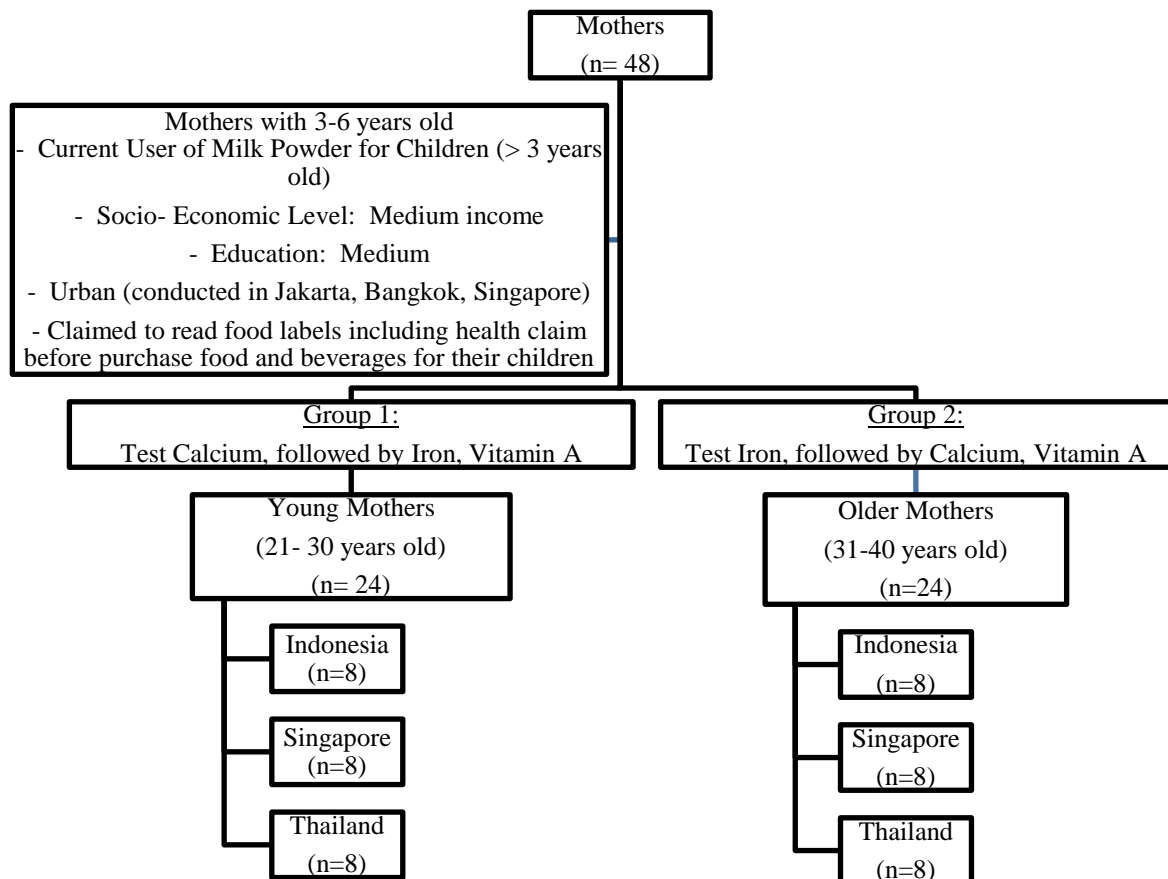


Figure 4.1: Subjects recruitment criteria

4.3.3 Choice of product and stimulus material

It is common practice in SEA for mothers to continue to provide milk to children in this age-bracket. Milk powder is more commonly served than fresh cow's milk as it is less perishable in the hot/humid weather conditions in SEA. These products carry nutrient function claims in the three chosen locations and therefore the participants would have been exposed to them

(based on their stated use of the products and that they read food labels and health claims on packaging).

To investigate the factors affecting understanding of health claims, the standard SEA-approved claims for three selected nutrients in milk powder, calcium, iron and vitamin A were used. The nutrients were carefully considered before selecting them. The selection of nutrients was based on the following two criteria: 1. the nutrients had similar health claims approved in each of the three selected countries; 2. the nutrients have significant impact on the growth and development of children aged 3-6 years old.

There are only 11 nutrients that have permitted health claims across the three SEA countries. The health impact of the nutrient to the health of a child first guided the researcher, followed by the familiarity and/ or awareness of nutrients. Several review papers have stated that familiarity with nutrients/ ingredients has an effect on the responses towards the health claims (Dean *et al.*, 2011; Lähtenmäki, 2013). The selected nutrients iron and vitamin A are commonly found to be deficient among children in SEA and calcium is commonly supplemented to pregnant women in the region (United Nations Children's Emergency Fund, 2015). Hence participants should have been exposed to information about these nutrients prior to their involvement in the study. Further scientific rationale for the selection of these nutrients as case studies in the research is described below.

1. Calcium

Calcium is important for the development of bones and teeth during the growth of children (United States National Institute of Health Office of Dietary Supplements, 2013). The latest National Nutrition Survey in Singapore in 2010 showed an improvement in calcium intake among the adult population over the last six years (Health Promotion Board Singapore, 2010). It is one of the common nutrients which is featured in nutrition education on the Singapore Health Promotion Board website (Health Promotion Board Singapore, n.d.). The Thai Public Health Agency encourages milk drinking for people of all ages (Thai Public Broadcasting Service (ThaiPBS), 2016) and the school milk programme has been implemented since 1992 to promote milk drinking among young people (Chungsiriwat and Panapol, 2009). Similarly, the Indonesian government recognised the importance of milk consumption and co-operated with the dairy industry to promote the health benefits of milk (Vanzetti *et al.*, 2013). The demand for dairy products in Indonesia has grown 10% on an annual basis for the past decade (Askew, 2014).

2. Iron

Iron is a crucial nutrient in blood cell formation with a major impact on the long-term health of the baby. The prevalence of anemia among children aged 6-59 months old in Indonesia, Thailand and Singapore was 32%, 29% and 19%, respectively and the World Health Organisation (WHO) classified the incidence of anemia in Indonesia and Thailand as moderate (World Health Organisation, 2015). The improvement of iron status has been listed as one of the United Nations Millennium Development Goals for the improvement in maternal health (World Health Organisation, 2012) and is a WHO Global Nutrition target for 2025 (World Health Organisation, 2014).

3. Vitamin A

Vitamin A is an essential nutrient for vision, the immune system, reproduction and proper functioning of major body organs (World Health Organisation, 2011). Vitamin A deficiency is a public health problem and it affects about 19 million pregnant women and 190 million preschool-age children, mostly in Africa and SEA (World Health Organisation, 2011). The statements on Vitamin A are commonly used by milk companies in SEA.

Three claim statements were presented for each nutrient and are classified as follows:

1. The national approved claim for each nutrient which differed slightly in wording between each country;
2. A short version of the claim derived by the research team which was made the same for each country and would be allowable under the current legislation for each country;
3. A health claim contrived by the research team which was scientifically inaccurate and would not be substantiated under the current legislation in the three countries.

The three types of claims were selected based on findings in the existing literature which investigated factors affecting perception and understanding of health claims (Grunert *et al.*, 2011; Lynam *et al.*, 2011; Svederberg and Wendin, 2011). The nationally approved claim and short version of the approved claim were selected to explore the consumers' recognition and understanding the claims based on their knowledge of the nutrients and the expectation that they may have seen the claims while purchasing milk products. The contrived claims were used to explore further whether the consumers' knowledge was sufficient to recognise that the claims were inaccurate. Thus, a total of nine different health claims statements were presented to the mothers in each group (see Table 4.2, Table 4.3 and Table 4.4). The claims were presented in Indonesian in Indonesia, English in Singapore and Thai in Thailand. The

claim statements on Vitamin A were not tested in the first focus group discussion among the younger mothers in Singapore due to the available time when conducting that group.

Country	Calcium		
	Calcium 1	Calcium 2	Calcium 3
	<i>Approved local authority claim statement</i>	<i>Derived short version of approved local authority claim statement</i>	<i>Contrived, inaccurate claim statement</i>
Indonesia	<p>Calcium plays a role in the formation and maintenance of bone density and teeth.</p> <p>Kalsium berperan dalam pembentukan dan mempertahankan kepadatan tulang dan gigi</p>	<p>Calcium makes strong bones and teeth.</p> <p>Kalsium membuat tulang dan gigi kuat</p>	<p>Calcium contributes to the height of the children.</p> <p><i>(Calcium helps you to grow taller.)</i></p> <p>Kalsium berperan terhadap tinggi badan anak-anak</p> <p><i>(Kalsium membantu Anda tubuh lebih tinggi)</i></p>
Singapore	<p>Calcium helps support development of strong bones and teeth.</p>	<p>Calcium makes strong bones and teeth.</p>	<p>Calcium contributes to the height of the children.</p> <p><i>(Calcium helps you to grow taller.)</i></p>
Thailand	<p>Calcium contributes to the formation of healthy bones and teeth.</p> <p>มีส่วนช่วยในกระบวนการสร้างกระดูกและฟันที่แข็งแรง</p>	<p>Calcium makes strong bones and teeth.</p> <p>แคลเซียมทำให้กระดูกและฟันแข็งแรง</p>	<p>Calcium contributes to the height of the children.</p> <p><i>(Calcium helps you to grow taller.)</i></p> <p>แคลเซียมช่วยเพิ่มความสูง</p>

Table 4.2: Health claims statements on calcium tested in the three countries

Country	Iron		
	Iron 1	Iron 2	Iron 3
	<i>Approved local authority claim statement</i>	<i>Derived short version of approved local authority claim statement</i>	<i>Contrived, inaccurate claim statement</i>
Indonesia	<p>Ferrum is a component of haemoglobin in red blood cells that carries oxygen to all parts of the body.</p> <p>Zat besi merupakan komponen hemoglobin dalam sel darah merah yang membawa oksigen ke seluruh bagian tubuh</p>	<p>Iron helps your body to produce energy.</p> <p>Zat besi membantu tubuh Anda untuk menghasilkan energy</p>	<p>Iron helps build strong muscles.</p> <p>Zat besi membantu membentuk otot-otot yang kuat</p>
Singapore	<p>Iron is an important component of red blood cells which carry oxygen to all parts of the body to help the body's production of energy.</p>	<p>Iron helps your body to produce energy.</p>	<p>Iron helps build strong muscles.</p>
Thailand	<p>An essential component of haemoglobin in red blood cells.</p> <p>เป็นส่วนประกอบสำคัญของฮีโมโกลบินในเม็ดเลือดแดง</p>	<p>Iron helps your body to produce energy.</p> <p>ธาตุเหล็กช่วยร่างกายให้พลังงาน</p>	<p>Iron helps build strong muscles.</p> <p>ธาตุเหล็กช่วยในการสร้างกล้ามเนื้อให้แข็งแรง</p>

Table 4.3: Health claims statements on iron tested in the three countries

Country	Vitamin A		
	Vit A 1	Vit A 2	Vit A 3
	<i>Approved local authority claim statement</i>	<i>Derived short version of approved local authority claim statement</i>	<i>Contrived, inaccurate claim statement</i>
Indonesia	Vitamin A can help to maintain the integrity of the surface layer (the eyes, gastrointestinal tract, respiratory tract and skin).” Vitamin A dapat membantu mempertahankan keutuhan lapisan permukaan.	Anti-oxidants like carotenes and Vitamin E support your child’s immune system. <i>Anti-oxidan seperti karoten menunjang kekebalan tubuh anak anda)</i>	Anti-oxidants like carotenes and Vitamin E reduce the chance of your child from falling sick. <i>Anti-oxidan seperti karoten mengurangi kemungkinan anak anda untuk jatuh sakit)</i>
Singapore	Anti-oxidants like carotenes and Vitamin E help to protect cells from free radicals that may have escaped the natural processes of our body system.	Anti-oxidants like carotenes and Vitamin E support your child’s immune system.	Anti-oxidants like carotenes and Vitamin E reduce the chance of your child from falling sick.
Thailand	To contribute to the body tissue maintenance. ช่วยเสริมสร้างเยื่อต่างๆของร่างกาย	Anti-oxidants like carotenes and Vitamin E support your child’s immune system. อนุมูลอิสระอย่างเช่น แคโรทีน และวิตามิน อี ได้มีการช่วยเหลือระบบภูมิคุ้มกันของลูกคุณ	Anti-oxidants like carotenes and Vitamin E reduce the chance of your child from falling sick. อนุมูลอิสระอย่างเช่น แคโรทีน และวิตามิน อี ช่วยลดโอกาสที่ลูกของคุณจะป่วยไม่สบาย

Table 4.4: Health claims statements on vitamin A tested in the three countries

4.4 Data collection

Two focus groups were conducted in each city. The mothers were divided into two groups; Group 1 consisted of the mothers aged 21-30 years old (Younger mothers) and Group 2 consisted of the mothers aged 31- 40 years old (Older mothers) as shown in Figure 4.1.

Each group discussion consisted of two parts. The first part of the discussion focused on the current knowledge, perceptions and attitudes towards health claims on milk for children. The mothers were also asked about their knowledge and trust of local food regulatory processes and the regulatory framework in their country.

The second part of the discussion aimed to investigate the understanding of the specific health claims and factors affecting this understanding using the three selected nutrients. In order to

reduce possible response bias, the nine statements were presented in a random order to the participants in each group. Each claim statement was flashed one at a time to the mothers on a projector screen or using a show card, followed by discussion to test the understanding of each claim statement before the next claim statement was presented to the group. The understanding of the claim statement was measured based on how the mothers would explain the claim to their friends.

The data were collected in March 2015. Each group discussion lasted approximately two hours, and all the groups were audio-recorded or video-recorded with permission of the mothers.

4.5 Data analysis

The focus group discussions were transcribed verbatim and translated into English. Participants were allocated a code based on age (young mother or older mother), country and participant number. For example, Y/T/4 refers to participant 4 in the younger mothers group conducted in Thailand. Thematic analysis was applied to analyse the data. The transcripts were analysed in an inductive process which began with open coding (Strauss and Corbin, 1990). Through a process of comparative analysis similar codes were classified into categories from which themes were abstracted (Braun and Clarke, 2006; Fade and Swift, 2011). The data analysis was facilitated using the qualitative software programme NVivo version 10 (QSR International Pty Ltd, Australia).

4.6 Results

There were no discernible differences in the responses between the younger and older mothers and a high degree of consistency among the mothers across the three countries so the results are presented and discussed across all participants within each country.

Awareness of nutrients and other constituents associated with health claims

The mothers were all aware of health claims on the milk powder for their children. When asked to recall these health claims, they could easily name specific nutrients such as calcium, iron, docosahexanoic acid (DHA) and other constituents such as prebiotics/ probiotics:

'Because today milk contains a lot of things; calcium, AA (arachidonic acid), DHA (docosahexanoic acid), Omega 3 too.' (Y/ I/ 8)

'Milk provides nutrients like DHA (docosahexanoic acid) and probiotic.' (O/ S/8)

'Kids drink milk for calcium, Vitamin B, DHA (docosahexanoic acid), Vitamin B12, Omega 3, 6, 9.' (Y/ T/ 8)

In addition, the mothers associated these nutrients and other constituents to specific musculoskeletal or body organs such as calcium with bones and teeth, iron with blood, docosahexanoic acid with brain and the prebiotics/ probiotics with the digestion system, but not always their role in the body;

‘Like vitamin A is for eyes, vitamin B1 is for something etc.’ (O/ I/8)

The mothers recalled the nutrients and the claims mostly at a category level and this was not related to individual brands. There was some confusion on the definition of ‘prebiotic’ and ‘probiotic’ and the name of some nutrients such as arachidonic acid ‘ARA’ with alpha hydroxyl acids ‘AHA’ among the mothers:

‘There is something else I can’t remember what supposed to help with the digest, Pre or Pro.’ (O/ S/ 8)

4.6.1 Knowledge of health claims

The main sources of information about health claims came from either the public domain or from the private/ commercial sector. Within the public domain, key sources included information gathered in schools, books, when visiting the doctors, via the internet and from other mothers. Product packaging and advertisements from the manufacturers also played a key role as sources of information. ‘Halo’ effects from non-food categories such as health supplements and skincare products were observed, in providing the mothers with the information on the nutrients and the claims:

‘I read from the Sangobion supplement product that iron helps you from sluggishness, tiredness, so the body stays fit.’ (O/ I/ 5);

‘Antioxidant is for anti-aging products to eliminate wrinkles.’ (O/ I/ 7)

‘Some supplement like carotene which is also the supplements for skin as well’. (O/ S/ 7)

Web-based searches and on-line fora with other mothers were typically used when searching for information on health claims:

“If I don’t get it clearly, I will search Google that what is good for. (O/ T/ 2)

4.6.2 Health claims as educational and a point of differentiation

In general, the mothers reacted favourably towards food related health claims which were viewed in three different ways. First, health claims were perceived as an educational tool,

providing information on nutrients which became learned through repeated exposure to the labelled products:

'Because we didn't know or understand before. For laypeople, they don't know what ARA (arachidonic acid) and DHA (docosahexaenoic acid) are for so this makes it clear.' (Y/ I/ 4)

'This also serves as a reminder in case we forget.' (Y/ S/ 1)

Second, the health claims were regarded as a form of collaboration between local authority and food manufacturers. Some mothers viewed the local authority was working with the manufacturers on health claims:

'I think the claim is based on the creativity of the producer, BPOM (Badan Pengawas Obat Dan Makanan also known as National Agency of Drug and Food Control of the Republic of Indonesia) is more responsible about the content. BPOM will check whether the content of milk meets with the nutritional facts stated on the pack so it would danger the health. So there is a strong connectivity between two sides i.e. Producer and BPOM.' (Y/ I/ 6)

Third, the health claims provided the basis upon which to differentiate competing products:

'I look on the pack to see what it says. Some brands have ingredients that nourish brain while others don't.' (O/ T/ 3)

4.6.3 Health claims to guide purchase

Most mothers viewed health claims as descriptions of the product benefits associated with the products and trusted the health claims on milk products. In general, the mothers paid more attention to the product labels before their first purchase from the brand and were less involved with subsequent purchases of the same brand; unless there was a change in the product packaging. Most mothers who read food labels wanted to get a better understanding of the products before making a first purchase:

'Before I let my child consume anything, I have to read the sides of the package or commercials.' (Y/ T/ 8)

4.6.4 Trust in health claims but no knowledge on the regulatory frameworks

High levels of trust in the health claims on milk products were consistent across the three countries, provided that the products were from 'international brands'. High levels of trust were also voiced in the participants' national governments and regulatory environments:

'I think that as long as it's sold in Singapore, it should be safe.' (Y/ S/ 5)

'So far I have no doubts towards current regulations.' (O/ I/ 8)

'Because it has FDA (Food and Drug Administration) approval, then it should be ok.' (O/ T/ I)

Despite this trust, most mothers had limited knowledge of the regulatory agencies or the processes and frameworks involved in health claim approval in these three countries. Most mothers were confused between the product quality and the regulation of the information on the product. However, the mothers believed the government bodies were mostly present to ensure food safety and quality:

'All I know, BPOM (Badan Pengawas Obat Dan Makanan also known as National Agency of Drug and Food Control of the Republic of Indonesia) regulates the product does not contain any substance that would damage the body.' (Y/ I/ 5)

'Food and Drug Administration is trustworthy and they monitor and control manufacture, materials and ingredients.' (O/ T/ 3)

4.7 Understanding of the health claims using three selected nutrients.

All the mothers knew the selected three nutrients very well and could link the nutrients to certain benefits such as calcium with bones, iron with blood and vitamin A with eyes. All mothers were most confident in the discussion on calcium claims, compared with iron and vitamin A in relation to milk powder. The knowledge on calcium came from school education and the reinforcement of this information on the food labels. In general, all the mothers agreed that the three selected nutrients were relevant for growth and development of children. The participants reported that the nutrients were classic nutrients which were typically present in milk powder for children and these nutrients did not stir any specific purchase intention for the products.

