

The Review of Food Registration Processes and Requirements in ASEAN

Survey Outcomes
and Recommendations



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Part 1

Introduction

Part 1(i): Progress of ASEAN harmonisation

The ASEAN Economic Community (AEC) was conceptualised to establish a single market. Since its conceptualisation, there has been tremendous effort made in developing instruments to pave the way towards harmonisation.

In the prepared food sector, a number of ASEAN standards and guidelines have been finalised, such as the *ASEAN General Standards for the Labelling of Prepackaged Food*. Further to that, it was announced in August 2018 that the ASEAN Consultative Committee on Standards and Quality Prepared Foodstuff Product Working Group (ACCSQ PFPWG) will begin to look into the area of nutrition labelling harmonisation. With nutrition labelling being identified as one of the top technical barriers to trade, the food sector can look forward to this new work under ACCSQ PFPWG to lower trade barriers faced by the food sector, especially the small and medium enterprises (SMEs).

In April 2018, the *ASEAN Sectoral Mutual Recognition Arrangement for Inspection and Certification Systems on Food Hygiene for Prepared Foodstuff Products* was signed by all ten ASEAN member states. The sectoral MRA is a display of the commitment from member states to facilitate trade in ASEAN and protect the health of consumers. This will be achieved through mutual recognition of inspection and certification systems on food hygiene with regard to the production, import and export of prepared foodstuff products that fall under Harmonised System (HS) code 16 to 22.

Moving forward, the agri-food sector will continue to be a key sector for ASEAN countries. Following the establishment of the AEC in 2015, the journey towards regional integration continues with the AEC Blueprint 2025. The next phase would be crucial as ASEAN and other stakeholders work together to achieve a more harmonised framework in the region.

Part 1(ii): Background of study

Product registration, also known as pre-market registration, is the food safety and regulatory control measures taken by food authorities to assess and approve the safety and compliance of food products before they are allowed to be sold in the country.

While principles to safeguard food safety are essential to manage potential risks of food products, inefficiencies arise as the implementation and enforcement of traditional regulatory models often give rise to non-tariff barriers.

According to a survey conducted in 2013 that involved members of the ASEAN Food and Beverage Alliance (AFBA), product registration was identified as one of the top technical barriers to trade. Continuing on the 2013 study, AFBA is keen to identify key approaches to overcome barriers to trade that are faced by the industry members, particularly in the area of product registration.

To gather a deeper understanding of the key issues and hurdles faced by the food industry, a survey was conducted

in 2018 to ascertain industry members' experiences with regards to product registration, identify gaps in the current regulations and present industry's recommendations. The survey covered four sections — product registration, laboratory tests, customs clearance and availability of information.

Besides product registration requirements, related topics such as laboratory tests and custom clearance requirements were examined as these are often closely related to product registration and affect the ability of new products to be launched successfully and to gain entry into the ASEAN market.

The survey consisted of 31 questions and companies were requested to provide individual responses for the ASEAN countries that are relevant to their businesses. The survey spanned a broad range of products, including non-dairy beverages, confectionary, dairy, specialty products, special dietary products, packaged food and snacks, canned and processed food and others.

A total of 26 companies participated in the survey and 98 unique survey responses were generated for the ten ASEAN countries. Based on the findings, a comparison study across ASEAN countries was carried out to identify opportunities and gaps in the current regulations, particularly on the procedural challenges. The survey outcomes were circulated and agreed amongst national industry associations in the region. By and large, this paper represents the collective voice of the food industry in the region.

Part 2

Product Registration Framework in ASEAN

Most countries require product registration to be carried out in order for food products to be sold in the country. Some regional examples that do not require product registration include:

MALAYSIA

- Product registration is not required for most of the food product categories.

SINGAPORE

- Product registration is not required.
- Food safety and regulatory controls are managed via:
 - Mandatory food importer licensing – Registered importers are allowed to engage in food importation businesses and are responsible for ensuring the compliance of imported food products with local food law and regulations.
 - Approval of source – Only high-risk food products from accredited source are permitted.
- Submission of supporting documents is required for high-risk food products such as eggs, poultry, meat and seafood.

VIETNAM

- A new decree enforced in February 2018 removed product registration for food products of lower risk and food additives already on the permitted list. This was replaced with a self-declaration process and post-market surveillance.
- Product registration is required for selected product categories, such as health supplements, medical food, food for special dietary uses, food for children up to 36 months, mixed food additives with new usages, food additives that are not on the list of permitted food additives, or food additives not intended for use for the food categories as prescribed by the Ministry of Health (MOH).



