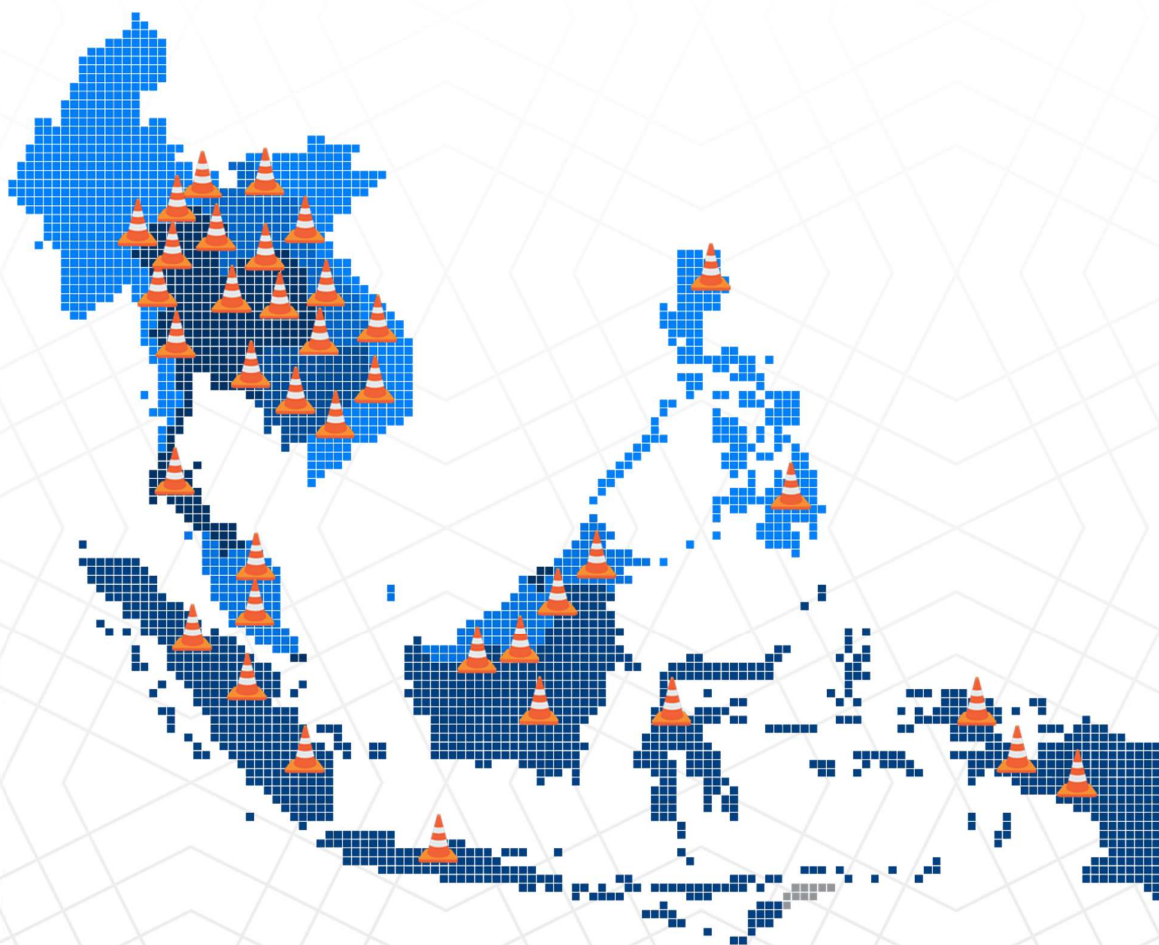


Non-Tariff Barriers (NTBs) in ASEAN and their elimination from a business perspective



Enhanced Regional EU-ASEAN Dialogue Instrument

E-READI

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Disclaimer

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Mission of the European Union to ASEAN

Menara Astra, 38th Floor
Jl. Jend Sudirman Kav 5-6
Jakarta 10220, Indonesia
+62 (21) 2554 6200
mission-asean@eeas.europa.eu
MISSION-ASEAN-EREADI-CONCEPTS@eeas.europa.eu



ASEAN Secretariat

70A Jl. Sisingamangaraja
Jakarta 12110, Indonesia
+62 (21) 726 2991
ereadi@asean.org

This study is prepared by the Asian Trade Center (ATC), a premier regional thought leader, advocate and educator for trade in Asia.