4.8 Factors affecting the understanding of the health claims

4.8.1 Familiarity of the nutrient

The familiarity of the nutrients had a great influence on understanding of the claim statements. The mothers from all three countries recalled and paraphrased the statements on calcium without difficulty. All the mothers felt very confident with regards to this nutrient as they were very familiar with the association between calcium, bones and teeth. Mothers across the three countries took the longest time to recall the claim statements on Vitamin A. This may be explained by the fact that most mothers perceived Vitamin A as a relatively new

nutrient in the milk powder and the functions as stated in the claims were different from their prior knowledge e.g. Vitamin A is good for eyes. The mothers were confused between the two terms such as vitamin A and carotenoids and these terms were used interchangeably by them.

Finally, the mothers seemed to be receptive to more information on the nutrient which they were more familiar with. The Singaporean mothers were able to accept more detailed claim statements, provided they were familiar with the nutrient such as ‘iron is an important component of red blood cells which carry oxygen to all parts of the body to help the body’s production of energy’. For unfamiliar nutrients, the Indonesian and Thai mothers preferred a claim statement to state the nutrient functions and/ or tangible benefits of the nutrient clearly and more direct, such as ‘iron provides energy’ or ‘vitamin A support the body’s immune system.’

4.8.2 Previous knowledge of the nutrient and observation

The previous knowledge of the nutrient and observation triggered the mothers to rationalise the claims. Notably, the mothers from all the countries agreed with both of the calcium statements related to strong bones and teeth as the statements were in line with their prior understanding. The mothers rejected all the contrived inaccurate claim statements. The mothers tended to rationalise the claims discussed using their knowledge and observations. For example, the majority indicated that there were other factors that contribute to height such as genes, other than the calcium intake from the diet. Some mothers doubted the effects of calcium on height after comparing their own children with others who were milk-drinkers, but had short stature. The contrived inaccurate statement on iron did not fit their existing knowledge on iron as playing a role in muscle building. Singaporean and Thai mothers associated muscle development with protein and calcium, respectively. The contrived inaccurate statement on Vitamin A was viewed as exaggerated. Their knowledge of falling sick was related to multi-factorial facts such as personal hygiene, and not associated with just nutrients and intake of other food constituents.

The understanding of claims was challenged when the information contradicted prior knowledge about the nutrients. Most mothers tried to rationalise the statements on iron but some were unable to make the connection between iron and energy/ muscle as the statements contradicted their prior knowledge on iron. All mothers associated iron with blood ‘generation’ and/ or blood circulation only.

Incomplete explanations of the health effects impacted the perceived clarity of the claim. The shortened claim statement on iron missed the link between iron and energy. Some mothers did not know that iron was involved in carrying oxygen to all parts of the body and the function of oxygen in relation to energy:

'It only connects me to blood, it doesn't connect me with energy so it will be question to me.'
(O/S/8)

The Thai mothers expressed reservations regarding the local authority approved claims on calcium as they felt calcium also functions to strengthen bones and teeth and not only contributed to the formation of healthy bones and teeth. In addition, the Thai mothers had difficulty understanding the authority approved claim statement on iron. The function of the nutrient was unclear, although they did recognise that the claim statement implied blood-related benefits:

'Yes, but I don't understand the benefits.' (Y/T/6)

'How does it help the body?' (Y/T/4)

Most mothers related one nutrient to one function or body organ. Some Indonesian mothers thought the approved claim on Vitamin A was exaggerated and doubted a role or function for other organs and systems. Most mothers agreed with the authority-approved claim statement on Vitamin A and thought that Vitamin A was associated with the eyes. Both Indonesian and Singaporean mothers believed the shortened claim statement on Vitamin A, as these mothers associated antioxidants with immunity. The shortened claim statement on Vitamin A did not resonate with the Thai mothers. The Thai mothers were uncertain how antioxidants were related to immune system or a reduction in the chances of falling ill. For all mothers the link between vitamin A, carotenoids and antioxidants was unclear and was not explained in the focus groups.

4.8.3 Relevance of the nutrient functions and benefits

The perceived relevance of the claim statement led the mothers to pay more attention to the claim statement. The mothers in Indonesia viewed the local authority-approved claim statement on calcium relevant as it was highlighting two ways through which calcium benefits bones and teeth, e.g. bone formation and maintaining bone density. Most mothers in Indonesia and Singapore responded positively to the provision of energy by iron as this could support the active children. The mothers could not relate to specific nutrient functions if they felt that the function was irrelevant such as muscles were important for adults, not children:

'For adults I think not for kids. Kids don't need muscles they need strong bones.' (O/ S/ 4)

4.8.4 Lexical issue such as the use of scientific terms and the choice of words

The presence of scientific terms was a clear barrier. Most mothers were confused about the scientific terms on the local authority- approved claim such as 'haemoglobin', 'antioxidants', 'carotenes', 'free radicals', 'natural processes of our body system', 'integrity of the surface layer'. Some mothers commented that the scientific terms sounded scary.

'I think haemoglobin is a medical term.' (O/ I/ 4)

The choice of words affected perception. The Singaporean mothers perceived the local authority- approved claim statement as credible due to the use of the scientific terms, despite the fact that they did not understand the scientific terms. Only the mothers in Singapore perceived the word 'make' in the shortened claim statement on calcium too absolute:

'Strong bones and teeth need calcium. Strong bones and teeth doesn't really make up with just calcium so cannot say made up.' (Y/ S/ 4)

4.8.5 Phrasing and length of the claim statement

Phrasing and the length of the claim statements were critical as these factors strongly influenced the understanding and the acceptance of the claims. For example, more lengthy claim statements reduced the ability to recall, whereas all mothers recalled the shortened claim statements. Mothers in Singapore understood and recalled the local authority-approved claim on iron but commented that the statement was too long. Indonesian mothers had difficulty in recalling the local authority-approved claim.

The Thai mothers found the shortened claim statement on calcium easier to understand and the statement communicated on the functions of the nutrient more directly compared with the local authority- approved statement:

'But they are talking about how to build too. It's a bit academic.' (O/ T/ 5)

The mothers preferred the claim statements which were phrased positively. The Indonesian and Thai mothers preferred the shortened claim statement on Vitamin A as it communicated the end benefit clearly, directly and positively. For example: 'Immune system' was selected over 'falling sick'. The Thai mothers commented that the local authority-approved claim statement on Vitamin A was too generic and the functions/ benefits were unclear, again highlighting the lack of understanding of the link between vitamin A, carotenoids and antioxidants.

4.9 Comparing observations between countries

In general, most mothers in Singapore were more sceptical about the health claims. The mothers were more individualistic and they focused on the performance of their own children to be equally important as the health of their children. The mothers wanted to know the mechanisms underpinning the nutrient functions on claim statements in particular for nutrients they were familiar with.

Mothers in Indonesia were not concerned about health claims as long as their children were happy and healthy, which included their emotional and social well-being. Not all mothers in Indonesia knew that there was a regulatory agency to regulate and control food products. The need for special dietary requirements such as halal food helped some mothers to know that the National Agency of Drug and Food Control of Republic of Indonesia (BPOM) was an agency regulating the food sold in Indonesia for food safety and halal certification. A majority of the Indonesian population (88.3%) are Muslim and food consumed by Muslim consumers need to be certified halal to meet the religion needs (Pew Research Centre, 2011). Indonesian mothers perceived that the manufacturers played a similar role as the government in educating them on the nutrients listed on the food labels (an educational tool).

Compared with the participants from Indonesia and Singapore, the Thai mothers recalled the most nutrients and health claims and identified medical professionals, nutritionists and psychologists as the educators on the nutrition and health claims.

The Indonesian and Thai mothers were more sociable and willing to share information in the discussion groups. They were motivated to find out information when they came across unfamiliar or unclear nutrients. Most of these mothers suggested that the claim statements which stated the functions of the nutrients were more direct and tangible.

4.10 Discussion

Health claims can refresh knowledge on specific nutrients and be a useful tool to educate the consumers on nutrient– function relationships. Our study showed that middle-income mothers across Indonesia, Singapore and Thailand could recall most of the selected nutrients associated with milk powder and the corresponding officially approved health claims. This could be due to the fact that more females generally read food labels, and were more awareness of health claims and as mothers they were particularly interested in identifying ‘healthy’ foods for their children. This is consistent with several studies which have shown that more females than males read food labels and were more favourable towards health claims due to their general interest in health (Lalor *et al.*, 2011; Lynam *et al.*, 2011; Nocella

and Kennedy, 2012; Wills *et al.*, 2012). The claims helped to increase their understanding of these nutrients. This corresponds to research in Australia and New Zealand where caregivers found health claims information on follow-up formulas and toddler milks useful to identify the benefits of one product compared with another (Yockney and Venise, 2013). A Danish study found the consumers were not misled by health and nutrition claims of a food (Orquin and Scholderer, 2015).

The familiarity and previous knowledge of a nutrient, the relevance of the benefits, the use of scientific terms, the choice of words, the phrasing and the length of the claim statements all influenced the understanding of claim statements among the mothers in the three SEA countries included in this study. Our findings were consistent with several papers reporting on consumer perception, attitudes and understanding of health claims in Western countries.

Familiarity and previous knowledge of the nutrients have been reported to influence the understanding of health claims (Nocella and Kennedy, 2012; Lähteenmäki, 2013; Wong *et al.*, 2014). This could be explained by the Elaboration Likelihood Model that the consumers process information and associate the existing knowledge to rationalise and facilitate understanding. The benefits on the health claims need to be of relevance to the consumers and be able to generate interest and motivate them to find out more information to enhance understanding. This study showed that the mothers could relate better on benefits they perceived to be important and relevant for their children and were interested to learn more new information such as the link between iron and energy which they were unaware of. Several reviews papers have highlighted that personal relevance of the nutrients and their benefits have a major influence on the perceived healthiness and intention to buy a product (Dean *et al.*, 2011; Lähteenmäki, 2013). A study conducted among Swedish consumers also showed that the concerns for family health influenced their decision to read and understand health claims (Svederberg and Wendin, 2011).

Lexical issues such as use of scientific terms and choice of words are one of the factors influencing understanding. Not all consumers have a science background, nor are trained in science at tertiary level. This study demonstrated that the use of scientific terms such as haemoglobin, carotenes, antioxidants etc., was clearly a barrier to the understanding of health claims. Others have also shown that scientific terms on claims such as ‘connective tissues’, ‘platelet aggregation’ were not understood (Richardson and Eggersdorfer, 2015). This study demonstrated that the choice of the words in a claim statement could result in different responses from different groups of consumers either positively or negatively. Nocella and

Kennedy (2012) reported that the word ‘may’ received mixed responses from different consumers. Some studies showed that the word ‘may’ reduced consumer confidence in the claim and it provided uncertainty on the statement while other studies did not show the effect. In contrast, the word ‘can’ was perceived as more credible and definite.

Short claims potentially improve the understanding of health claims. Previous research has suggested that consumers preferred short, succinct claim statements without scientific terminology on the front of the pack and context-specific health claims (Williams, 2005; Verbeke *et al.*, 2009). A study among Irish consumers suggested they had a preference for simpler nutrition and health claims such as structure-function and content claims (Lynam *et al.*, 2011). For US consumers, Wills *et al.* (2009) suggested that health claims should be phrased in simpler language as the regulatory process and the level of scientific evidence required to approve claims was poorly understood by consumers. It has been suggested that the communication effectiveness of health claims could be improved by the use of visual aids such as graphic and concise messaging on a prominent location on the packaging (Geiger, 1998; Hooker and Teratanavat, 2008). The nature of the claim statements, the lack of education on health claims and/ or overestimate on the consumers’ ability to understand the scientific or technical terms negatively affects the understanding of the health claims. A consumer-friendly claim statement should state the functions/ benefits of the nutrient in a clear, direct, short and simple language using non-scientific terms to help the consumers make informed food choices.

Our findings could help to close some of the gaps on SEA consumers’ understanding of health claims and assist in the development of an action plan involving different stakeholders to educate the consumers. Nutrients include macronutrients such as protein, fat and carbohydrate and micronutrients such as vitamins and minerals which are supported by an established science which is commonly found and explained in a number of different ways. These are mostly obtained from a variety of sources such as school, books, doctors/health professionals, and increasingly from the private sector and the internet. Information on nutrients from the public domain could serve as the education platform while information from the private sector, such as the food industry, can help to reinforce the messages. A closer collaboration between food industry and government bodies (including regulatory bodies) could help to build the understanding and awareness of nutrients and other constituents and their associated health benefits. It is a win-win for the consumers, the government and the food industry. This could potentially strengthen the messages and information to consumers, preserving the balance between consumer protection and

dissemination of emerging knowledge on diet and health. Other stakeholders such as academia, health professionals, consumer organisation could also contribute towards educating the consumers. The education on nutrients should be in a holistic approach to include not only the benefit but also any side-effects related to overconsumption of the nutrient and in the context of a balanced, varied diet.

The regulatory bodies and the marketers should take cultures and differences in languages into account when developing health claim statements, information and communication strategies. Overall, this study did not find significant differences in the understanding of claim statements across the three SEA countries investigated. This is likely to be due to the nature of the nutrients selected for this study which were all well-recognised nutrients.

However, there were subtle differences in understanding and perceived credibility between the countries. For example, the mothers in Singapore were sceptical on the use of absolute words such as ‘make’ and preferred to know the ‘how?’ in the claim statements while the mothers from the other two countries did not demonstrate such information needs.

Previously, age and consumers’ self-confidence in information acquisition were reported to contribute towards Singaporeans’ scepticism toward health claims (Tan and Tan, 2007). In contrast, consumer understanding of nutrition and health claims and perception of benefits differed substantially by country in a large scale cross national study in Germany, Italy, the United Kingdom, the United States (van Trijp and van der Lans, 2007). In another cross-country study conducted in Denmark and the United States, the Danish consumers responded more positively towards the soft framing of information while the American consumers preferred the scientific framing of information (Aschemann-Witzel and Grunert, 2015). Cultural differences in SEA consumers’ response to food and health communication should be taken into account as there are different languages and cultures between the ten SEA countries.

Food manufacturers should consider the relevance and appeal of the health motives from the perspectives of the target audience, and the claim statements need to be scientifically credible to consumers. This study clearly showed that the mothers perceived that the need for strong bones is more relevant to the children instead of strong muscles. The mothers in Singapore believed the claim statements with more complete and scientific information compared with the mothers in the other two countries. Similarly, the focus groups conducted among 35 Irish women who were responsible for most of their grocery shopping in their home, found out that most participants had a more holistic approach to health and the total intake and the consumption of whole fresh foods were much more important and believed there was no

individual product which can improve one's health (Lalor *et al.*, 2011). The carrier food could also have an influence on the mothers' perception on the credibility of the health claims on the milk powder as the mothers had no doubts about most of the claim statements. Several review papers have concluded that the base product or carrier food to which a health claim is attached, affects acceptance and is perceived more positively on food products with healthier images such as bread, yoghurt, cereals rather than less healthy images such as meat replacers, biscuits and ice-cream (Dean *et al.*, 2011; Wills *et al.*, 2012; Lähteenmäki, 2013).