Part 2(i): Documents required for product registration

Table 1: Documents required for product registration in Brunei, Cambodia, Indonesia, Laos, Myanmar, Philippines and Thailand (processed food)

	Brunei	Cambodia	Indonesia	Laos	Myanmar ¹	Philippines	Thailand
Brand Certificate			✓*				
Certificate of Analysis/ Laboratory Test Report			✓	✓	✓	✓ ³	✓
Claims Substantiation			✓*			✓*	
Declaration on Additive and its Source	✓*		✓				
Declaration on Manufacturing Location	✓*						
Declaration on Production Code			✓				
Declaration on Shelf Life	✓*		✓				✓
Declaration on Source of Fats/ Oils/ Shortening	✓*						
Declaration on Standards Reference		✓					
Flow Chart			✓	✓			✓
Food Safety Certificate	✓		✓	✓	✓	✓	✓ ⁴
Formulation			✓	✓			✓
Free Sale Certificate/ Health Certificate [#]			✓	✓	✓	✓ ²	✓ ⁴
GMO-Free Certificate			✓*				
Halal Certificate			✓*				
Import Licence							✓
Importer Registration Number			✓				
Ingredient List		✓	✓	✓	✓		
Letter of Appointment			✓			✓	
Letter of Authorisation			✓*			✓	
Licence/ Certificate for Irradiated Food	✓*		✓*				
Licence for Artificial Sweetening Substance	✓*						
Manufacturing/ Business Licence	✓	✓	✓	✓		✓	✓
Product Label		✓	✓	✓	✓	✓	✓
Product Photo	✓		✓		✓	✓	
Product Sample		✓		✓	✓		
Proforma Invoice						✓	
SNI Certificate			✓*				
Specification (Raw Material, Packaging)			✓				✓
Specification (Product)			✓		✓	✓	✓

* Product-dependent
Free Sale Certificate and Health Certificate are issued by the exporting country
1 Import Recommendation Letter (Importers of food additives that are included in the General Standards for Food Additives issued by Codex Alimentarius Commission, low risk food products (1008 items) and sample to be submitted to FDA are not required to provide both Import Recommendation Letter and Import Health Certificate)
2 Attested by recognised regulatory body or chamber of commerce/ Philippines Consulate in the country of origin
3 For assessment of compliance for medium and high risk products with standards of identity, as well as fortified food products
4 Notarised and authenticated by issuing organisation, embassy or governmental office

Table 2: Documents required for product registration in Malaysia and Vietnam (selected product categories)

	Malaysia ¹	Vietnam ²
Certificate of Analysis		✓
Certificate of Origin	✓	
Declaration on Ingredients	✓	
Flow Chart	✓	
Food Safety Certificate	✓	✓
Free Sale Certificate/Health Certificate [#]	✓	✓
Halal Information	✓	
Import Licence	✓	
Material Safety Data Sheet	✓*	
Particulars of Establishment	✓	
Product Composition	✓	
Product Label	✓	✓
Scientific Evidence		✓
Specification (Product)	✓	

* Product-dependent
Free Sale Certificate and Health Certificate are issued by the exporting country
1 Pre-export approvals to be obtained from the Malaysian Department of Veterinary Services under the Ministry of Agriculture and Agro-based Industry (MOA) (Application for Export of Meat, Poultry, Milk, Egg and Products to Malaysia (DVS/VPH/APP/1)
2 Product declaration applies to health supplements, medical food, food for special dietary uses, food for children up to 36 months, mixed food additives with new usages, food additives that are not on the list of permitted food additives, or food additives not intended for use for the food categories as prescribed by the Ministry of Health (MOH)

Part 2(ii): Timeframe to obtain product registration approval (months), from the time of documents submission to eventual approval

Table 3: Timeframe to obtain product registration approval (months) based on the experience of industry members

Brunei	Cambodia	Indonesia	Laos	Malaysia	Myanmar	Philippines	Thailand	Vietnam
0.5-3	1-1.5	2-9	2	0.2-9	2-3	1-9	0.25-12	0.5-6

Note: Not applicable for Singapore

Part 2(iii): Issues encountered during product registration

TOP TWO ISSUES

- **Burdensome paperwork/ procedure**
 - Extensive document list required by food authorities (Part 2(i)).
 - Breakdown of product formulation is required in Indonesia and Thailand, which constitutes confidential proprietary information.
 - Selected documents are required to be notarised or legalised, for example, Free Sale Certificate in the Philippines and Food Safety Certificate in Thailand.
 - In Indonesia, the original document must be verified by an officer from the National Agency of Drug and Food Control (BPOM) before the document can be uploaded to the online registration portals.
- **Unavailability/ Rejection of Free Sale Certificate or Health Certificate**
 - Exporters unable to provide Free Sale Certificate or Health Certificate as exporting country does not have an official body that issues these documents.
 - Free Sale Certificate or Health Certificate is issued in a different document format which results in the rejection of document by importing country authorities.