ASIAN TRADE CENTRE

Asian Trade Center

41A Ann Siang Road
Singapore, 069717
+65 6536 3415
info@asiantradecentre.org

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Executive Summary

As ASEAN continues to make progress toward the goals of the Blueprint 2025, the dream of creating a highly integrated and cohesive economy with enhanced connectivity and sectoral cooperation is potentially at risk.

One important source of risk comes from ASEAN's difficulties in effectively tackling the proliferation of barriers to trade. As tariffs have fallen, member states have responded by placing an increasing number of new obstacles in place. Not all trade actions taken by ASEAN Member States are an automatic trade barrier. States have legitimate policy objectives to achieve in protecting public health and safety, for example. But it is possible for such actions to cross over and become barriers to trade or for governments to design measures from the beginning to obstruct foreign firms from participating fully in domestic marketplaces.

In spite of repeated commitments to eliminate such barriers to trade, ASEAN has struggled to identify non-tariff measures (NTMs) and non-tariff barriers (NTBs), much less assess the impact of these challenges, nor to stop the continued rise in obstacles of all sorts across the region. Failure to effectively address the increase of unjustified, difficult and costly trade issues undermines the progress towards the ASEAN Economic Community's Blueprint goals and objectives.

This report is designed to assist ASEAN members in achieving deeper integration in the region. It examines barriers to trade in three sectors: automotive, agri-food (alcoholic drinks, biscuits and seafood) and healthcare (pharmaceuticals and medical devices). The study complements existing NTM and NTB literature by identifying and assessing specific barriers to trade faced by businesses trading today across the ASEAN region. The results give policymakers a better understanding of the range of company concerns and helps officials devise and implement appropriate strategies to assess and reduce NTBs.

Automotive Sector

Under the AEC and the emergence of tariff-free trade, ASEAN's automotive industry is poised to experience stronger economies of scale and further growth. However, the automotive industry is still affected by a broad suite of challenges that prevent the development of a truly integrated automotive industry. Interviews with firms across the sector revealed challenges in the automotive market due to controls in the form of quotas and licensing, complex conformity assessment procedures, unique national standards, high taxation regimes, and discriminatory policies favouring local manufacturers.

Agri-Food

The Agri-Food sector is essential for the ASEAN economy as a driver of food security and a source of export earnings. However, agri-food companies face many regulatory and technical constraints. This study examined three areas (alcohol, seafood and biscuits) that operate in heavily to more lightly regulated environments.

A rising middle class and recent growth in alcoholic sales and consumption across ASEAN provide significant opportunities for alcoholic drinks manufacturers selling their

products across the region. However, the study's assessment shows that those opportunities continue to be undermined by high levels of taxation, often associated with counterfeit trade, complex licensing procedures, increasingly burdensome labelling requirements, and marketing restrictions.

Rising income levels across the world provide both the boon of higher seafood demand as well as the challenge for greater food safety standards. While firms interviewed in the project did not highlight many major obstacles to trade, seafood exporters still face inconsistencies during customs procedures, and strict conformity assessment and product registration procedures.

The ASEAN biscuits sector is rapidly expanding as consumption around the world increases. Even in an area of relatively lighter regulation, biscuit makers still struggle with inconsistencies in customs clearance, complicated product registration processes and national halal certification standards.

Healthcare Products

Fueled by an expanding middle class, a rise in personal income and a surge in private insurance coverage, ASEAN's healthcare sector is instrumental in meeting the needs of growing middle income and often ageing populations. According to interviews, ASEAN's pharmaceuticals sector — one of the fastest growing in the world — is affected by an underdeveloped IP regime, inconsistent, discriminatory and opaque government procurement processes, and limited access to the public pharmaceuticals market. ASEAN's relatively new medical devices sector faces fewer obstacles, such as new product registration requirements, a lack of access and transparency in public procurement procedures, and issues around halal laws, particularly when some devices cannot meet halal requirements (because they deal with blood products, for instance).

ASEAN-Level Recommendations

ASEAN has made repeated commitments over the past decade to tackle the rising tide of non-tariff obstacles to trade. Starting well before the ASEAN Trade in Goods Agreement (ATIGA) came into force in 2008, ASEAN Member States recognized the harm that could be done by allowing non-tariff measures to be used as disguised barriers to cross-border trade. The most recent formal attempt to tackle the problem, the NTM Guidelines, came out in August 2018.

Despite years of effort, the firms interviewed in this report continue to note a wide and increasing array of challenges in the three sectors under examination. This suggests that ASEAN's past efforts to tackle NTMs and NTBs have not been successful. There are two broad reasons for this disconnect between repeated pledges and failure to deliver results on the ground: 1) the commitments have not always addressed the right target and 2) timely and effective implementation has hamstrung efforts to tackle existing commitments.