It is of note that in this study the trust of health claims stemmed from the 'international brand' manufacturers and the government, although the participants did not know the regulatory process and systems related to health claims on food. Most of the participants in this study trusted the health claims they were used to seeing on milk products. For example, the mothers placed high levels of trust in these 'international brand' manufacturers providing accurate information, perceiving a partnership with the government to provide accurate and truthful information. Similar trends were identified in two studies conducted in Sweden and Ireland. The Swedish study found the lack of understanding of the concepts was counterbalanced by confidence in the manufacturers, and/ or the Swedish food legislation (Svederberg and Wendin, 2011) while the Irish study found that more than half of the participants trusted big food companies to provide accurate information on the products as they have the financial ability to conduct research to substantiate claims (Lalor *et al.*, 2011). However, some consumers in the Western countries did not trust the health claims (Verbeke *et al.*, 2009; Van buul and Brouns, 2015).

In this study, trust among the mothers in the regulatory process and the government was important for both the development of health claims as well as the education of consumers. The Japanese Food of Specific Health Use (FOSHU) programme is an interesting example of a public-private partnership to disseminate accurate information on 'health food' to the consumers. The Japanese National Institute of Health and Nutrition entrusted the training of the health professionals on 'health food' to the private sectors and the consumers obtained the information from professionals. In addition, a web-based database containing evidence-based information on the effectiveness, safety and interactions of 'health food' can be publicly accessed from the Japanese ministry's website (Yamada *et al.*, 2008). This could potentially help the consumers to better understand the health claims on food.

4.11 Limitation of the study

Focus group discussions provide a range of perceptions on a phenomenon of interest but caution should be taken when extrapolating the findings to the general population as the sample in this study is on very specific subgroup of the population. The local authority- approved claim statements varied across the three countries which may have affected our comparison between countries. Also, there might be different understanding and perception of wording of the claim statements due to the translations into the different Asian languages. The participants recruited into the study were of middle income and the majority had a higher education level. In addition they were recruited because they said that they read labels and health claims on food packaging. Whilst the purpose of the study was not explained to them during the recruitment process it is possible that their views were biased by their prior knowledge and may not be representative of the general population. However, we believe that the results have broad applicability and form a strong basis for further research in SEA consumers.

4.12 Implication for public policy

Although the findings in the focus groups cannot be generalized to the whole population, the results may help to indicate directions for future research, particularly in SEA. This study provided insight on factors affecting the understanding of health claims among SEA mothers. Our findings are relevant to the different stakeholders such as regulatory bodies, policy makers, the food industry, academia and non-profit organisations to develop effective communication with consumers. It is necessary to monitor the consumer attitudes and education on health claim especially when the regulatory environment is evolving in SEA.

4.13 Conclusion

Food innovation as well as the regulations and/ or guidelines on health claims on food will likely continue to evolve in Southeast Asia. There should be a balance between accurate health claims and understanding of them by the consumers. Different stakeholders should work together to develop solutions to improve this understanding. The high level of trust in the government and industry suggests that consumer education efforts via Public - Private Partnerships⁴ could be an approach to develop strategies to educate the Asian consumers to learn about and better understand nutrients and other constituents and their different functions. This cooperation among the public sector and private industry could potentially address national health issues by promoting health in the population, and working jointly on the same goals of the health ministries, for example by reducing non-communicable disease in the population.

⁴ Appropriate safeguards must be in place to ensure no conflict of interest; one such safeguard could be governance of this scheme by an independent committee.

This could help the government to reduce the healthcare cost (Umegaki, 2015) and achieve more efficient use of available resources.

Health claims on food should help the consumers to make informed food choices to support a healthy diet, provided the consumers understand the intended health messages. The current study has identified some gaps, and perhaps some opportunities in the Asian consumers understanding of the tested health claims. This topic is currently under-researched in this fast-growing region and more research is needed to investigate SEA consumers' understanding of the health claims. Future studies could include the participants from a greater socio-economic status, investigate the rationale on the high level of the trust in the local regulatory authorities among the SEA consumers, understand why mothers do not read food labels and have a more consistent methodology to measure the consumer understanding on health claims. This could help the regulators and the marketers to formulate health claims that consumers can understand and develop effective public health education and communication.

Chapter 5 Health Claims in Southeast Asia- Conceptual and Harmonised Regulatory framework

5.1 Executive Summary

The aim of this chapter is to propose a conceptual and harmonised regulatory framework on health claims for foods in SEA to support ASEAN economic integration. The objectives of the framework are to provide a clear and transparent structure which provides confidence for the food consumers in health claims, and encourage innovation in the food industry in the development of healthy food choices. This framework looks at the following key aspects from the strategies, tools, processes and key actors/ institutions. The elements of good regulatory governance such as clear objectives, transparency, accountability, efficiency, effectiveness, responsiveness are also incorporated. The key features of this framework are as followed, 1) introduce communication among the stakeholders at different stages of the framework, 2) state explicitly the clear objectives and principles of health claims on the regulation, 3) develop clear tools or resources for consistency such as the application forms, the guidelines on how to substantiate a health claim which could assist the applicants in the application procedure or certain topics, 4) establish an expert committee to provide scientific and technical expertise in the evaluation of the applications and identify key actors at the various stages with clear roles and responsibilities, 5) make available the regulatory documents, the approved health claims and update on regulations on the official governments' or ministries' webpages, and 6) include a time frame on the outcome of each claim application. The impact of this framework is to promote scientific confidence and public trust through engagement with the stakeholder in a transparent manner and private-public partnership. A concerted effort by all stakeholders is the way forward for consumers to benefit from credible health claims on food.

5.2 Introduction

Food innovation begins with a food product concept and application of basic food science and it will be affected by new technologies, product development, and regulatory feasibility before any new product launches. The Association of Southeast Asian Nations (ASEAN) has established the ASEAN Economic Community in 2015 with the aim of regional economic integration (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015b). There is inconsistency pertaining to the regulatory structures governing health claims in Southeast Asia (SEA) and this could potentially hinder trade across the region (Tan *et al.*, 2015). The aim of this chapter is to propose a conceptual and harmonised regulatory framework on health claims for foods in SEA. The objectives of the framework are to provide a clear and transparent structure which provides confidence for the food consumers in health claims, and encourage innovation in the food industry in the development of healthy food choices. The purpose of a conceptual and harmonised regulatory framework in this context is to propose a roadmap for the development of health claims on food in SEA with relevant structures and processes to facilitate health claim substantiation for industry and at the same time protect the consumer.

5.3 Proposed regulatory framework

An ideal regulatory framework needs to have clear objectives, developed with all relevant stakeholders in the society, supported by good science and in line with current international and regional regulations. It needs to be practical and enforceable for the regulatory agencies to carry out the work. This section will propose a regulatory framework for health claims on food in the SEA Region as described in Figure 5.1. This framework will look at the following key aspects from the strategies, tools, processes and key actors/ institutions. The elements of good regulatory governance such as clear objectives, transparency, accountability, efficiency, effectiveness, responsiveness are incorporated in the framework. These elements are the principles for regulatory quality and performance published by the Organisation of Economic Co-operation and Development (OECD) and complement the ASEAN good regulatory practices (Organisation of Economic Co-operation and Development, 2005; Jacobzone, 2007; Association of Southeast Asian Nations (ASEAN) Secretariat, 2009a; Organisation of Economic Co-operation and Development, 2012).

Strategies	1. Develop the regulation	2. Prepare the process	3. Establish procedure	4. Substantiate & evaluate	5. Review & monitor system
Description	a. Examine existing food regulation based on Codex b. Develop regulation or alternatives c. Define objectives, scope and terminology d. Establish principles of health claims e. Review draft regulation against International standards	a. Identify types of application b. Decide on nature, and requirement of application c. Form advisory/ expert committee d. Establish terms of reference	a. Establish application procedure b. Assign appropriate staff as secretariat c. Identify key contact for applicant d. Arrange meeting to review and evaluate application	a. Develop criteria for substantiation of claims b. Evaluate claims application and provide scientific and technical recommendation to ministry	a. Revise and update existing regulation b. Implement enforcement action (depending nature of policy)
Tools	- Dialogue with stakeholders for public comments - Decision tree to differentiate food and drug/ health supplement	- Application form - Guidelines on the documents required - Consult and communicate with the stakeholders	- Clear application procedure with timeline - Consult and communicate with the stakeholders - Training stakeholders	- Guidelines to substantiate claims - Guidance documents - Consult and communicate with the applicant	- Publish list of approved claims on website - Consult and communicate with the stakeholders
Institutions/ Key actors	- Inter- ministries (food, public health, economic, legal) - Stakeholders (industry, consumers, academia, interest groups)	- Ministry in-charge of food or health (depending on the country) - Expert committee	- Ministry in-charge of food or health (depending on the country) - Expert committee - Industry	- Expert committee - Secretariat - Industry	- Ministry in-charge of food or health (depending on the country) - IT support
Elements	Transparency	Accountability	Timely	Credible, Trust, Confidence	Responsiveness

Figure 5.1: Conceptual and harmonised regulatory framework on health claim

Source: Author constructed

The intention of this proposed framework is to address current limitations and aid in moving towards a more harmonised approach by identifying similarities and gaps in the systems which currently co-exist in Southeast Asia, for application across all the ASEAN nations. The best practices observed in major jurisdiction such as Europe, United States, Canada and Australia and New Zealand are suggested for inclusion in this framework. The existing regulatory framework for health claims in various Southeast Asian countries such as Indonesia, Malaysia, Singapore, Thailand and the harmonised regulatory framework on health claims proposed by the International Life Science Institute (ILSI) Southeast Asia Region were taken into consideration when constructing this framework (Ministry of Health Malaysia, 2010; Agri-Food & Veterinary Authority, 2010 (with amendments to 2016); Ministry of Public Health Thailand, 2011; National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Chan, 2013). The safety of the food constituent/ product is not part of this framework as it is assumed to have been evaluated before any health claim is applied for in most SEA countries. The term ‘regulation’ will be used throughout this chapter and it refers to regulations or alternatives such as guidelines and standards.

5.4 Key features in this proposed framework

The key features of this framework are to;

- 1) introduce communication among the stakeholders at different stages of the framework,
- 2) state explicitly the clear objectives and principles of health claims on the regulation,
- 3) develop clear tools or resources for consistency such as the application forms, the guidelines on how to substantiate a health claim which could assist the applicants in the application procedure or certain topics,
- 4) establish an expert committee to provide scientific and technical expertise in the evaluation of the applications and identify key actors at the various stages with clear roles and responsibilities,
- 5) make available the regulatory documents, the approved health claims and update on regulations on the official governments’ or ministries’ webpages, and
- 6) include a time frame on the outcome of each claim application

5.4.1 Communication with the stakeholders involved in health claims regulation

(refer to the proposed framework, under Tools for all strategies)

Communication among the stakeholders involved is essential for any regulatory system to be successfully implemented and to benefit the target audience. This could be conducted via mapping out the key stakeholders such as the private sector, academia, interest groups, and

lay public to engage in dialogue with them at the different stages of the process. There are various channels of communication to explore and it could be in the form of dialogue sessions, seeking public comments and, establishing guidance documents. For example, the Asia roundtable on food innovation for improved nutrition consists of senior representatives from government, academia, industry and civil society, and allows the multi-stakeholders to exchange views on the role of food innovation in tackling obesity and chronic diseases (Asia roundtable on food innovation for improved nutrition (AROFIIN), n.d.).

This communication promotes transparency as it provides an insight on whether the regulation is clear, practical and meets the intended objectives based on the feedback and suggestions received. It helps to make the regulation more robust with the perspectives from different stakeholder involved. It will indirectly improve awareness and encourage compliance towards the regulation as it cultivates the same common understanding of the regulation. An example from Europe is that the European Food Safety Authority (EFSA) has conducted several rounds of scientific and technical consultation with the stakeholders on health claims on general scientific guidance, related to different health topics such as cardiovascular health, gastrointestinal tract, immune system to assist the industry in preparing the applications dossier for scientific evaluation (European Food Safety Authority, 2011a; European Food Safety Authority, 2016b; European Food Safety Authority, 2016c). In order to protect consumers from misleading claims, EFSA requires that the claims on foods can be understood by the consumers (European Food Safety Authority, 2006). For SEA, it could be worthwhile to consider allowing the applicant to present their application to the expert committee at the early stage of the application process to clarify any issue or doubts that the expert committee might have on the application due to differences in languages and cultures.

Effectiveness and efficiency of the system will increase when the regulation has clear objectives, principles, terminology, scope and regulation, coupled with dialogue with the stakeholders on the draft regulation before implementation.

Figure 5.2 illustrates the relationship among the key stakeholders involved in health claims regulation. There are also other stakeholders such as policymakers, key opinion leaders, academia, scientific institutions and various interest groups involved in health claims regulation.

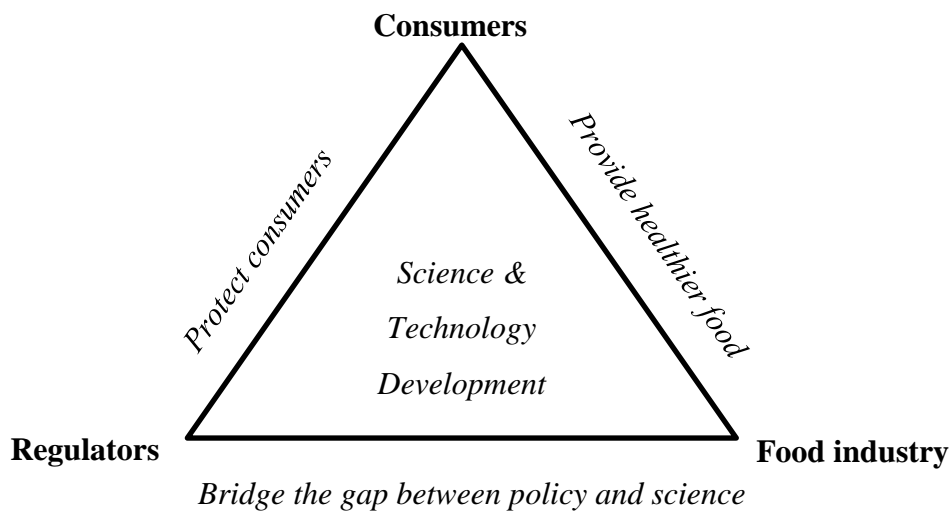


Figure 5.2: Relationship between the key stakeholders involved in health claims regulation

5.4.2 Clear objectives of the regulation

(refer to the proposed framework, under Strategy 1 develop the regulation, Description point 1c & 1d)

Clear objectives of the regulation and principles of health claims should be stated explicitly as they form the key fundamentals of the regulation. These fundamentals will serve as a guide for all the stakeholders to align the understanding and mindset of the regulation and affect the implementation and enforcement of the regulation. The clear objectives for the regulatory framework should be to protect consumers, promote public health, facilitate trade or stimulate innovation and research (European Food Safety Authority, 2006; United States Food and Drug Administration, 2009; Health Canada, 2015; Food Standards Australia and New Zealand, 2016b). The principles of health claims should be clear, truthful, scientifically substantiated, non-misleading and do not imply to prevent, cure, treat a disease(s) which is aligned with International Standards such as Codex Alimentarius (Codex Alimentarius, 1997 (last amended in 2013)).

The definition of technical terms and the scope of the regulation have to be clearly defined to help the applicant understand what information needs to be submitted and when. The definitions have to align with the international and regional regulations or standards to

facilitate the trade. The scope of the regulation should provide the applicant an idea on the boundary and the types of materials which required to be submitted for regulatory approval or how to apply the approved health claim.

5.4.3 Develop resources for consistency

(refer to the proposed framework, under Tools at Strategy 2, 3, 4)

Resources such as the application form, guidelines on the evidence required for scientific substantiation, guidance documents on the application or certain health topics, are good tools to guide the applicant when applying for new health claims. These resources provide consistency on the information required and they save time for the regulators from answering the same questions from the interested applicants. This probably explains why most of the major jurisdictions such as the European Union, United States, Canada, Australia and New Zealand have established application forms and/ or published guidance papers and frequently asked questions on their official websites (Health Canada, 2009; United States Food and Drug Administration, 2009; European Food Safety Authority, 2016b; European Food Safety Authority, 2016c; Food Standards Australia and New Zealand, 2016b). The guidance papers from the EFSA and Health Canada provide the industry with insights on the application such as examples of ‘specific’ health claims and ‘vague’ health claims, factors affecting the outcome of the scientific evaluation like bias in the studies, relevance and appropriateness of the target group (Health Canada, 2015; European Food Safety Authority, 2016b). The industry professionals would then be able to understand the current thinking of the regulators and expert committee and the critical points in each application to help them in preparing an application dossier with required information for submission. It is vital to have the date-marking on the documents to help identify the updated documents to use. This helps the interested parties identify the updated information as the regulatory environment on health claims evolves rapidly.