OTHER ISSUES

- **Inefficient electronic systems**
 - While authorities are moving towards digital platforms to handle administrative procedures, companies often encounter difficulties in accessing the online registration portals.
- **Arbitrary interpretations and limited manpower**
 - Inconsistencies in the evaluation and approval process, where different officers have different interpretations on the requirements.
 - Limited resources within the food authorities slow down the process of approval.

Figure 1: Ease of obtaining documents experienced by industry members during product registration

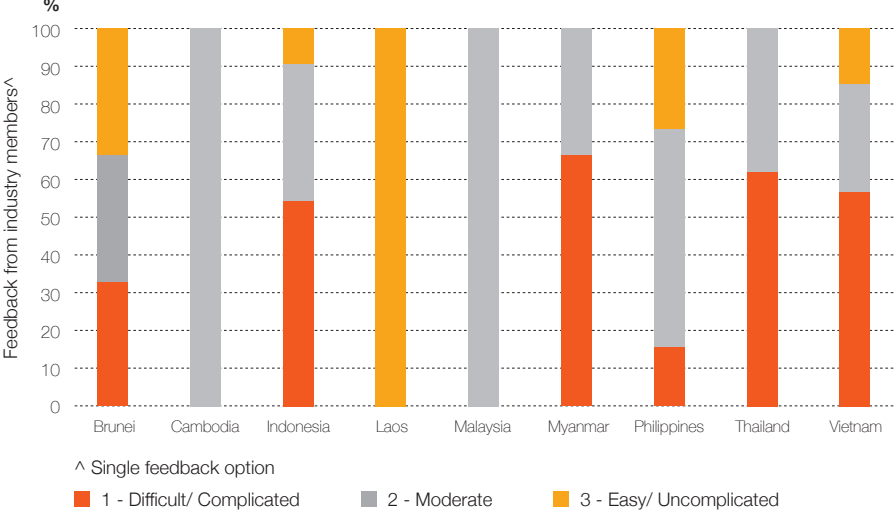


Figure 2: Documents submission methods used by industry members during product registration

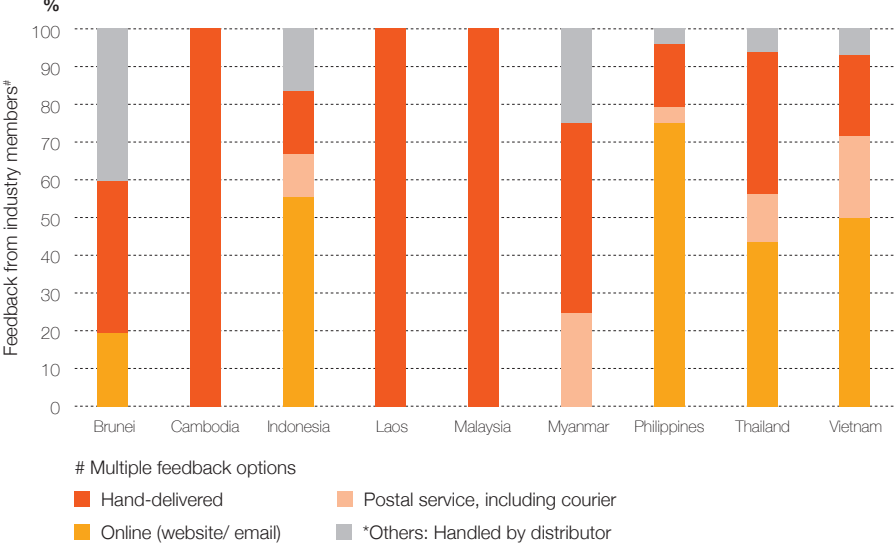
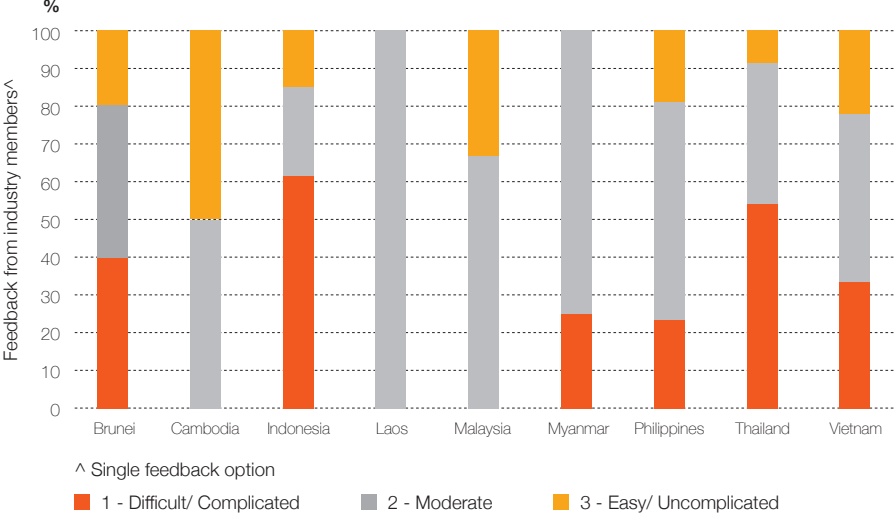


Figure 3: Ease of submitting documents experienced by industry members during product registration



Part 3

Product Laboratory Analysis

Product laboratory analysis is often required as part of the documents to be submitted for product registration and customs clearance to validate the safety and quality of food products through appropriate test parameters.

Part 3(i): Standards for laboratories and testing methods

Most ASEAN member states have national reference standards for laboratory tests. Codex standards are also recognised. In principle, test reports from accredited laboratories are accepted by authorities in ASEAN.

Table 4: Laboratories standards in ASEAN member states

Brunei	Cambodia	Indonesia	Laos	Malaysia	Myanmar	Philippines	Singapore	Thailand	Vietnam
Codex standards, national standards	Codex standards, national standards	Codex standards, USP, BP, national standards	Codex standards	Codex standards, national standards	Codex standards	Codex standards, USP, BP, national standards	Codex standards, national standards	Codex standards, USP, BP, national standards	Codex standards, USP, BP, national standards

Note: USP – United States Pharmacopeia, BP – British Pharmacopeia

Part 3(ii): Timeframe to obtain laboratory test results (weeks), from searching for the right laboratory to obtaining final test results for submission

Table 5: Timeframe to obtain laboratory test results (weeks) based on the experience of industry members

Brunei	Cambodia	Indonesia	Laos	Malaysia	Myanmar	Philippines	Singapore	Thailand	Vietnam
2-6	3-6	2-8	4-8	3-24	3-12	0.25-12	1-3	2-12	2-8



Part 3(iii): Issues encountered in meeting test requirements

TOP TWO ISSUES

- **Repetition of existing tests certifications**
 - Tests completed in overseas laboratories have to be repeated in local laboratories due to lack of recognition.
- **Request for additional test parameters**
 - Additional test parameters requested by authorities which are usually not required in other countries.

OTHER ISSUES

- **Differences in test methods**
 - Lack of alignment in test methods are used among laboratories, amidst other challenges listed in Figure 5.

Figure 4: Ease of fulfilling testing requirements experienced by industry members

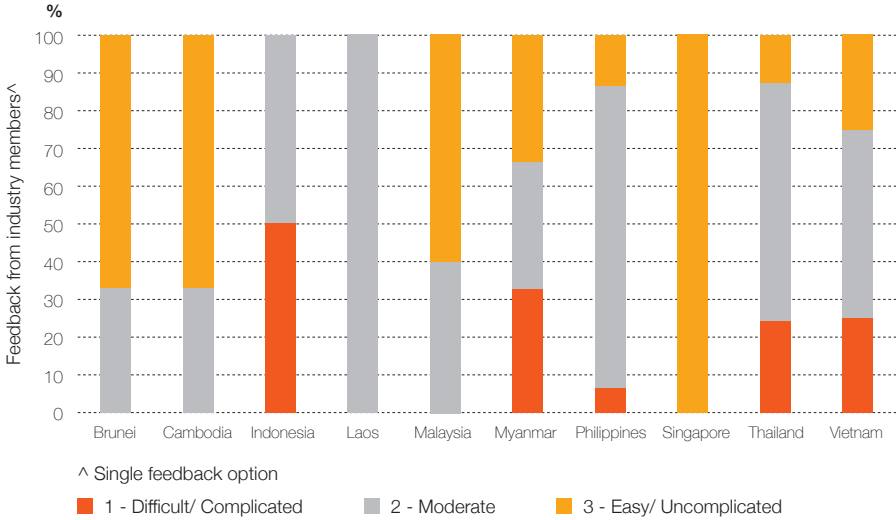
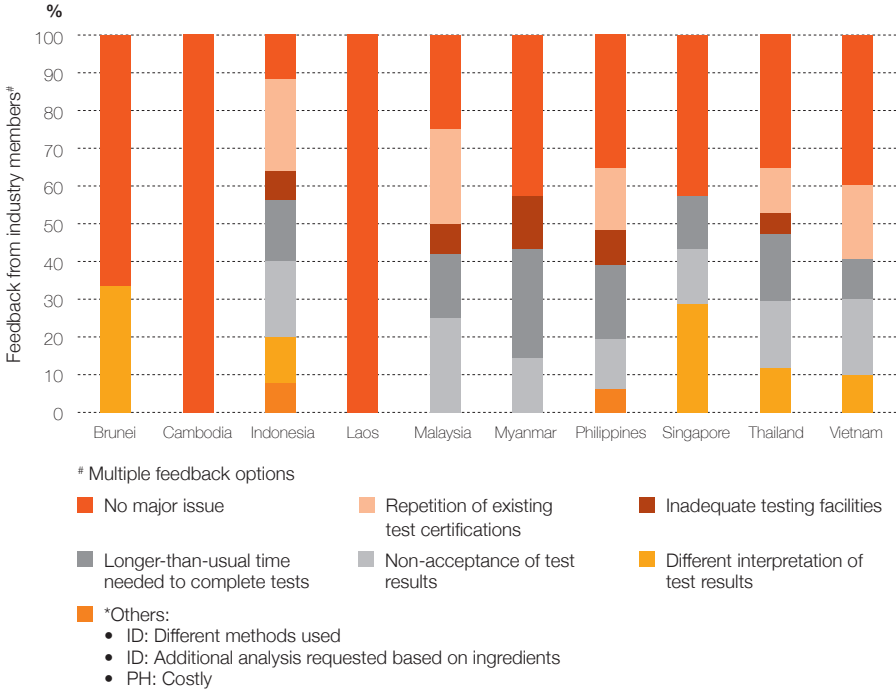