5.4.4 Scientific substantiation of health claims

(refer to the proposed framework, under Strategy 4 Substantiation and Evaluation)

Scientific substantiation has been highlighted as a key element for all health claim evaluations. In principle, the application needs to answer these following basic questions:

- 1) What food constituent is added?,
- 2) What is the proposed benefit of the food constituent?,

- 3) Who is the target audience?,
- 4) How much of ‘the food constituent’ was added and needs to be consumed, in order to have the proposed health benefit?,
- 5) Can the cause-effect health relationship be scientifically substantiated, preferably by human studies?,
- 6) Are the studies relating to the proposed ingredient and its effects of high quality and published in peer-reviewed journals?,
- 7) Are the outcomes of the total available studies consistent?,

High quality studies generally evaluate the factors such as i) study design and methodology, ii) appropriate number of, and relevant subjects, iii) availability of control group, iv) appropriate duration of exposure, v) generally recognised biomarkers and/ or surrogate endpoints, vi) consumption of food/ constituent consistent with the studies of appropriate dosage, vi) effect of food matrix and dietary context has been considered, vii) have obtained ethical and other approval such as registration with appropriate agencies ie. US Clinical Trial.gov, International Standard Randomised Controlled Trial Number (ISRCTN) and viii) are appropriately statistically powered.

Wider scope and different level of scientific evidence can be considered to be accepted for scientific substantiation for health claims. The Codex Alimentarius classifies health claims into three types; nutrient function claims, other function claims and reduction of disease risk claims (Codex Alimentarius, 1997 (last amended in 2013)). Different types of health claims could require different levels of scientific evidence. For instance, reduction of disease risk claims are generally considered high level claims as they are linked to diseases. Therefore these require to be substantiated by more rigorous types of evidence such as human intervention studies while human observation studies are accepted for substantiation of other function claims. This approach could address one of the biggest challenges faced by the food industry and nutrition scientists. Unlike drug trials, there are a number of difficulties in conducting food-based human intervention trials such as ethical issues, identify the specific benefits linked to specific nutrients/ food constituent since food contains many nutrients (Tapsell, 2008; Aggett *et al.*, 2012; Richardson, 2012). Authoritative reference texts, scientific opinion from scientific organisation and regulatory authorities, scientific review and documented history of use are valuable information that should be considered as supporting evidence for some types of health claims instead of relying on human intervention studies

alone for all types of health claims. The evidence required to support different types of health claims (refer to Figure 5.3) published in the ASEAN guidelines on claims and claims substantiation for health supplements, could be a good reference point (Health Sciences Authority of Republic of Singapore, 2015). The definition of health claims in these ASEAN guidelines follows the same as the Codex Alimentarius guidelines on nutrition and health claims.

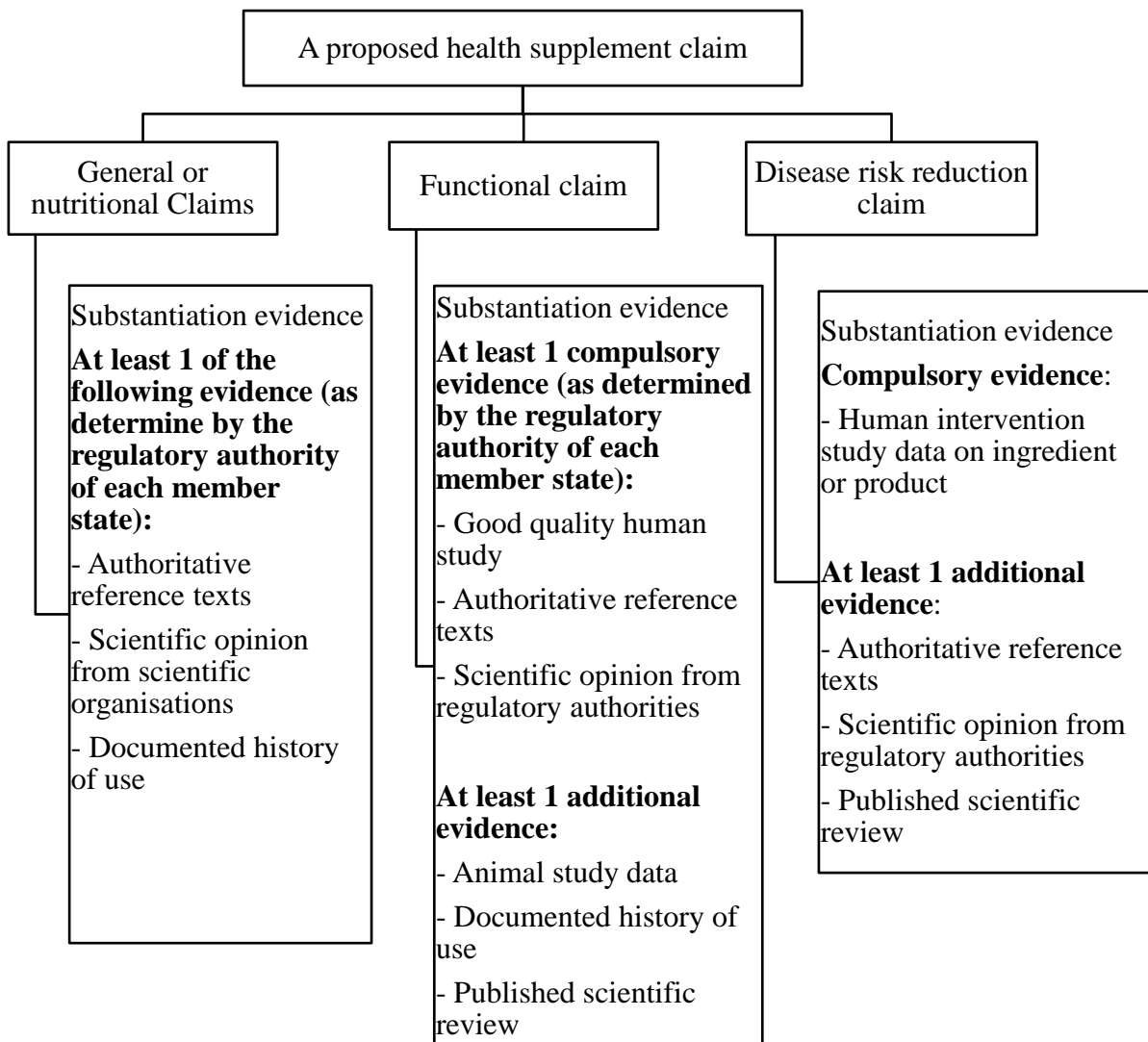


Figure 5.3: Evidence required to support the different types of Health Supplement claims

Source: adapted from ASEAN Guidelines on Claims and Claims Substantiation for Health Supplements (Health Sciences Authority of Republic of Singapore, 2015)

A decision tree on how to classify food and health product can be developed to assist in differentiating food and health products as food innovation is advancing rapidly. Some SEA regulators had encountered difficulties in categorizing claims between foods and drugs when they were being interviewed in this research (refer to earlier chapter 3 of this thesis). For

instance, a drink containing Coenzyme 10 could be considered either as a food or a health product. The form in which the product is being consumed such as tablet, drink, the nature of constituent added to it and the benefit claimed are some factors used for comparison between food and health products. Notably, the words used in the health claims on food should not imply therapeutic claims linked to prevention, treatment or cure of a disease or illness. Food authorities in Canada and Singapore considered several factors to identify food and natural health products (Health Canada, 2015). Health Canada considered the factors such as product composition, product representation, product format and perception of history and use. While in Singapore, the classification tree between food and health products jointly developed by two regulatory agencies which regulate medicinal health products and food such as Singapore Health Sciences Authority and Agri-food Veterinary Authority respectively, considered the role of the product as part of a diet or supplement, product presentation or format and restriction on the dosage to consume (Health Sciences Authority of Republic of Singapore, n.d.)). The expert committee established in evaluation of health claims, could be consulted to provide different perspectives and assessment in this matter.

5.4.5 Establish expert committee to provide scientific and technical expertise

(refer to the proposed framework, under Stage 2 Prepare the process, Description point 2c and 2d)

The members in the expert committee play an important role to provide scientific and technical expertise on the application. The regulatory agency of each SEA country should appoint the panel of experts in this committee and these experts should be independent from the regulatory agency. This panel should represent the different stakeholders involved such as the different ministries, food regulators (pre-market approval and enforcement), public health policymakers, food industry associations, academia, scientific institutions, consumer groups and should be composed of people with multi-disciplinary skills and expertise such as nutrition, toxicology, risk assessment, public health, communication to provide holistic and comprehensive evaluation of the different health claims applications. To further increase the scientific confidence and credibility in the assessment of new health claims, co-opting experts of the certain discipline on an ad-hoc basis depending on the nature of the health claim application is a valuable alternative. For instance, if a person has been detected to have heart problem, they will be referred to consult a heart specialist or cardiologist for further investigation. There are many different specialities in medical and nutrition- related fields which could be represented in this way.

The terms of reference of the expert committee need to be established so the members know their roles and responsibilities. This provides a guide to the applicant on ‘who is doing what’ and who to approach when they apply for health claims. In most existing frameworks such as Europe, Australia and New Zealand, Indonesia, Malaysia and Singapore, the expert committee evaluates the science and make recommendation to the regulatory agency (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a; Eksan, 2015; Food Standards Australia and New Zealand, 2015b; Neo, 2015; European Food Safety Authority, 2016b). The regulatory agency makes the final decision to adopt the recommendation from the expert committee and approve the application.

5.4.6 Make available the information such as the approved claims and update on regulations

(indicated in all strategies on the proposed framework)

Transparency can be improved when information is readily available. The provision of these documents helps the stakeholders to be connected with the development of the subject and provide feedback or concerns. Transparency provides an insight on the current thinking and opinions on the subject matters for the stakeholders. The consumers can better understand and trust the list of approved health claims which have undergone rigorous scientific assessment by the regulatory agency to protect their interest. The food industry should be informed on the development on the regulation and receive updates on recent health claims. The food industry and researchers are aware of how to plan their research to be able to communicate to the consumers accurately. A good example to illustrate the current thinking of the regulatory agency is the Guidance for industry on the evidence-based review system for the scientific evaluation of health claims published by United States Food and Drug Administration (2009) that contained non-legal binding recommendation which covered the legal implication (United States Food and Drug Administration, 2009). This is also an effective channel of communication and engagement with the stakeholders. At present, most of the information on health claim in SEA is not readily available on the internet.

5.4.7 Time frame on the outcome of each claim application

(refer to the proposed framework, under Stage 3 establish procedure)

A system without a definite time frame would pose challenges to the stakeholders in the food industry. It is also an indicator on the quality of the system in terms of efficiency and effectiveness. Time is extremely critical for the food industry as there is a need to develop a detailed plan with timeline before a new product is launched in the marketplace for the

consumers. The new product needs to be relevant to meet the current consumer needs when it is launched and the food industry needs to manage all the other issues such as research and development, supply chain, production, regulatory approval. Hence a time frame will provide an idea to the applicant whether the new product with the new health claim can be launched in time or to terminate the idea to have new health claim. The time required for health claim application could either encourage food innovation and research or hinder and dampen it if the timing were perceived to be unachievable to have a new health claim. Having no time frame indicated in the application procedure has the potential to breed stagnation.

Figure 5.4 illustrates an application procedure with a time frame of 6- 9 months for the applicant to know the outcome of the application and the key actors at each stage indicated on the procedure. It is developed based on the existing procedures and the average time frame in selected Southeast Asia countries such as Indonesia and Singapore. The Indonesian regulation stated that a maximum time frame of 6 months is required for new health claim applications to be processed (National Agency of Drug and Food Control of the Republic of Indonesia, 2011a) and the Singapore regulatory agency took around 9 months to complete the system depending on the complexity of the claims and turn-around time by advisory members (Neo, 2015). The information on the time frame for health claims application was unavailable for Malaysia and Thailand while the other SEA countries do not have processes on health claims application.

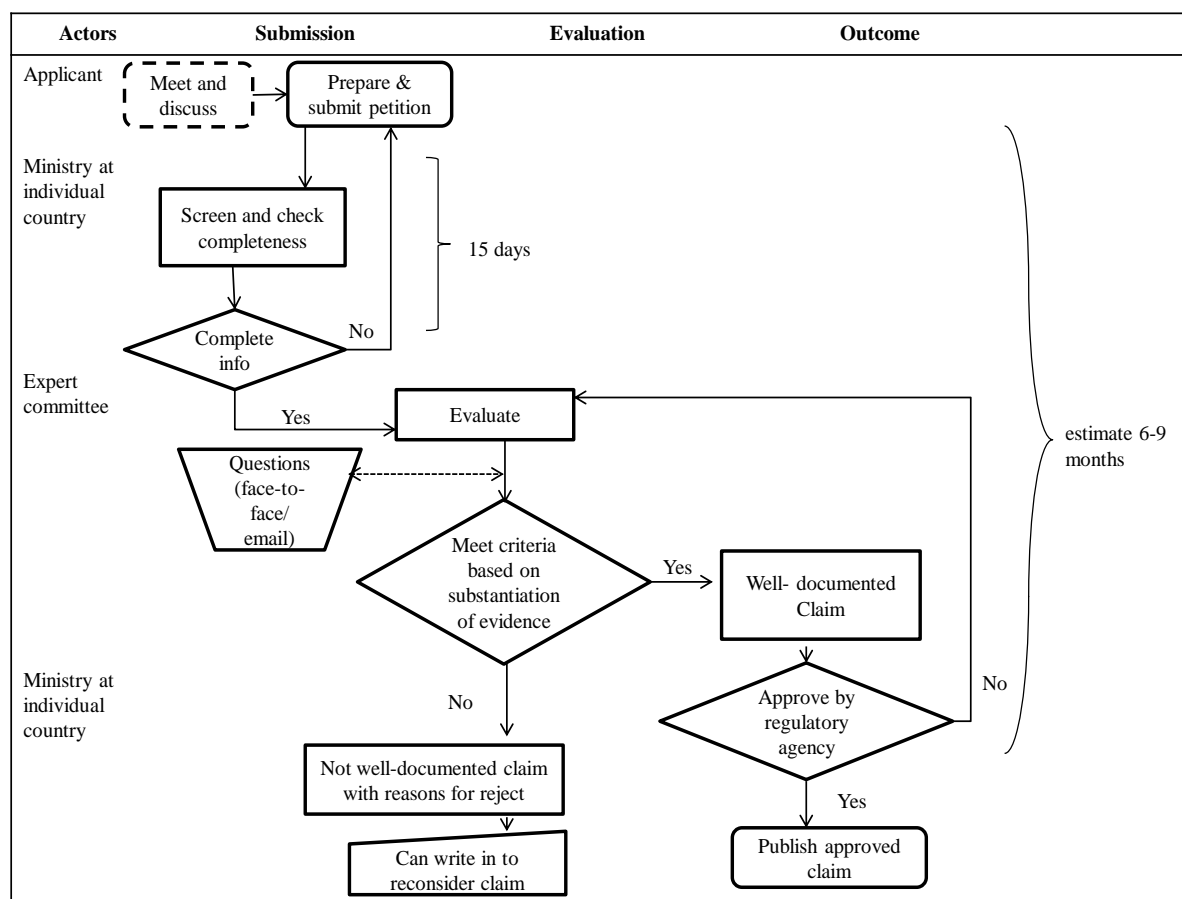


Figure 5.4: Proposed application procedure

Source: Author’s construction

5.4.8 Review and monitor the system

(refer to the proposed framework, under Strategy 5 review and monitor of system)

The review of health claims regulations are good initiatives to ensure the intended objectives of the regulation and the interest of the stakeholders are met. The ability to respond to societal changes and the willingness to re-examine the existing policies, institutions or procedures is important to protect the general public interest with the rapid changes in the demographic and health trends in the society. For example, there is a need for consumers to obtain the sufficient information to assist them in making food choices to support healthy diet. Consumers are getting more health-conscious due to the increase in diet-related chronic diseases, and the shift towards an aging population (Kearney, 2010; Baroke, 2014; Futures Centre, 2014). More innovative, healthier food products with health claims have been actively developed by the food industry. Thereby it is important to protect the consumers from over-claimed or unsubstantiated health claims in food products and provide consumer

confidence on the food sold in the country. This approach achieves a secondary purpose, in that it facilitates a level playing field for the industry, provided that the regulation (from conception till implementation) had had open consultation with the stakeholders involved. The system needs to be reviewed periodically to make sure it remains relevant and responsive to the current and anticipated trend of the society. The OECD recommends for each member country to appoint a specialised department or group of experts in each line ministry and regulatory institution to conduct regulatory impact analysis (OECD, 2008; Jacobzone, 2007). This aims to evaluate the effectiveness and efficiency of the existing regulation. For example, Australia has already established the Office of Best Practice Regulation to assist the regulators in assessing the regulations (Asia Pacific Economic Co-operation Secretariat; 2010).

5.4.9 Integration of the regulation

(refer to the proposed framework, under Strategy 1 develop the regulation, description point 1e.)

The regulations or guidelines should be developed, in a manner that is consistent with the other regulations and policies in the country, and aligned with International Standards. The ASEAN Good Regulatory Practice (2009) recommends ‘the regulation to be based on international or national standards that are harmonised in international standards, except where legitimate reasons for deviations exists’ to be least trade restrictive. The standards from Codex Alimentarius, an body established by Food and Agriculture Organisation and World Health Organisation is a good reference point when developing regulations (Codex Alimentarius, n.d.). The World Trade Organisation recognises standards from Codex Alimentarius (World Trade Organisation, n.d.-b). The regulations from major jurisdictions such as Europe, Canada, Australia and New Zealand and most of Southeast Asia countries such as Indonesia, Malaysia, Singapore share similarities with the standards on health claims by Codex Alimentarius.