Figure 5: Issues encountered by industry members in meeting laboratory test requirements



Part 4

Customs Clearance

The importation of food products involves documentation and/or physical inspection at the border. The requirements for customs clearance vary across ASEAN countries.

Part 4(i): Documents required for food imports, for first and subsequent imports

There was no reported difference for the documents that are required for customs clearance in the first and subsequent imports.

Table 6: Documents required for food imports (processed food)

	Brunei	Cambodia	Indonesia	Laos	Malaysia	Myanmar	Philippines	Singapore	Thailand	Vietnam
Approval of Food Labelling									✓ ^{2*}	
Business Registration Certificate	✓									
Certificate of Analysis/ Laboratory Test Report		✓	✓			✓	✓		✓ ³	✓
Certificate of Statement of Product Standards										✓
Cargo Clearance Permit								✓		
Company Registration Certificate	✓			✓	✓	✓				
Customs Import Declaration	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Declaration of Dutiable Value					✓ ¹	✓				✓
Food Formula Registration									✓ ³	
Food Record/ Food Declaration									✓ ²	✓
Food Safety Certificate			✓				✓		✓ ³	✓
Free Sale Certificate / Health Certificate			✓	✓			✓		✓	✓
Import Licence/ Permit	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Importer Identification Card/ Number			✓						✓	
Importer Registration			✓		✓	✓	✓	✓		
Insurance Certificate					✓	✓		✓	✓	✓
Manufacturing/ Business Licence			✓				✓			
Product Registration Certificate/ Licence	✓		✓	✓			✓		✓	✓
Shipping Documents ⁺	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tax Payment Receipt			✓							
Traders and Agents Registration Certificate	✓									

+ Airway Bill, Bill of Lading, Certificate of Origin, Invoice, Packing List
* Product-dependent
1 Required for customs clearance of commercial imports with a value of 10,000 MYR or more
2 Standardised foodstuff, products with a standard label
3 Specially controlled foodstuff

Part 4(ii): Timeframe to complete customs procedures (weeks)

In general, there is no significant difference between the time taken to clear customs for the first import and subsequent imports for most countries, with the exception of Indonesia (1-8 weeks for first import, 1-4 weeks for subsequent imports) and Thailand (1-2 weeks for first import, 1 week for subsequent imports).

Table 7: Timeframe to complete customs procedures (weeks) for first import and subsequent imports based on the experience of industry members

	Brunei	Cambodia	Indonesia	Malaysia	Myanmar	Philippines	Singapore	Thailand	Vietnam
First Import	4	0.5-4	1-8	0.5-4	2	0.3-3	1	1-2	1-2.2
Subsequent Imports	4	0.5-4	1-4	0.5-4	2	0.3-3	1	1	1-2.2

Note: No data available for Laos

Part 4(iii): Issues encountered in clearing customs

TOP TWO ISSUES

- **Arbitrary processes and regulations**
 - Inconsistent administration of customs procedures that is subject to individual inspector and customs channel leads to unclear estimation of lead time for customs clearance.
 - Fragmentation in process flow due to involvement of different government agencies, such as customs, food authority, agriculture department.
- **Faulty or cumbersome electronic submission systems**
 - System downtime that causes delay in clearance process.

OTHER ISSUES

- **Overly rigorous customs inspection**
 - Clearance of goods held up due to slight discrepancy detected on documents, such as punctuations and minor details.
- **Complex customs requirements**
 - Unwieldy documents and information to be presented prior to or during customs inspection.