5.5 Discussion

The development of health claims regulatory framework in SEA has come a long way and has progressed rapidly in the last few years. SEA countries such as Indonesia, Malaysia, Singapore, Thailand and Vietnam have established regulatory frameworks on health claims on food to ensure claims are truthful and non-misleading, although there is different regulatory development among the ten ASEAN countries. The regulatory systems in these countries differ considerably. The key features of the proposed regulatory framework that could

address the differences among the health claim systems in SEA⁵. Firstly, the clarity in the regulation is fundamental. It can be achieved by having clear purpose and objectives of the regulation with working principles. This will align the mindset of all stakeholders involved such as the industry, academia and regulators and facilitate working together for the same purpose such as to benefit the consumers, facilitate trade and / or support innovation. Secondly, the communication and consultation with the stakeholders is essential for transparency. Consultation with different stakeholders, including private sectors and institutions can help to identify potential issues at the earlier stage of the regulation and develop possible solutions which are aligned with the interest of the stakeholders. There are many channels of communication among the stakeholders which can be achieved across the different groups such as the regulators, experts, food industry and consumer groups at a national level. The different groups will disseminate the information within this group through working groups, advisory groups that are set up at national and regional level. For instance, the establishment of the Food Industry Asia (FIA) allow the food companies based in Asia to share information and discuss common issues faced (Food Industry Asia (FIA), n.d.). The formation of business advisory groups comprised of small-medium enterprises can be a way to reach out to this sector of food manufacturers to increase awareness and gather feedback on new regulations. Most of the time, the small-medium enterprises are greatly affected when new regulations are implemented as they are either unaware or have not reacted to meet the regulation. A phase- in time of a minimum six months should be in place before the full implementation of the regulations and standards (Association of Southeast Asia Nations Secretariat, 2009). This would allow time for the regulators and the industry to adapt to the new regulation, provided the regulations and relevant documents are publicly available.

To achieve the ASEAN Economic Community (AEC), there is a need for communication at a regional level. The existing Prepared Foodstuff Product Working group under ASEAN Consultative Committee on Standards and Quality (ACCSQ) can be leveraged as a platform for the ASEAN regulators to discuss on health claims on food and relevant regulations. A regional ASEAN expert committee such as the ASEAN Committee on Science and Technology can be asked to facilitate the sharing of expertise across the SEA region. Due to the different languages used in SEA, the ASEAN website can be used as a contact point to direct the interested parties to the official government websites in SEA and obtain the English version of the regulations and relevant documents issued by the regulatory agencies in the various SEA countries. This ASEAN or Asia Pacific Economic Co-operation (APEC)

⁵ Roadmap/ framework to adopt at national level, then at the ASEAN level.

secretariat should lead on the development of this website as it will potentially increase trade within the ASEAN region which align with the aim of AEC. Each country can learn and adapt the best practices on health claims in major jurisdiction such as Europe, United States, Canada, Australia and New Zealand and related industries such as the pharmaceutical, health supplement instead of reinventing the system. The best practices include consulting stakeholders, making available regulations and relevant documents, guidance papers on the key critical point for each application, clear processes, and requirements for scientific substantiation. This could optimise the existing resources available for health claims administration as regulatory agencies might have other priorities. A key area of discussion is to identify the current best practices which can best fit to be adapted in SEA. The legal aspect of the regulation or alternatives has to be considered. The implementation which could be in the form of regulation or regulatory alternatives such as co-regulation, quasi-regulations such as standards, guidelines or code of practices or self-regulations such as code of conducts provides flexibility to the regulators, policymakers depending on how the country would like to deal with the issue (Asia Pacific Economic Co-operation Secretariat, 2010). The country needs to consider how the regulation or alternative could influence the enforcement actions to be taken. For example, can enforcement action be taken if there is non-compliance observed, but the guidelines are not legally binding?

A Public- Private Partnership should be considered to ensure that the health claims process works. The food industry can be a valuable partner to the regulators in contributing to the system. It is imperative to engage with the food industry at all different stages through fora, roundtable discussions or dialogue sessions. The academic partners or research institutions such as Institute of Southeast Asian Studies (ISEAS)- Yusof Ishak Institute or ASEAN studies centre could help in drafting the guidance papers or even start with frequently asked questions to aid the process. Implementation of a regulation and framework is only a starting point. The system need to be reviewed on an agreed basis to make sure it is still relevant and workable. Educating the systems to all the stakeholders is equally important as educating health claims to the consumers. Capacity building and training of the relevant key personnel and enforcement agencies involved could be made available to carry out the process smoothly and consistently. It is the responsibility of the local food regulatory body to do so. Although this framework does not cover education of health claims to the consumers, this aspect should also be addressed jointly with the different ministries such as health, education and with the industry partners. Figure 5.5 summarises the next steps in which movement towards standardisation can be achieved (as presented in the discussion).

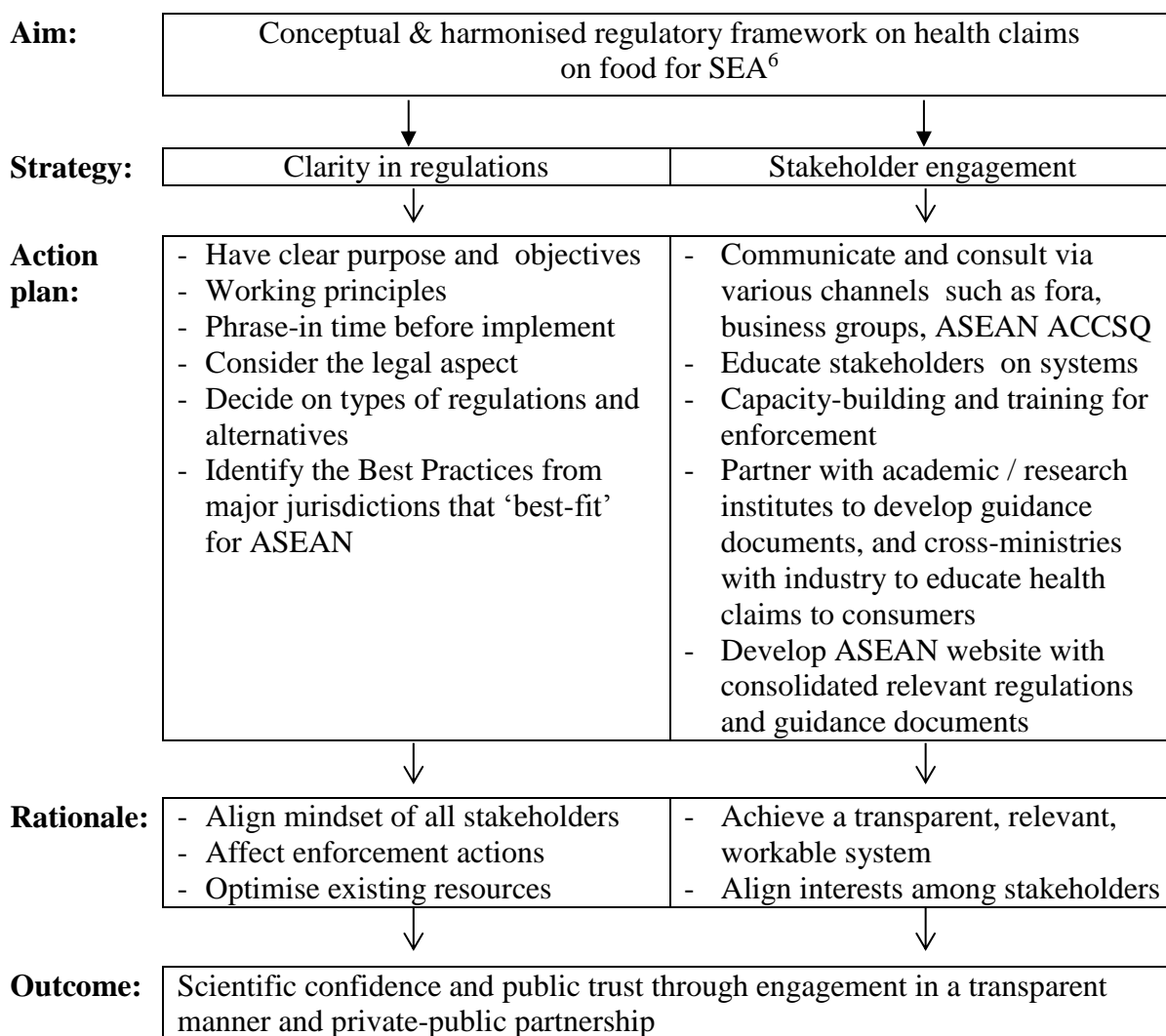


Figure 5.5: Summary diagram on the next steps in which movement towards standardisation can be achieved

5.6 Conclusion and future perspectives

The proposed regulatory framework on health claims in this chapter emphasizes the processes needed when working towards a harmonised approach. A harmonised regulatory framework in this context does not mean harmonised regulations in SEA. This harmonised regulatory framework provides a concept for discussion among the regulatory agencies in SEA. The food industry still needs to apply health claims in each SEA country as the charter for ASEAN states that each Southeast Asia nation has its national sovereignty (Association of Southeast Asian Nations (ASEAN) Secretariat, 2008). This framework could ignite more discussion on this topic and could be used it as a reference for the rest of the Southeast Asian countries which do not have existing health claim regulatory frameworks. Health claims on food might not be a priority at present in all countries as Southeast Asian countries are still

⁶ Prepared Foodstuff Product Working Group under ASEAN Consultative Committee on Standards and Quality (ACCSQ-PFPWG)

grappling with food safety and more general labelling issues. Discussion on health claims can be initiated gradually starting from now as regulations take time to develop. ASEAN platform is the most suitable platform to further discuss this topic in working towards achieving the aim of ASEAN Economic Community.

A regulatory framework on health claims serves as a guide to protect consumers, support research and product innovation and facilitate fair trade. The impact of this framework is to promote scientific confidence and public trust through engagement with the stakeholder in a transparent manner and private-public partnership. A concerted effort by all stakeholders is the way forward for consumers to benefit from credible health claims on food. Ultimately, health claims on food products aim to assist the consumers to make informed food choices for a healthful diet.

Chapter 6 Conclusion and recommendation

This research is a study in the topic of health claims on food in SEA which are likely to have a significant impact on health, trade, innovation and is currently under-researched. Health claims on food have potential to impact not only on one's health, but they influence many areas including research, innovation, public health policy, legal policy, trade and economics in a wider perspective. This final chapter concludes this thesis by providing an overview of the research carried out with the main findings of the research summarised in three key points. Prediction of the future developments of health claims regulations/ guidelines on food products in SEA are discussed. Recommendations for future research and limitations of the study are included. The contribution and concluding thoughts of this research are highlighted and reflected upon to summarise the findings from this research.

6.1 Background information

Health claims on food products facilitate communication of nutritional benefit of high-value specialist food products for the food industry. The food industry needs to generate evidence to substantiate health claims for regulatory approval from most countries, in order to be able to communicate health benefit of a product or a nutrient/ ingredient to the consumers. ASEAN aims to achieve free movement of goods under the ASEAN Economic Community by 2015. There is a need to understand the regulatory frameworks for food products with health claims to be sold in various ASEAN countries.

According to Codex Alimentarius, health claims on food products are a tool to help consumers make informed food choices. The different stakeholder such as regulatory bodies, food industry has invested resources to make health claims available to the consumers. To date, there are no data on whether Asian consumers understand health claims. Most consumer studies on health claims are conducted in Western countries. It would be useful to know whether health claims on food products are reaching out or benefiting the Asian consumers.

6.2 Research aims and objectives

The research topic is on the health claims on food products in SEA, with the aim of having a clear situation awareness of how the information flow through the existing regulatory frameworks in SEA effectively communicates understanding to the consumers. To achieve this aim, the existing regulatory frameworks of health claims on food products in SEA and from the major jurisdictions such as European Union, United States, Australia and New Zealand were reviewed; the practices and perspectives were elicited from the stakeholders with professional interests in health claims; and as a counter-balance of viewpoints, the

perspectives of Asian mothers' understanding of health claims as well as their understanding of the regulatory settings of the local regulatory frameworks were explored.

The stakeholders identified in this research, play an important role in helping the consumers to make informed food choices through using health claims. The stakeholders were grouped into different clusters; based on the work flow of the health claim application process and the end users of health claims. These range from the representatives from the food association filing in the application, to the regulators involved in the administration, to the key opinion leaders, policy makers, and representatives from scientific organisation involved in the evaluation of health claims in the country, and last but not least, to consumers represented by the Asian mothers.

Two key research questions guided the collection of the data and perspectives from the different clusters of stakeholders; 'how are health claims on food products in SEA substantiated and evaluated in SEA?'; and 'Do the Asian consumers' understand health claims?'.

6.3 Main findings

The findings of this research can be summarised in three key points; namely 1) variations in the existing regulatory frameworks and the perspectives of the stakeholders, 2) building bridges of communication and 3) consumer education effort via public and private partnerships. The conceptual, harmonised regulatory framework for health claims (as proposed in chapter 5) could create opportunities to close the gaps found in the existing systems in the SEA.

6.3.1 Variations in the existing regulatory frameworks and the perspectives of the stakeholders

The differences identified across countries in this study, fall into three categories, starting from the SEA countries with or without the health claim regulations/ guidelines, followed by the details listed in the health claim regulation/ guidelines, and finally the perspectives on the challenges faced by the different clusters of stakeholders.

Firstly, the regulation / guidelines of health claims are at different stages among the ten SEA countries. There are six of the ASEAN countries Indonesia, Malaysia, Singapore, the Philippines, Thailand and Vietnam with health claims regulations/ guidelines whereas the other four ASEAN countries do not currently have regulations. This could be due to the different levels of economic development of each SEA country. Figure 6.1 illustrates the

status of the health claims regulations in the 10 SEA countries under ASEAN according to the perspective of the author.

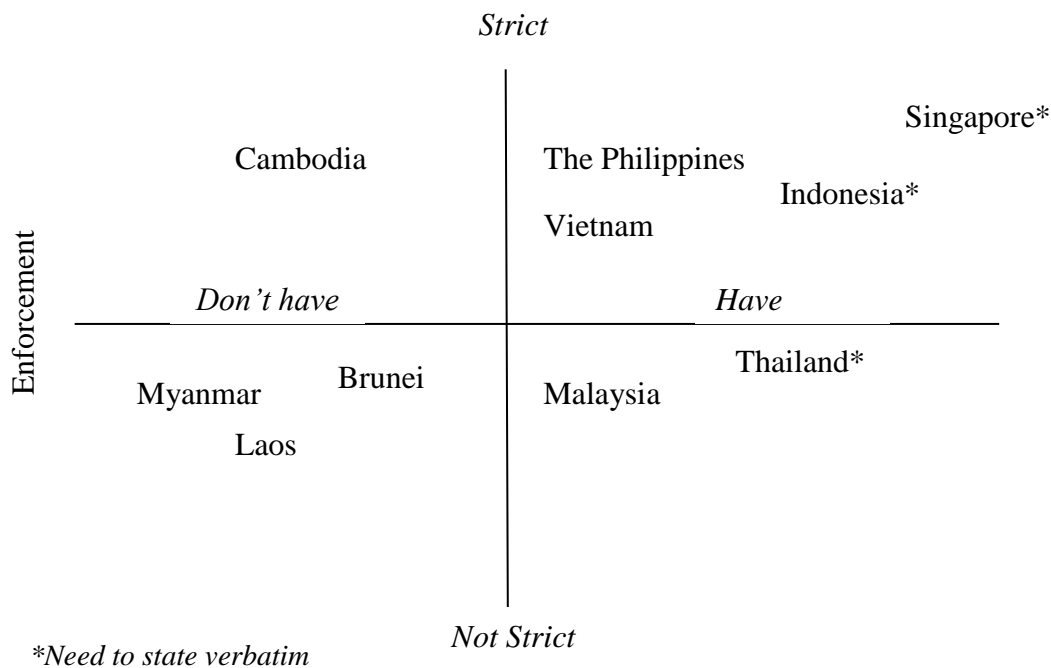


Figure 6.1: Status of health claims regulations/ guidelines in the 10 SEA countries

Source: Author’s personal construction drawing based on the existing literature on health claims regulations in SEA and previous work experiences when managing the regulatory issues in the countries (Ministry of Health Malaysia (2010); National Agency of Drug and Food Control of the Republic of Indonesia (2011a); Agri-Food & Veterinary Authority (2010 (with amendments to 2016)); Agri-Food and Veterinary Authority of Singapore (n.d.-b); Ministry of Public Health Thailand (2011); Ministry of Health Vietnam (2014))

Secondly, the regulations/ guidelines on health claims that currently co-exist in SEA, had some areas of convergence and divergence (as explained in Chapter 2). The areas of convergence among SEA countries with health claims regulations/ and guidelines include the establishment of an expert committee in each SEA country to evaluate health claim applications, publication of a list of approved health claims permitted in each SEA country and the requirement on the approval status of the health claims from the major jurisdictions in each application. On the other hand, the areas that diverge in the health claims regulations/ guidelines among the SEA countries are unclear scope, objectives and principles in health claims regulations/ guidelines, inconsistencies on types and amount of evidence required for health claim substantiation, and different languages used on the health claims in different SEA countries.