Figure 6: Ease of clearing customs for imports experienced by industry members

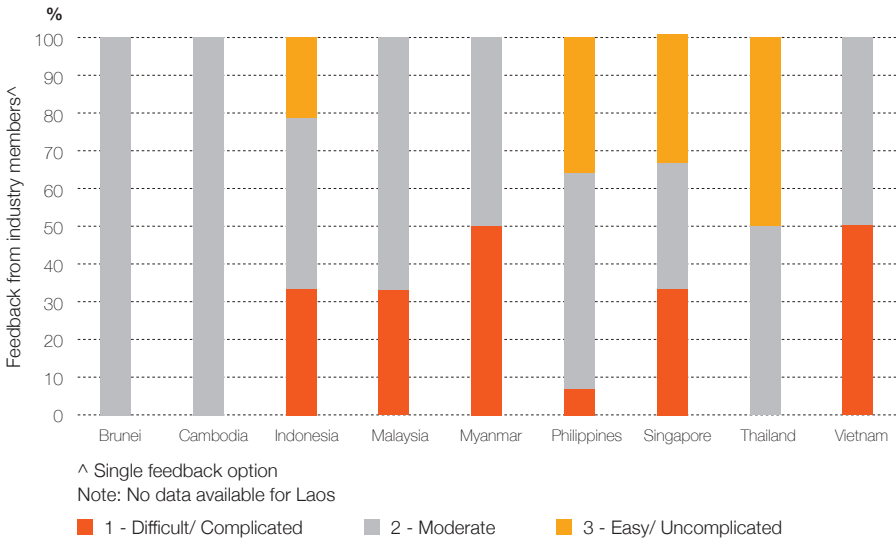
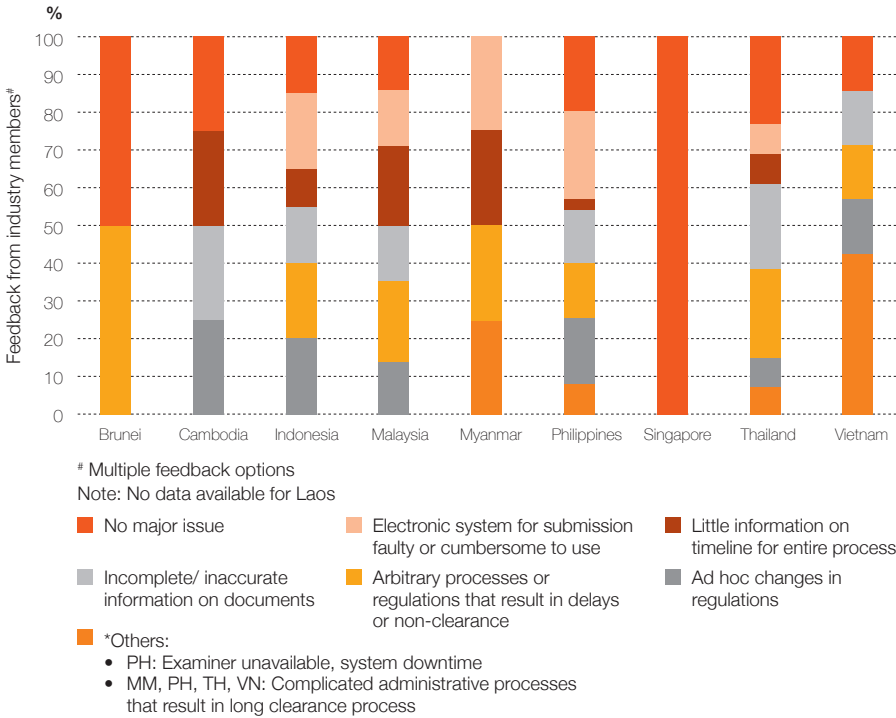


Figure 7: Issues encountered by industry members during customs clearance



Part 5

Availability of Information

The access to timely, updated information on the various processes required for the processes covered earlier in Parts 2 to 4 is the key to ensure easy market access of products across countries in ASEAN.