Thirdly, the semi-structured interviews conducted in this study draw a distinction between the perspectives on the challenges faced by the stakeholders among the different clusters (as

described in Chapter 3). In this study, the regulators faced difficulties in differentiating health claims and medical claims in more complex applications as well as allowing more compelling health claims and flexibility of rewording approved claims for commercial viability, while most key opinion leaders commented they could not evaluate new health claim applications as the applications were ill-prepared and lacked strong evidence to substantiate the claimed benefits. Apparently, some regulators and key opinion leaders had different expectations on the robustness and rigor of scientific evidence depending on the types of health claims submitted. The representatives from the food association consistently raised the rigorous, pharmaceutical approach to substantiate health claims for food, which they described as being challenging for the industry to achieve. Their view was that food was not a drug, and that scientific evidence should not stringently follow the pharmaceutical standards which are considered relevant for treatment in medical-concerned population. Clearly the differing viewpoints outlined by this study could potentially affect the availability of health claims on food for the consumers.

The different perspectives and viewpoints shared by the clusters of stakeholders could have resulted from the different professional training and/ or field of expertise, and job responsibilities of the stakeholders, and not their individual competencies. All of the interviewees were scientifically-trained and had extensive experience in their field. The differing perspectives from the stakeholders could be contrasted with differing professional approaches, for example when a medical doctor will look at heart disease from the perspectives of diagnosis and treating the disease, a dietitian will look at the dietary intake to manage the risk of the disease and a country's health minister will look at the prevalence and implications of heart disease in order to reduce the national healthcare cost. The different ways of looking at an issue could be due to years of their specialist training that mould the thoughts to function in a certain manner, and their job responsibilities to perform certain expected tasks. Hence it is understandable that there are different perspectives among the different clusters of stakeholders as the key objective of the regulators is to protect consumers from being misled, while the key opinion leaders need to uphold the highest scientific standards and the food industry has to provide a solution to satisfy the need and wants of the consumers.

In a positive light, there was similar current thinking and issues about this topic among the stakeholders across the SEA in Chapter 3. These issues include the factors affecting the approval of new health claims applications such as the common errors which occur in health claim applications, or having a coherent opinion on the objectives and principles of health

claims, using the guidelines established by Codex as a basis to evaluate new health claims and the challenges faced by the different clusters of stakeholders. These commonalities create opportunities to narrow the variations in the existing regulatory frameworks and perspectives of the stakeholders in SEA. All forms of communication among the stakeholders such as dialogue sessions or availability of guidance documents to apply health claim, are necessary to pave the way for the development of health claims in SEA.

Table 6.1 summarises the commonalities and divergences found in the regulations/ guidelines (Chapter 2) and the current practices and perspectives on the health claims administration among the key stakeholders in SEA (Chapter 3).

Topic	Commonalities	Divergences
Regulatory frameworks on health claims	<ul style="list-style-type: none"> • List of approved claims • Expert committee to evaluate health claim applications • Regulatory status/ approval of health claim application issued by national/ international bodies 	<ul style="list-style-type: none"> • Different definitions, scopes, objectives • Principles of health claim • Languages used • Inconsistent types and amount of evidence for substantiation
Current practices and perspectives from key stakeholders	<ul style="list-style-type: none"> • Congruent opinion on the objectives and principles of health claims • Codex as basis for evaluate new application • Similar criteria applied when evaluate claims such as quality of studies, human intervention studies, proposed wording, condition of use, totality of evidence, approval of health claim by issued by national/ international bodies • Comprehensiveness of data, common errors such as ill-prepared dossiers, outdated data, availability of experts affect approval 	<ul style="list-style-type: none"> • Request for local data • Different development in health claims regulations/ guidelines • Expectation on scientific substantiation depending on types of claims • Time for approval process • Challenges faced by the clusters of key stakeholders <p><i>Regulators/ Policymakers:</i></p> <ul style="list-style-type: none"> - Differentiate health claims and medical claims - Allow compelling/ flexibility in health claims <p><i>Key opinion leaders:</i></p> <ul style="list-style-type: none"> - Difficulty in evaluating health claim applications <p><i>Representatives from food associations:</i></p> <ul style="list-style-type: none"> - Challenging to meet the pharmaceutical-like approach to support applications - Difficult to understand the rejection of claim applications

Table 6.1: Summary on commonalities and divergences in the regulatory frameworks and current practices and perspectives from the key stakeholders in SEA

6.3.2 *Building bridges of communication*

Bridges of communication should be built to help the different stakeholders better understand the perspectives from one another. More regular, open communication and collaboration among the stakeholders should take place in different forms such as roundtable discussions, public consultation on draft regulations/ guidelines etc. The flow of exchange includes vertical communication among the individual cluster of stakeholders and horizontal communication between the different clusters of stakeholders. Sharing the common issues and viewpoints such as the objectives and principles of health claims, the expectations of a well-prepared dossier (in Chapter 3) explicitly can be a starting point for this information exchange. Insight on the current thinking of the different stakeholders would be provided through the different platforms e.g. guidance documents, meetings with the different clusters of stakeholders etc. Potential solutions could be developed with the knowledge of the different issues under discussion and engaging the stakeholders involved to discuss the issues. More trust and development of partnership among the stakeholders could be established during the process.

The proposed harmonised regulatory framework in Chapter 5 provides suggestions on the approaches to bridge the gaps identified on the different regulatory frameworks on health claims that currently co-exist in SEA. This conceptual regulatory framework contains the elements of good regulatory governance such as clear objectives, transparency, accountability, efficiency, effectiveness, responsiveness. In addition, the proposed framework looks at the following key aspects from the strategies, tools, processes and key actors/ institutions. The key features of the framework include 1) introduce communication among the stakeholders at different stages of the framework, 2) state explicitly the clear objectives and principles of health claims on the regulation, 3) develop clear tools or resources for consistency such as the application forms, the guidelines on how to substantiate health claim which could assist the applicants on the application procedure or certain topics, 4) establish expert committees to provide scientific and technical expertise in the evaluation of applications and identify key actors at the various stages with clear roles and responsibilities, 5) make available the regulatory documents, the approved health claims and update on regulations on the official governments or ministries' webpages, and 6) include a time frame on the outcome of each claim application which could encourage the food industry to have more food innovation. This proposed framework should be led by the individual SEA country, followed by ASEAN level. The regulators in the 10 SEA countries under ASEAN could apply the framework to review the current status of the local regulatory framework on health claims, identify gaps

which can be improved and align the mindsets of the stakeholders on the basic concept of health claims using a common basis. Involving different stakeholders is fundamental in the development of regulations to allow successful implementation. The perspectives from the various key stakeholders such as industry, consumers, and scientific organisations should be incorporated during the development of the regulatory framework, provided active participation and comments from the key stakeholders are taken seriously by the regulatory agencies. Eventually, such a regulatory framework will provide confidence for consumers in health claims and encourage innovation in the food industry in development of healthy food choices.

6.3.3 Consumer education efforts via Public and Private Partnerships

Consumer education via Public and Private Partnership⁷ can help the SEA consumers more effectively understand health claims. Most mothers in this research could recall health claims but did not have full understanding of the health claims. Knowledge on the nutrients was obtained from a variety of sources such as school, books, doctors, and increasingly from the private sectors. Information from the public domain could serve as the education platform while information from the private sector such as food industry can help to reinforce the messages. The Asian mothers trusted the health claims on the milk powder for their children and this trust stemmed from the ‘international brand’ manufacturers and the government. The trust in the government and the ‘international brand’ manufacturers suggest opportunities for collaboration between the public sector and private sectors to educate the consumers for mutual benefits. Several factors affecting the understanding of health claims such as the familiarity and previous knowledge of the nutrient, the perceived relevance of the nutrient, the use of scientific terms, the choice of words, and also the phrasing and length of the claims should be taken into consideration by marketers and food regulators when formulating and approving new health claims. Cultural differences in SEA consumers’ response to food and health communication should be taken into account due to different languages and cultures in the 10 SEA countries under ASEAN. Provision of education to consumers on the nutrients and food constituent should be in a holistic approach to include not only the benefit but also any side-effects related to overconsumption of the nutrients and/or food constituent. Consumers should also be given a chance to provide feedback on health claims through public consultation, direct contact with the regulatory agencies or food companies if the approved health claims are unclear.

⁷ Appropriate safeguards must be in place to ensure no conflict of interest such as governance of this scheme by an independent committee.

6.4 Prediction on the future development of health claims regulations in SEA

In the opinion of this author, the future of health claims regulations in SEA can be analysed from two perspectives; 1) the presence and development of health claims in SEA and 2) the administrative approaches of health claims regulations and guidelines. Firstly, there is likely to be a trend for more SEA countries to develop and publish health claim regulations and guidelines. The development on the ASEAN Economic Community (AEC) and the free movement of the goods could partly contribute to the trend. The priority sectors identified in AEC such as pharmaceutical, cosmetics and electronics have developed harmonised regulatory frameworks and standards across the SEA countries to facilitate inter- country in SEA. It is worth noting that food is also identified as one of the twelve priority sectors under AEC (Association of Southeast Asian Nations (ASEAN) Secretariat, 2015b).

Secondly, in the personal opinion of the author, there are two possible scenarios on the administration approach to health claims regulations in SEA. The approach could be either more industry-friendly or very stringent like the pharmaceutical standards. If the approach is to be more industry-friendly, this could suggest the potential for different levels of approval. For example, different types of health claims could require different levels of substantiation or scientific evidence ranging from textbooks/ published reviews and articles for nutrient function claims to specific evidence from human intervention trials for reduction of disease risk claims. In addition, there will be more nutrient function claims in the approved list as there could be adoption of health claims that have been approved in major jurisdictions outside SEA. There is a recent development that the food regulatory agencies in Australia and New Zealand and Singapore have increased the number of approved nutrient function claims by adopting selected nutrient function claims that have been approved in major jurisdictions.

On the other end of the spectrum, a more stringent approach to regulate health claims on food could happen as a result from the increasingly blurred boundary between food and medicine to protect consumers especially for other function claims and disease- risk reduction claims. Such an approach will imply that more high quality human intervention trials are required using pharmaceutical-like procedures and standards. In view of this matter, communication of the benefit of the nutrient/ other constituent will be impacted and possibly restricted to health professionals only. The restriction on communicating the benefits of food constituent is similar to the current practices in the pharmaceutical industry where the drug representative will communicate the information on the drugs to the health professionals and this information is censored to the consumers. Food manufacturers put health claims on food with

the aim of helping the consumers to make informed food choices. The food regulators and the food industry are serving the consumers. It is better to provide consumers with reliable sources of information instead of driving them to obtain misleading information from unreliable, non-credible sources that could result in public health problems. There is a need to have a balance between consumer protection and the rights of the consumers to know the right information.

Harmonising the regulatory frameworks on health claims in SEA is challenging to achieve for the stakeholders. Different issues such as food safety, food and nutrition labelling are given differing priorities by each country to resolve in this region. The movement to harmonise health claims on food could potentially take at least 5-10 years to take place unless there is a push from the regional food association or international, government-linked trade councils or through a 'top-down approach' from the ministerial level to expedite the topic. The food industry and/ or research institutions should continue to engage with the regulatory agencies, using consistent messages to understand on the current thinking and processes of health claims, with the interests of the consumers in mind.

6.4.1 Other influential factors

Other factors have direct and indirect influence on the approaches and implementation rate of health claims regulations and guidelines in SEA. These key factors are health policy, economic/ trade policy, national issues and political environment of the country.

The targets and objectives of local health policies and global health trend could affect the health initiatives to be executed in a country. A sugar tax is a good example of one of the health policies initiated by the governments in Mexico, United Kingdom and highly possibly in Thailand to reduce obesity rates in each of these countries (Brownell *et al.*, 2009; Sarlio-Lähteenkorva and Winkler, 2015; Colchero *et al.*, 2016; Tan, 2016). A ban on trans fat in food is another example taken by some governments such as the Danish, New York state in US to reduce healthcare cost on cardiovascular diseases, resulted from consuming trans-fat in the diet (Mozaffarian *et al.*, 2006; Restrepo and Rieger, 2016a; Restrepo and Rieger, 2016b). There is also global movement to consume more wholegrains in the diet to reduce cardiovascular disease, manage weight etc. and this recommendation has been incorporated in the dietary guidelines in many countries (Seal *et al.*, 2016). This could infer there is a need for health claims regulations, in order to communicate the health benefits of not taking too much sugar or trans-fat and eat more whole grains in the diet to the consumers.

From trade perspectives, the standards and regulations are important to protect the consumers and facilitate fair trade. Standards and regulations are established to make sure the consumers have access to a product of certain quality, and this product can be traded freely across the different countries. For example, milk powder is required to meet the Codex/ national standard on milk powder. The standard on milk powder includes different requirements such as nutritional level before the product can be sold as a milk powder for infants. This product will be allowed to be sold in all countries which adopt Codex standards on milk powder. In the implementation of AEC, some sectors such as cosmetics, electronics applied a mutual recognition agreement to remove regulatory and technical barriers. This approach will help with the integration with regional and international standards to facilitate trade. In contrast, this would also mean the regulatory agency of each country has to accept what has been approved by another SEA country which has been effectively achieved in the European Union (EFSA). The development in the priority sectors of similar nature could also have an influence on each other such as the ASEAN traditional medicine and health supplement which are related to health, just like health claims on food. The priorities or resources of the ASEAN secretariat office could sway the development of regulations in different ways.

Other than AEC, global trade development such as the Trans-Pacific Partnership (TPP), the biggest trade agreement in history will have significant impact on the existing free trade agreements in SEA. Four out of 10 SEA countries namely Brunei, Malaysia, Singapore and Vietnam signed up to the TPP agreement in early 2016. The TPP could potentially tamper the existing ASEAN free trade agreements, if not managed properly. Barriers in the inter-country trade within ASEAN could be resulted.

Next, the political environment and national interest in the country will affect the priorities given to address certain issues as the issues require efforts and time. For instance, the progress of AEC has been criticised to be slow due to different level of commitment from the ASEAN countries. Myanmar which is slightly more politically stable in last two years, is progressive in trying to meeting the integration while Malaysia, the ASEAN chair in 2015 has been in political crisis in these two years (Pang, 2015). Nationalism and protectionism reported in some SEA markets such as Indonesia has caused barriers in the integration of AEC (Food Industry Asia., 2013). The political environment and national interest add to the difficulty to harmonise the standards to meet the goals of AEC.

Ultimately, each SEA government will have to decide the future of health claims regulation/ and how to proceed from here for their countries at their comfort level. Maybe it could be as

simple as the consumers are willing to pay for high-specialised nutritious food for good health and the government can collect taxes to run the country. In whatever way, health claim regulations/ guidelines involves more stakeholders and not just the food regulators, key opinion leaders, health policymakers, food industry, academia and consumers. It is important to bear in mind that the SEA will never operate like the European Union on the basis of the ASEAN charter which states each member state has its own sovereignty. The registration and approval of health claims would still be required in each SEA country.

6.5 Limitations of the research

This qualitative research has gained in-depth insight and detailed understanding on the research topic. The findings are responsive to local situations, condition and the perspectives of the stakeholders involved. The limitations of this study include limited amount of participants, self- reporting bias, lack of prior research studies in SEA to compare and different languages and cultures in SEA.

This research should not be viewed as representing the whole SEA region on health claims on food. The data was collected from a limited number of participants and the information reflected the opinions of the people who have agreed to be interviewed. Three SEA countries, Laos PDR, Cambodia and Myanmar are not represented in this research as it was not possible to recruit participants for the research. These countries do not have health claims regulations/ guidelines at the time of this research was completed. There could be bias in self- reported data as it is based on what the participants say due to the methods used in this research which include semi-structured interviews and focus groups discussions.

There is limited or no prior research on health claims on food in SEA available in English at the point when the thesis was prepared. The data from this study, therefore, had to be compared with other major jurisdiction worldwide. It would provide a clearer comparison on the development on health claims regulations in SEA and the Asian consumers' understanding on health claims if the data of this study could have been compared with other publication in the SEA context.

The different cultures among the SEA and languages used in Southeast Asia could affect the understanding of certain words and restrict the search for more information. This could result in bias or differences in understanding the responses as many of whom were native English speakers. The translation to a different language could further filter and change the meaning of information. There could be existing non-English literature available in the local

publications and/ or new draft regulations or guidelines on health claims in the SEA countries available in other SEA languages.

More development and changes on the regulations on health claims in various countries could take place during the submission of this thesis such as the publication of regulations in Vietnam which occurred after Chapter 2 was completed. The regulatory environment on health claim regulations is evolving rapidly in major jurisdictions worldwide and/ in SEA countries. Consistent effort was required to access the official information sources regularly to monitor and keep updated with the changes on regulations or government documents during the course of this study.

6.6 Future studies

This research leads to more questions and creates opportunities to discover more information on health claims on food in SEA. Future work on this research should, if possible, extend the interviews to more clusters of stakeholders such as the trade ministers, economists, consumer associations, ASEAN secretariat, and academia in SEA to bring in different facets in this discussion. Those SEA countries without health claim regulations/ guidelines should also be re-approached to understand their perspectives. The association of health claims in health policy of the country could be interesting to investigate to better understand the influence of policy on regulation.

More studies on the understanding of health claims among SEA countries are needed to better understand SEA consumers due to different languages, cultures in this region. These studies could be conducted in different SEA countries, using different stimuli, demographics such as socio-economic status, gender, education etc. for effective communication to the SEA consumers. It will be useful to understand the culture and SEA consumers' perspectives on food, traditional herbs and medicines which are commonly consumed in this SEA region to promote normal well-being and how these relate to products carrying health claims. These factors could influence the food choices and purchase behaviours of the consumers. The findings of this study could be used as a basis for a larger scale questionnaire-based survey in the various SEA countries.

It could be of interest to investigate the paradigm between 'Western' and 'Asian' types of health claims. The different concepts of Traditional Chinese Medicine (TCM) and Ayurvedic medicine which are accepted and commonly practiced in Asia for well-being, could face difficulties in obtaining an approved health claim. It is challenging to conduct clinical trials using the ingredients in the TCM or Ayurvedic medicine. The active constituent in each of

the ingredients need to be identified first, to meet the fundamental requirement for health claim applications.

6.7 Contribution of this research

This research is a pioneering work in the research field. The findings in this study are important in the light of recent development in health trends, food innovation and changes in the regulations on health claims. This research has contributed in the following ways:

1. Provide clear direction and strategy for innovation, and help industry to focus resource on research and better planning to generate evidence for health claim application.
2. Provide guidelines for regulatory community in food industry to better support innovation, taking into account the perspectives and expectations from different clusters of stakeholders, including the consumers.
3. Bring knowledge for regulators, researchers, food industry into Singapore and establish connections of the regulators from SEA & major jurisdictions
4. Create opportunities for more future research in this topic and in SEA region

6.8 Concluding thoughts

Active engagement and inclusive consultation with all key stakeholders is critical to shape the regulatory development of health claims in SEA. Clearly, the relationship between nutrients and health is a complex issue. It involves many key stakeholders such as the consumers themselves, food industry, food regulatory agencies, academia, policy makers from social, health and economic sectors, educators, health professionals. Although food regulatory bodies in some SEA countries are still grappling with food safety and general labelling issues, it is timely to initiate discussion on health claims to protect the SEA consumers and facilitate trade in this fast-growing region.

For health claims to truly benefit consumers, it is important to be clear and align on the aim of using health claims that is to help the consumers make informed food choices. There are two contrasting sayings to describe and summarise this phenomenon. The sayings go “*A boat doesn't go forward if each one is rowing their own way.- Proverb*” and “*Alone we can do so little, together we can do so much - by Helen Keller*”.

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**Appendix 1: Health Claim Application Forms for three SEA countries:
Indonesia, Malaysia and Singapore**

Indonesia:

REGULATION OF THE HEAD OF THE DRUG AND FOOD SUPERVISORY AGENCY
NUMBER HK.03.1.23.12.11.09909 YEAR 2011
ON THE CONTROL OF CLAIMS IN LABELING AND ADVERTISING OF PROCESSED
FOOD

Form A

To

Head of the Drug and Food Supervisory Agency

Cq. Director of Food Products Standardization

Jl. Percetakan Negara No. 23

Jakarta

Dear Madame,

Enclosed please find:

Application

1. Applicant's Data

Name :

Position :

Acting on behalf of the business entity :

Name :

Address :

.....

Telephone :

Fax :

E-mail :

2. Product specifications and product data

Type of product :
Trade brand :
Net weight :
Type of packaging :
Product composition :

3. Name of component added with / without chemical structures

.....
.....

4. Objective of the Addition

.....
.....

5. Claims filed

.....
.....

6. Daily intake of components

.....
.....

7. The production process

.....
.....

8. Regulatory status of the component/claims filed in various countries

.....
.....

9. Methods and results of analysis of nutrients and other components in the finished product

.....
.....

10. History of use as food

.....
.....

Jakarta, (date, month, year)

Applicant

(.....)

Full Name

Form B

Evidence and or Scientific Reference

Document evidence and or scientific reference :

Title of document :

Date of publication :

Author :

Published in the media:

Summary information :

Note : This sheet may be reproduced, if the evidence document and or scientific reference is more than one.

HEAD OF THE DRUG AND FOOD SUPERVISORY
AGENCY OF THE REPUBLIC OF INDONESIA

w.s.

KUSTANTINAH

Malaysia:

APPLICATION FOR NUTRITION CLAIMS (REG 18C, 18D, 18E)

Guide for application:

- i. All sections in this form must be completed.
- ii. Where relevant, provide summaries of information required so as to assist the Committee members in understanding the application.
- iii. Submit copies of all references cited in the text as appendices.
- iv. If the nutrient concerned is already in the NRV list, information for item numbers 9, 10, 11, 15, 16 and 17 need not be provided.
- v. All information requested in this format must be submitted in Bahasa Malaysia or English.
- vi. Twenty copies of this format must be submitted together with the necessary supporting document.

Application should be addressed to:

Senior Director

Food Safety and Quality Division

Ministry of Health Malaysia

Level 3, Block E7, Parcel E

Federal Government Administration Centre

62590 PUTRAJAYA

1. Name of applicant (in full and in block letters) *:

2. Business address:

3. Mailing address:

4. E-mail address:

5. Telephone number: Fax Number:

6. Type of business:

* State:

a. Whether applicant is manufacturer or its agent.

b. Whether this application is on behalf of a single firm or organization.

c. Whether this application is on behalf of a food processing industry or other firms or organizations.

- d. If on behalf of the food processing or other industries or organizations, names and addresses of these.
7. State the nutrient concerned and the proposed nutrition claim (nutrient content claim, comparative claim or nutrient function claim). If the said nutrient is to be added to food and it is not listed in Table (I) of Twelfth Schedule as a permitted nutrient supplement, a submission for its inclusion to the list has to be made to Ministry of Health Malaysia using the format entitled Application for Addition to Nutrient Supplement List [Table (I) of Twelfth Schedule].
8. Name the food(s) to which this nutrient is to be added.
9. State the limits of the probable daily intake of the nutrient in the diet.
10. State the chemical structure and formula of the nutrient(s) and describe it in precise chemical terms and state all physical properties.
11. Provide detailed information on the physiological role(s) of this nutrient.
12. If proposing a “nutrient content claim” or “comparative claim”, state the proposed criteria for making these claims and provide scientific justification.
13. If proposing a new “nutrient function claim” and the level of that nutrient to be considered as a “source” of that nutrient per 100 g or per 100 ml of the food, if it is not already in Table (II) in the Fifth A Schedule. Provide scientific justification for the proposed level.
14. If proposing a new “nutrient function claim”, provide sound scientific evidences for the claim. All available literature including both positive and negative findings on the proposed claim must be provided. If the list is too extensive, provide hard copies only for more recent studies. Other studies can be provided in a bibliographic listing. Data from human intervention trials are preferred. Epidemiological and experimental studies and reviewed papers may be included as supportive evidences. Studies should include those conducted by other organizations or institutions. Result of all these studies should be published in refereed journals.
15. Show information regarding the stability and bioavailability of the nutrient(s) in the food(s) in which it is to be added.

16.State the analytical method to determine the amount of the nutrient(s) in the raw, processed and/or finished food

17.Submit all data on safety evaluation derived from both chronic and acute studies conducted on the nutrient(s).

18.Give examples of approval by other countries or recognized international agencies of this application.

19.Provide other relevant information.

Declaration:

I _____ (full name), identity card / passport number

_____, hereby declare:

a. that this application is made by myself / on behalf of

b. that all particulars given in this form including all appendices attached are true and correct.

Signature:

Name (capital letter):

Designation:

Official stamp:

Date:

Singapore:

**APPLICATION FOR USE OF HEALTH CLAIMS FOR
FOOD INTENDED FOR SALE IN SINGAPORE**

The guidance information, application form and checklist incorporated in this document are meant for applications for use of health claims on food products.

"Food" means any substance, liquid, product or preparation which is intended for human consumption through ingestion and includes —

- (i) any form of chewing gum; and
- (ii) any substance or preparation that is used or intended for use as a colouring agent, condiment, preservative or additive in the preparation of any substance, liquid, product or preparation intended for human consumption;

but does not include —

- (i) any medicinal product (whether or not such medicinal product has been licensed under Section 5(1) of the Medicines Act (Cap. 176) and registered under Section 10 thereof, or exempted from such licensing under Section 8 or 9 of that Act);
- (ii) any substance, liquid, product or preparation which is documented in the latest edition of the "*Martindale Extra Pharmacopoeia*", "*A Dictionary of Chinese Pharmacy*", "*The Chinese Herbal Medicine Materia Medica*" or such approved pharmacopoeia as a bulk laxative or as a substance, liquid product or preparation for use for a medicinal purpose;
- (iii) any substance which is listed in Part I of the Schedule to the Poisons Act (Cap. 234);
or
- (iv) any substance, liquid, product or preparation which, although intended for human consumption, is excluded from this definition by the Minister by order published in the *Gazette*.

Applications involving products containing non-permitted food ingredients will not be considered. Applicants must first seek approval from AVA for use of these ingredients in food before applying for use of health claims for these products.

The completed application form should be submitted to the following contact:

Regulatory Administration Department

Agri-Food & Veterinary Authority

52 Jurong Gateway Road, #13-01,

Singapore 608550

Tel: 68052914/68052915

For clarification, please write to AVA_LabelsAndClaims@ava.gov.sg

GUIDANCE INFORMATION

The application form consists of the following seven sections:

Part A: Applicant information

Part B: Summary of proposed claim

Part C: Summary of studies submitted

Part D: Table of content of supporting documents submitted

Annex 1: Synopsis of individual studies

Annex 2: Summary of application

Annex 3: Checklist

Applicants are required to follow the steps listed below in completing the application form:

Step 1: Complete all information required under Part A to Part D of the application form.

Step 2: Systematically review all available studies and select only relevant studies which substantiate the proposed claim for completion of Annex 1. These studies provided should preferably be well designed human intervention studies. Human observational studies alone are not adequate but may contribute to the totality of the evidence. Animal model studies, *ex-vivo* and *in-vitro* studies may be provided only as supporting knowledge to illustrate the relationship between the food/food constituents and the proposed health effects. There should be at least 5 relevant studies, preferably published within the recent 10 years. Applicants should also ensure that the studies submitted best substantiate the proposed health claims.

Step 3: Summarise all studies submitted using Annex 2.

Step 4: Provide other supporting documents, for example, approval letter/document from national food authorities on the proposed claims, verification of proprietary/ confidential data etc.

Step 5: Use Annex 3 to countercheck if all necessary information or documents have been submitted.

Please indicate 'Nil' if the information required is not available. A separate application form is required for each health claim. Failing to provide information required may prolong the evaluation or disqualify the application.

APPLICATION FORM

Part A: Applicant Information

Company Name:

Address:

Contact Person Name:

Company Name (if different from above):

Address (if different from above):

E-mail:

Telephone:

Fax:

Part B: Summary of Proposed Claim

Types of claims (please tick where relevant):

<input type="checkbox"/>	Nutrient function claim
<input type="checkbox"/>	Other function claim
<input type="checkbox"/>	Disease risk reduction claim

Food or food constituent (eg. nutrients, other substances, or a combination of nutrients/ other substances) for which the claim is made (to define):

Targeted consumers (age/ gender/ recommended for specific medical condition etc):

Proposed wording of the claim:

Description of the relationship between the active component(s) and the health claim:

Conditions of use: (indicate quantity of the food/food constituent and pattern of consumption required to obtain the claimed effect; and whether this quantity could reasonably be consumed as part of a balanced diet)

Declaration of proprietary data

	Yes	No
The application contains proprietary data	<input type="checkbox"/>	<input type="checkbox"/>
If yes, has the verifiable justification/ declaration been provided?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, has the proprietary data in the application been located?	<input type="checkbox"/>	<input type="checkbox"/>

National and International Regulatory Status

State whether this claim has been assessed and approved for food use by any national regulatory body and provide evidence of approval, if any. Fill out relevant boxes under “Effective Date” to reflect the dates when the processes took place.

Regulatory Body	Effective Date			
	Accepted	Rejected	Under consideration	Withdrawn

Part C: Summary of studies submitted

All published or unpublished human and non-human studies that are relevant for substantiation of the proposed claims should be submitted for consideration. Both data in favour and data not in favour should be included. To facilitate the evaluation, applicants should submit the deemed most relevant and not repeated information of at least 5 independent peer-reviewed reports of studies, preferably published in the last 10 years. Applicants may be requested to submit more information if necessary.

Important notice:

- Abstracts and articles from in-house reports, newspapers, newsletter, magazines that have not been peer-reviewed should not be cited.
- Books or chapters of books for consumers or the general public should not be cited. Classic texts or textbooks for professional trainings maybe submitted as side references.

Study type	Full citation (to provide original papers)	Information provided		
		(a)	(b)	(c)
		(a) Characteristics of food/food constituent (b) Consumption pattern or quantity to consume to obtain the claimed benefit (c) Relationship between food/food constituent with the proposed health claim (please tick where appropriate)		
1. Human studies: a) Experimental intervention studies eg. RCT, RT	<ul style="list-style-type: none"> • • 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Observational studies eg. cohort studies, case-control studies, cross-sectional studies	<ul style="list-style-type: none"> • • 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Non-human studies eg. animal, <i>ex vivo</i> , <i>in vitro</i> studies	<ul style="list-style-type: none"> • • 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Systematic reviews such as pooled analysis, meta-analysis	<ul style="list-style-type: none"> • • 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Contradictory information	<ul style="list-style-type: none"> • • 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Part D: Table of contents of the supporting documents

Title	Page

ANNEX 1: SYNOPSIS OF INDIVIDUAL STUDIES

Please provide one synopsis for each study.

DECLARATION AND SIGNATURE

I hereby confirm that to my best knowledge, all relevant data to support use of the proposed health claim have been submitted in the application.

Signature:

Name:

Designation:

Date:

1. Identification of study

Authors:

Article titles:

Source/ Year/ Volume/ Pages:

Declaration of interests:

Source of funding:

Good Clinical Practice status/ ethical approval:

2. Objective(s) of the study

3. Description of the study population

Population (for example, general population, sub-population with particular medical condition) and number of subjects under studied:

Age range:

Gender:

Ethnicity:

Geographical region:

4. Study design

Brief description of the methods used from sampling till analysis of results. This should also include design information (for example, randomized control trials, cohort studies, cross-sectional studies, meta-analysis).

5. Study results

Include all results supporting the proposed claims such as:

- Comparison of pre- and post-test values
- Levels of intake in order to deliver the function claimed
- Adverse effect reported, if any

6. Summary

Describe the key findings of the studies that are in favour and not in favour for substantiation of the proposed claim.

ANNEX 2: SUMMARY OF APPLICATION

<p>Proposed wording of the claim:</p>
--

Characteristics of foods/ food constituents (eg. nutrient or other substance or a combination of nutrients/ other substances)

Name/ characteristics/ bioavailability

List down individuals studies by the study types given. Provide summary of the key findings of each study and discuss the quality of the studies.

Full citation of studies	Key findings	Study quality ¹
A) Human studies • •		
B) Non-human studies • •		
C) Systematic review • •		
D) Contradictory information • •		

Overall conclusion (should not exceed 1 A4 page)

¹ Discuss the study quality by addressing areas below:

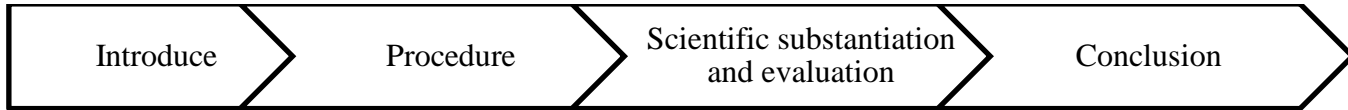
- Study limitation (eg. method of randomization, blinding, case-control)
- Risk of bias (eg. selective outcome reporting)
- Consistency of results (eg. dose-response relationship)
- Directness of evidence (eg. differences in population, interventions, interpretation of results)

ANNEX 3: CHECKLIST

	Items	Yes	No
1)	Has the food/food constituents for which the health claim is made been characterized?	<input type="checkbox"/>	<input type="checkbox"/>
2)	Has the specification of the food/food constituents for which the health claim is made been provided?	<input type="checkbox"/>	<input type="checkbox"/>
3)	Has the bioavailability data of the food/food constituents for which the health claim is made been provided?	<input type="checkbox"/>	<input type="checkbox"/>
4)	Has the food or food category for which the health claim is made been provided?	<input type="checkbox"/>	<input type="checkbox"/>
5)	Has a synopsis been provided for each study submitted?	<input type="checkbox"/>	<input type="checkbox"/>
6)	Have the copies/ reprint of full study reports been provided and annexed?	<input type="checkbox"/>	<input type="checkbox"/>
7)	Have other supporting documents such as approval letter from national food authorities been provided?	<input type="checkbox"/>	<input type="checkbox"/>

Appendix 2: Interview Guide for semi- structured interviews with key stakeholders

Structure and rationale of the interview:



<ul style="list-style-type: none"> - Understand their roles - Break the ice and gain trust (ethic, use of data, consent form) - Understand the scope and objective of the health claim regulations 	<ul style="list-style-type: none"> - Understand the criteria for screening - Understand the timeline for approval - Understand the selection of the members in the expert committee 	<ul style="list-style-type: none"> - Understand how regulators review health claim application such as the key information - Understand the concerns of the regulators when they review health claim application 	<ul style="list-style-type: none"> - Understand the problems faced by the regulators and possible solutions they suggest - Engagement after the interview (have the opportunity for clarifying information, sharing of data, request for the report)
---	--	--	--

Sample of the interview and questions

Thank you so much for accepting this interview.