Part 5(i): Sources of information

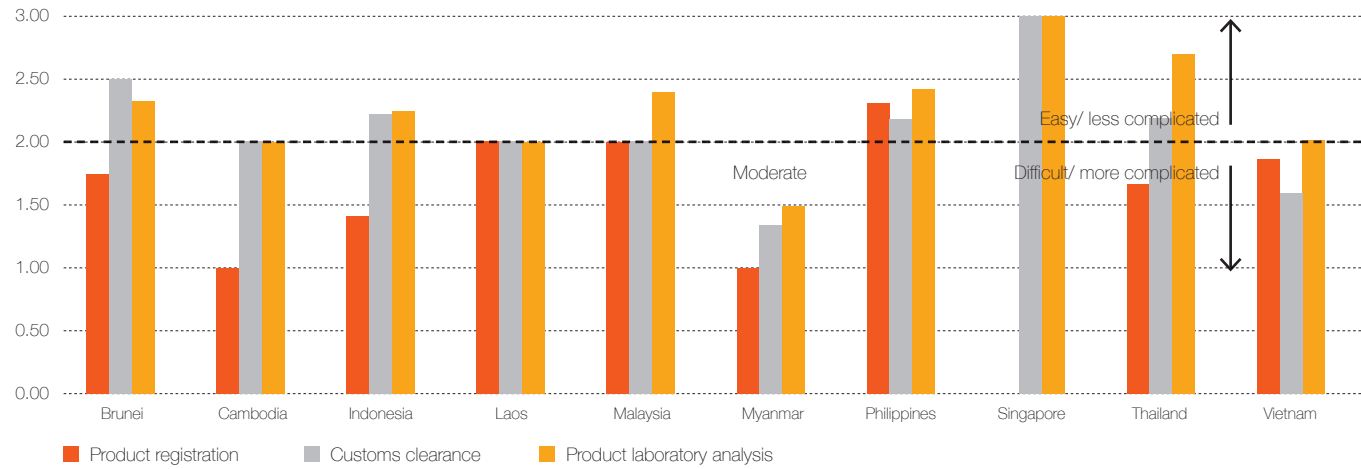
The characteristics and quality of information sources depend on the parameters of timeliness and accessibility.

The most open and readily available source would be websites, whereas face-to-face meetings with authorities and personal connections constitute the least open and most time-consuming source.

Figure 8: Information sources based on the dimensions of timeliness and accessibility (graphical representation only, not quantitative)



Figure 9: Overall ease of obtaining information based on weighted score (1 – Difficult/ Complicated; 2 – Moderate; 3 – Easy/ Uncomplicated)



Part 5(ii): Issues encountered in obtaining information for requirements on product registration, product laboratory analysis and customs clearance

ISSUES

- **English is not used as the official language**
 - In ASEAN, most of the companies rely on local teams, business partners or networks including trade associations to gather information on food product registration as well as manage the various processes of conducting laboratory tests and clearing customs.
- **Information is not made available to public and companies are not informed on changes in requirements**
 - The lack of clarity results in companies relying more on connections with government officers to enquire on specific information, making it more time consuming.
 - Face-to-face meetings and personal connections with authorities are common sources of information for several countries such as Indonesia, Malaysia, the Philippines and Thailand.



Part 6

Conclusion and Recommendations

A tight food safety and regulatory control framework is necessary to safeguard the food products traded domestically or between borders. However, this could come at the expense of trade potential if companies are faced with burdensome registration requirements that are beyond their capabilities to cope or comply.

To facilitate fair practices in food trade and remove technical barriers to trade without compromising the safety of consumers, industry members put forward the following recommendations for the consideration by country authorities in the region.

Part 6(i): Long-term recommendations

- **Adoption of a risk-based approach in the framework of product registration**
 - Authorities could differentiate risk categories and identify definitions for each category. The reference from Table 8 is taken from the Food and Agriculture Organization of the United Nations (FAO) publication *Guidelines For Risk Categorisation of Food and Food Establishment Applicable to ASEAN Countries*¹. Based on the reference, the possibility of pathogenic microorganisms' growth in food in transit is set as the basis for the development of risk categories.
 - Authorities could carry out food safety assessment measures based on the risk categories (Table 9).
 - Food safety and regulatory controls in Malaysia, Singapore and recently, Vietnam, place emphasis on industry's food safety practices through post-marketing surveillance. Such control measures reduce the burden on companies in meeting registration requirements and help improve products' speed to market. The shift in emphasis towards post-marketing surveillance and checks, on the basis of the degree of risk, are measures to safeguard food safety and quality of products that are distributed in ASEAN. This could serve as a reference for other ASEAN countries.



Table 8: Definition of high-, medium- and low-risk food

Risk level	Definition
High	Food that may contain pathogenic microorganisms that support the formation of toxins or the growth of pathogenic microorganisms and food that may contain harmful chemicals. Raw meat, fish, oysters, poultry and milk are examples of high-risk food. Other examples include tofu, meat pies and salami. These food pose a particularly high risk if they are not processed or cooked adequately.
Medium	Food that may contain pathogenic microorganisms but will not normally support their growth because of food characteristics; or food that are unlikely to contain pathogenic microorganisms because of food type or processing, but may support the formation of toxins or the growth of pathogenic microorganisms. Examples are some fruits and vegetables, juices, canned meats, pasteurised milk, dairy products, ice cream, peanut butter, cooked rice and lasagne and milk-based confectionery.
Low	Food that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics and food that are unlikely to contain harmful chemicals. Examples are grains and cereals, bread, carbonated beverages, sugar-based confectionery, alcohol and fats and oils.