Hello, my name is Ms Karin Tan. I am currently a full-time PhD candidate with the Newcastle University UK and formerly an employee of Danone Asia Pacific Holdings Pte Ltd whom is currently on study leave to complete my PhD study. This research is mainly funded by the Singapore Economic Development Board, a government statutory board in Singapore and Danone Asia Pacific Holding Pte Ltd.

My research is designed to understand the different aspects of the regulatory frameworks on health claims in Southeast Asia. During the interview, I would like to discuss on the following topics: the procedures on applying for new health claim, the types of scientific evidence required for health claim substantiation, the evaluation of the scientific evidence which lead to the approval or rejection of the new health claims and the enforcement actions in place in your country. At the end of the study, you can request for summary finding of the study.

With these topics in mind, I would like to start the interview. You can choose not to answer any question which you are not comfortable with and do feel free to ask any questions at any point of time.

1. Introduce

Main questions	Additional questions	Clarifying questions
<ul style="list-style-type: none"> Can you tell me what do you do in your current role? 	<ul style="list-style-type: none"> What are you trained in? How many years have you been in your current role dealing with health claims? 	<ul style="list-style-type: none"> Can you expand a little on this? Can you give me more examples? Can you provide me more information on this point?
<ul style="list-style-type: none"> In your opinion, what does the word 'health' mean to you? 	-	
<ul style="list-style-type: none"> What is the scope of the health claims in the regulations/guidelines? 	<ul style="list-style-type: none"> What elements are considered under the scope? 	
<ul style="list-style-type: none"> What are the objectives of health claims? 	<ul style="list-style-type: none"> Why? 	

2. Procedure of health claim application

Main questions	Additional questions	Clarifying questions
<ul style="list-style-type: none"> Can you tell me when is the last time you processed the health claim from receiving the claims until informing the applicant on the outcome? 	<ul style="list-style-type: none"> How long does it take to finish the process? What are the factors that could affect the approval time? In your view, should the applicant consult the authority, prior to the submission or before the result of the outcome? 	<ul style="list-style-type: none"> Can you expand a little on this? Can you give me more examples? Can you provide me more information on this point?
<ul style="list-style-type: none"> What do you screen for in the application before it is submitted to the expert committee for evaluation? 	<ul style="list-style-type: none"> Why? 	

Main questions	Additional questions	Clarifying questions
<ul style="list-style-type: none"> What are the criteria for selecting the experts in the expert committee? (eg. expertise, multi-government agencies, academic, consumer group, industry association) <p>OR</p> <ul style="list-style-type: none"> How do you select the experts to be in the expert committee? (eg. expertise, multi-government agencies, academic, consumer group, industry association) 	<ul style="list-style-type: none"> Why? Can you co-opt other experts in your expert committee? 	
<ul style="list-style-type: none"> Do you know whether the applicant need to state the claims exactly as it is being approved? 		
<ul style="list-style-type: none"> What are the enforcement actions if there is a violation? 		

3. Scientific substantiation and the evaluation of the health claim application

Main questions	Additional questions	Clarifying questions
<ul style="list-style-type: none"> What information do you look out for in the petition or dossier submitted? <p>OR</p> <ul style="list-style-type: none"> Which are the most important types of scientific information you look for in the application 	<ul style="list-style-type: none"> Why? What is considered as the appropriate and relevant target group? How do you view the strength of evidence from the human observation studies to substantiate nutrition research? 	<ul style="list-style-type: none"> Can you expand a little on this? Can you give me more examples?

Main questions	Additional questions	Clarifying questions
<p>to prove the cause-and-effect relationship?</p>	<ul style="list-style-type: none"> • Do you accept studies conducted by industry and are published in scientific journals? • How do you evaluate health claim on the food component such as ginger which has long history of use and has limited scientific evidence? • Question for Indonesia only: What is considered under certain conditions when the local studies are required? • For Malaysia, Singapore, Thailand: Do you accept studies conducted in other countries and are published in scientific journal? If not, what are the conditions when you require the studies to be conducting using local population? • For Malaysia, Singapore and Thailand only: How much emphasis does the authority put on the number of studies to be submitted? 	<ul style="list-style-type: none"> • Can you provide me more information on this point?
<ul style="list-style-type: none"> • Why do you require the ‘rationale to add’ and the ‘Approval by other regulatory authority’? 	<p>-</p>	

Main questions	Additional questions	Clarifying questions
<ul style="list-style-type: none"> • How does the expert committee review the scientific evidence? <p>OR</p> <ul style="list-style-type: none"> • What are the guiding principles to evaluate health claims? 	<ul style="list-style-type: none"> • How do you evaluate whether the claims are non-misleading or it can be understood by the consumers? 	
<ul style="list-style-type: none"> • What are the challenges you face when you evaluate health claims? 	<ul style="list-style-type: none"> • Why? 	

4. Conclusion of interview

Main questions	Additional questions	Clarifying questions
<ul style="list-style-type: none"> • In your opinion, what area(s) do you think the existing process have done well and what can be improved? 	<ul style="list-style-type: none"> • Why? 	<ul style="list-style-type: none"> • Can you expand a little on this?
<ul style="list-style-type: none"> • How can the food industry work with you to improve the process or make your work easier? • 	<ul style="list-style-type: none"> • Why? 	<ul style="list-style-type: none"> • Can you give me more examples?
<ul style="list-style-type: none"> • How can my research help you and the food industry? 	<ul style="list-style-type: none"> • Why? 	<ul style="list-style-type: none"> • Can you provide me more information on this point?
<ul style="list-style-type: none"> • How can we educate consumers to better understand health claims? 		
<ul style="list-style-type: none"> • Do you want to add any other comments on health claim? 		

Appendix 3: Focus Group Discussion Guide

Note: This discussion guide is intended as a “checklist” for the moderator. The objective, during the time of the interview, is to make the discussion as relaxed and natural as possible in order for the respondent to feel able to open up and share their experiences and attitudes.

The moderator will treat this as a menu from which to select topic areas and guide the general flow of discussion. The guide is thus a springboard for discussion; respondents’ responses may often lead the discussion in new directions or change the order of topics. Some questions or techniques may be skipped if issues have already been sufficiently covered at an earlier stage.

SUMMARY FLOW OF DISCUSSION

Section	Time allocation	Objectives
1. Introduction & warm up	10 minutes	<ul style="list-style-type: none"> • Introduce market research, and acquaint each other • To build rapport between respondents and cue them towards the context of discussion • Introduce discussion rules
2. Usage & attitude towards child’s diet	10 minutes	<ul style="list-style-type: none"> • Understand the role of milk in child’s diet
3. Areas of consideration in selecting milk powder	20 minutes	<ul style="list-style-type: none"> • Identify the areas of consideration in choosing milk powder • Understand the role of that product labels shape consumer decisions in their choice of products
4. Consumers’ understanding of product labels	30 minutes	<ul style="list-style-type: none"> • Understand the role of product labels • Understand respondents’ expectations of local food regulations
5. Comprehension of Calcium & Iron	5 minutes	<ul style="list-style-type: none"> • Understand current perceptions of Calcium & Iron
6. Claims testing	40 minutes	<ul style="list-style-type: none"> • Assess claims test in terms of how well it resonates with respondents • Identify areas of improvement
7. Decision Making Process	5 minutes	<ul style="list-style-type: none"> • Understand the decision making process in milk powder purchase
8. Wrap Up	5 minutes	<ul style="list-style-type: none"> • End discussion

<p>1. Introduction & warm up</p> <ul style="list-style-type: none"> • Introduce market research, and acquaint each other • To build rapport between respondents and cue them towards the context of discussion • Introduce discussion rules 	<p>Duration: 10 minutes</p>
	<p>Cumulative: 10 minutes</p>
<p>Warm welcome!</p> <p>Explain market research</p> <ul style="list-style-type: none"> • Purpose of discussion • Safe & confidential environment • No right or wrong answers, merely gathering point of views • Inform respondents that session will be recorded – both audio and video <p>Quick round of introduction</p> <ul style="list-style-type: none"> • Name • Age • Occupation • Number of children and respective age 	

<p>2. Usage & attitude towards child's diet</p> <ul style="list-style-type: none"> • Understand the role of milk in child's diet 	<p>Duration: 10 minutes</p>
	<p>Cumulative: 20 minutes</p>
<p>All of us here have young children. For the purpose of this study, let us concentrate on your child age 3 to 6 years. So if you have a child age 2 and another age 4, please respond based on the 4 year old child.</p> <p>I would first like to understand their typical diet. This covers their main meals, snacks, beverages...basically everything edible!</p> <ul style="list-style-type: none"> • What do you feed your child with? • How are these F&B given out? <ul style="list-style-type: none"> ○ Breakfast ○ Lunch ○ Snack ○ Dinner ○ Others • <i>[Moderator to probe for milk if not mentioned]</i> <ul style="list-style-type: none"> ○ How often do you give your child milk? ○ What are your reasons for giving your child milk? <i>[Listen for: calcium, iron etc]</i> ○ What is the difference between a child who takes milk and a child who does not? ○ Do you mix anything with the milk to feed your child? ○ Why do you do so? 	

3. Areas of consideration in selecting milk powder <ul style="list-style-type: none"> Identify the areas of consideration in choosing milk powder Understand the role of that product labels shape consumer decisions in their choice of products 	Duration: 20 minutes
	Cumulative: 40 minutes

When it comes to purchasing milk powder, I would like to know what do you look out for...

[Moderator to list factors on the board]

- Probe for:**
 - Brand ***[Listen for: popular, well-known etc]***
 - Why is this an area that you look out for?
 - How is branding important to you?
 - What are the brands that you consider? Why?
 - What are the brands that you would not consider? Why?
 - Price
 - Nutritional value ***[Listen for: iron, calcium, etc]***
 - Why is this an area that you look out for?
 - How do you know if this is available? ***[Listen for: food labels]***
 - From what source?
 - What do you understand from the nutritional value? How do you think it will impact your child?
 - To what extent would you believe it?
 - Health benefits ***[Listen for: bone growth etc]***
 - Why is this an area that you look out for?
 - How do you know if this is available? ***[Listen for: food labels]***
 - From what source?
 - What do you understand from it?
 - How believable is it?
 - Recommendations ***[Listen for: by family/friends, doctor etc]***
 - Why is this an area that you look out for?

- What exactly did that person share with you?
- Taste
 - Why is this an area that you look out for?
 - How do you know how it'll taste like? [***Listen for: food labels***]
- Availability [***Listen for: specialty stores only, supermarkets etc***]
 - Why is this an area that you look out for?
- Country of manufacture
 - Why is the country of manufacture important?
 - How do you know where is the country of manufacture? [***Listen for: food labels***]
 - What are some of the countries that you prefer to buy from?
 - What are some of the countries that you would never buy from?
 - When you come across a product made in Country A and sold in your home country, in your opinion, which country's regulation does the product comply? Home country? Or the country of manufacture?
- Can you rank the top 3 factors?
 - Why this ranking?

4. Consumers' understanding of the role product labels and regulations <ul style="list-style-type: none"> • Understand the role of product labels • Understand respondents' expectations of local food regulations 	Duration: 30 minutes
	Cumulative: 70 minutes

Earlier, you mentioned that you look at product labels when shopping for milk powder.

- What type of information do you expect to get from the product label? [**Listen for: weight, nutritional value, benefits claim, ingredients etc**]
- How useful do you find the information from the product label?
 - Did you learn something new from reading product labels?
 - If yes, what was it?
 - If no, what else would you like to know?
 - Are you happy with the content of product labels?
 - Do you understand what is written on the label?
 - If no, what was not clear to you?
 - How did you cope with it? [**Listen for: made the effort to find out more information, leave it alone**]
- Was there a time when you went to a store with a certain product in mind but bought something else, after reading the food label?
 - If yes, what happened?

Now I would like to discuss about health claims. Health claim refers to the health benefits of the ingredients in the milk.

- What do you think when you see health benefit claims? [**Listen for: healthier choice etc**]
 - What do you think is the purpose of having health benefit claims on product labels? [**Listen for: marketing, raise awareness**]
 - What do you think of products with health claims?
 - What do you understand from it?
 - What happens when you don't understand it?
 - Would you want to find out more information?

- If yes, what sources do you go to?
 - If no, why not?
- Does health benefit claims influence your decision to buy the product in any way? How so?
- How credible are these health benefit claims?
 - Do you trust the health benefit claims on the product if it's permitted to be sold in <country>?
 - Are there any health benefit claims regulations in <country>?
 - If yes, what do you think is the regulation for health benefit claims?
 - Which organization would oversee these regulations? Overall, what do you think the role of this organization is?
 - How keen would you be to see more health benefit claims on your product? Please rate on a scale of 1 to 10 with 1 being least keen and 10 being most keen.
 - What are your reasons for giving this score?
 - Is there any way that the regulators can help you understand health benefit claims better?

5. Comprehension of Calcium & Iron & Vit A <ul style="list-style-type: none"> • Understand current perceptions of Calcium & Iron & Vit A 	Duration: 5 minutes
	Cumulative: 75 minutes
<p><i>[Moderator's note: probe if not covered earlier]</i></p> <p>Could you tell me what you do understand of the following?</p> <p><i>[Moderator's note: please rotate below order for every FGD]</i></p> <ul style="list-style-type: none"> • Calcium • Iron • Vit A 	

6. Claims testing <ul style="list-style-type: none"> Assess claims test in terms of how well it resonates with respondents Identify areas of improvement 	Duration: 40 minutes
	Cumulative: 115 minutes

For the next exercise, I am going to show you some health benefits claims.

Firstly, I wanted to know if you had seen any health benefits claims relating to calcium/iron before this discussion?

- If yes, where did you see/hear about it?
- What do you recall about it?

[Moderator's note: please test in following order:

Group 1: Calcium 1, Calcium 2, Calcium 3

Group 2: Iron 2, Iron 1, Iron 3

Claim on Calcium	Claim on Iron	Claim on Vit A
1) Calcium helps support development of strong bones and teeth.	1) Iron is an important component of red blood cells which carry oxygen to all parts of the body to help the body's production of energy.	1) Anti-oxidants like carotenes and Vitamin E help to protect cells from free radicals that may have escaped the natural processes of our body system.
2) Calcium make strong bones and teeth.	2) Iron helps your body to produce energy.	2) Anti-oxidants like carotenes and Vitamin E support your child's immune system.
3) Calcium contributes to the height of the children. <i>(Calcium helps you to grow taller.)</i>	3) Iron helps build strong muscles.	3) Anti-oxidants like carotenes and Vitamin E reduce the chance of your child from falling sick.

For each claim, moderator to flash claim on board then cover slide. i.e. hide it from respondent

- [Write on paper]** What do you recall seeing from the health claim?

For each claim:

- On the whole, what do you think of this claim?
 - [Write on paper]** What is it trying to say to you?
 - Do you agree with the claim?

- Is this claim in line with what you know?
- Is this clear to you?
- Any questions that you have?
- How can this claim be improved?
- How unique is this compared to what you already seen in the market?
- Does it, in any way, affect your decision in purchasing the product?
- How credible is this to you?
- How do you think this claim can be improved to be more relevant to you?
- Imagine if you have a friend who would like to know more about calcium/ iron, what would you say to them?

[Moderator to complete all claims before proceeding]

- Ask separately for calcium, iron & Vit A:
 - For claim 1 and 2: Does 1 and 2 refer to the same health benefit? What makes you feel this way?
 - Which claim is the most compelling in getting you to try a product for your kids? Why is that so?
 - Which claim is most relevant to you? Why is that so?

If time permits

[Moderator to split respondents into 2 groups and provide paper, markers etc]

- Now imagine that you are a milk powder manufacturer and you need to finetune the product claim.
 - How would you change the claim?
 - Why is that so?

<p>If time permits</p> <p>7) Decision making process</p> <ul style="list-style-type: none"> Understand the decision making process in milk powder purchase 	<p>Duration:</p>	<p>5 minutes</p>
<p><i>[Moderator to draw out purchase journey on board]</i></p> <ul style="list-style-type: none"> How do you go about purchasing your milk powder? <i>[Listen for: talk to friends/family, buy from specialty stores, supermarket etc]</i> <ul style="list-style-type: none"> <i>[Probe if respondents purchase online]</i> Specifically, where do you obtain the information on milk powder from? <i>[Listen for: word-of-mouth, doctor, product label, company website, sales person etc]</i> <ul style="list-style-type: none"> What made you go to these sources? In your opinion, how credible are they? How do they influence your purchase decision? <p>Probe if not mentioned, do you read the product labels?</p>		
<p>8) Wrap up</p> <ul style="list-style-type: none"> End discussion 	<p>Duration:</p>	<p>5 minutes</p>
<p>Cumulative:</p>		<p>120 minutes</p>
<p>We've come to the end of our session! Do you have anything else you would like to add?</p> <p>Thank you!</p>		

Appendix 4: Published paper 1

Tan, K. Y. M., van der Beek, E. M., Chan, M., Zhao, X. and Stevenson, L. (2015) 'Health claims on food products in Southeast Asia: regulatory frameworks, barriers, and opportunities', *Nutrition Reviews*, 73(9), pp. 634-641.



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Appendix 5: Published paper 2

Tan, K. Y. M., van der Beek, E. M., Kuznesof, S. A. and Seal, C. J. (2016) 'Perception and understanding of health claims on milk powder for children: A focus group study among mothers in Indonesia, Singapore and Thailand', *Appetite*, 105, pp. 747-757.



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