Table 9: Suggested assessment approach based on risk level of food

Risk level	Assessment approach
High	<ul style="list-style-type: none">• Products are subjected to full safety/ quality evaluation and approval by food authorities.
Medium	<ul style="list-style-type: none">• Products are not subjected to evaluation and approval by food authorities.• Companies are responsible for ensuring that products comply with regulatory requirements.• Food authorities could implement a notification/ listing process to ensure traceability of the food products in the market.
Low	<ul style="list-style-type: none">• Products are not subjected to evaluation and approval by food authorities.• Companies are responsible for ensuring that products comply with regulatory requirements.• Food authorities may consider a notification/listing process to ensure traceability of the food products in the market.

1 <http://www.fao.org/docrep/015/i2448e/i2448e00.pdf>

Part 6(ii): Short-term recommendations

The removal or simplification of production registration process is set out as the long-term goal. In the shorter term, industry members propose the following recommendations to address specific challenges faced by companies.

Table 10: Specific challenges related to product registration, product laboratory analysis, customs clearance, availability of information and the recommendations

	Challenges	Recommendations
Product registration	Difficulty in obtaining Free Sale Certificate and Health Certificate as not all exporting countries issue these documents and there may be variation in document format.	<ul style="list-style-type: none">Acceptance of food safety certificates, such as Hazard Analysis and Critical Control Points (HACCP), Good Manufacturing Practices (GMP) and International Organization for Standardization (ISO) certifications to demonstrate the safety of imported food products and serve the purpose of Free Sale Certificate and Health Certificate.Flexibility in the acceptance of certifications that are presented in different formats, given that the documents are valid and recognised by the competent authorities in the exporting countries.
	Request for proprietary product information such as product formulation.	<ul style="list-style-type: none">Flexibility in the request for product-related information without requiring the disclosure of confidential information.
	Slow internet speed and limited server capacities, the need for submission of original documents and in some cases, authenticated documents.	<ul style="list-style-type: none">Further work to enhance the current network capacities to increase efficiency of online proceduresGreater recognition of electronic documentation as equivalent to the original documents, including the acceptance of e-signatures.

	Challenges	Recommendations
Product laboratory analysis	Repetition of laboratory analysis in local laboratories due to the lack of acceptance of test reports issued by other countries.	<ul style="list-style-type: none">Country-to-country acceptance of test reports through the adherence to internationally recognised standards and aligned laboratory practices among countries, including testing methods.
	Inconsistent test parameters requested by country authorities in the assessment of product safety.	<ul style="list-style-type: none">A risk-based approach to identify relevant test parameters to validate the safety of food products and avoid unnecessary tests.
Customs clearance	Uncertainties in inspection at the border due to inconsistent customs clearance procedures, complex documentation requests, and conflicting administrative requirements.	<ul style="list-style-type: none">Streamline involvement of different government agencies to avoid overlapping requirements, and, at the same time, ensure consistent interpretation of import requirements.Enhance technical competencies of customs officers to ensure consistent inspection procedures are carried out at the border.
	Inefficient trade-related information technology infrastructure	<ul style="list-style-type: none">Capitalise on ASEAN Single Window (ASW) to integrate intra-ASEAN trade data and streamline coordinating efforts to simplify customs processes.
Availability of information	Fragmentation and lapses on key information that is related to import and/or export requirements.	<ul style="list-style-type: none">Make available relevant information and regulations with English translation on trade portals or websites of national authorities.
	Updated regulations and information not readily available	<ul style="list-style-type: none">Capitalise on online information repositories, such as the ASEAN Food Safety Network, to disseminate updated regulations.Develop communication channels to keep companies abreast of changes or new regulations put in place.Improve information technology platforms such as websites and portals for registered users to check on approval status and submit enquiries.



About ASEAN Food and Beverage Alliance

Who We Are

The ASEAN Food and Beverage Alliance (AFBA) is a group of national associations in South East Asia involved in the manufacturing, distribution and sale of food and beverage products. We are a dedicated non-profit body committed to effectively representing the food industry within the Association of South East Asian Nations (ASEAN).

Vision & Mission

AFBA seeks to support harmonisation efforts across South East Asia and to provide a voice for the ASEAN food industry at the policy table. We aim to coordinate industry efforts to deliver effective input and practical guidance on ASEAN policies, which in turn will unlock the growth potential for intra-and extra-regional trade of food products.

Our Promise

AFBA will help to facilitate intra- and extra-regional trade in ASEAN by supporting and accelerating the ASEAN harmonisation process for the benefit of small, medium and large enterprises, and their consumers in the ASEAN markets.





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