As an illustration, ASEAN has focused much effort on addressing obstacles to trade related to standards. While these clearly matter and should continue to stay in the mix of policies reviewed by ASEAN officials, the firm-level interviews show that companies face challenges that go beyond just problems with inconsistent product standards. Even the best, most effectively implemented Mutual Recognition Agreement (MRA) cannot address topics that are not included in the remit of an MRA.

This report therefore provides a range of recommendations to improve the scope of ASEAN's work on NTMs and NTBs and significantly strengthen the institutional capacity of the organization to address the former and eliminate the latter. The final section of the report provides additional details, but in brief, these recommendations include the following:

1: Create improved systems to effectively identify and collect information on both NTMs and NTBs

- 1.1: Promote transparency in NTMs through an open database system
- 1.2: Quickly follow and implement ASEAN's 2018 NTM Guidelines
- 1.3: Allow for ASEAN member state response to NTMs
- 1.4: Streamline NTMs
- 1.5: Ensure appropriate and effective mechanisms to allow firms to notify ASEAN about probable NTBs

2: Effectively manage identified NTMs and reduce NTBs

- 2.1: Ensure that ASEAN has appropriate institutional body in place to address NTM and NTB issues
- 2.2: Craft targeted, time-bound NTB reduction commitments
- 2.3: Set principles for regulatory reform based on international best practices

3: Develop clear procedures and institutional frameworks for tracking the elimination of NTBs

- 3.1: Ensure that the review body has the capacity to track the elimination of NTBs
- 3.2: Ensure that the review body has the mandate and resources to develop work plans and support the elimination of identified NTBs

4: Continue to ensure the harmonization of standards and build capacity of ASEAN Member States and firms to meet those standards

- 4.1: Continue to effectively implement programs using international standards; MRAs especially for conformity assessment; and accreditation of testing facilities
- 4.2: Include appropriate follow-up mechanisms to ensure compliance
- 4.3: Ensure process in place to engage and hold accountable non-compliant members

5: Strengthen work with the private sector to identify, eliminate and conduct compliance reviews of NTBs across the region

- 5.1: Invite the private sector to participate in ASEAN working committees
- 5.2: Work with the private sector to identify areas of most significant cost to help prioritize efforts

Note that these recommendations need not be followed sequentially. In other words, it is not necessary to have identified every single NTM or NTB before taking steps to remove unnecessary NTMs or eliminate NTBs. Instead, ASEAN must proceed in

parallel — identifying existing arrangements, limiting new obstacles, while working to streamline and remove barriers that impede trade.

Absent a much clearer, more sustained and tighter focus on reducing the number and scope of existing NTMs and eliminating NTBs, ASEAN will not accomplish the objectives of the AEC and it will fail to meet the targets contained in the Blueprint 2025. Growth will not be as high as ASEAN Member States could have achieved and much of the promise embedded in the ASEAN exercise will have been lost.

List of Acronyms

Abbreviations	Description
ABAC	ASEAN Business Advisory Council
ACCSQ	ASEAN Consultative Committee on Standards and Quality
ACE	Agency for Care Effectiveness
ACTD	ASEAN Common Technical Dossiers
ACTR	ASEAN Common Technical Requirements
AEC	ASEAN Economic Community
AFSRF	ASEAN Food Safety Regulatory Framework
AFTA	ASEAN Free Trade Area
ALADI	Asociación Latinoamericana de Integración or Latin American Association Integration
AMDD	ASEAN Medical Device Directive
APWG	Automotive Product Working Group
ARF	Additional Registration Fee
ARTNeT	Asia-Pacific Research and Training Network on Trade
ASEAN	Association of Southeast Asian Nations
ASSIST	ASEAN Solutions for Investments, Services and Trade
ATF-JCC	ASEAN Trade Facilitation Joint Consultative Committee
ATIGA	ASEAN Trade in Goods Agreement
ATR	ASEAN Trade Repository
AVA	Agri-Food and Veterinary Authority of Singapore
BE	Bio-Equivalence
BFAR	Bureau of Fisheries and Aquatic Resources
BMI	Business Monitor International
BPJS	Social Insurance Administration Organization
CAGR	Compound Annual Growth Rate
CBU	Complete Built-Up
CCA	Coordinating Committee on the Implementation of ATIGA
CLM	Cambodia, Laos and Myanmar
CLMV	Cambodia, Laos, Myanmar and Vietnam
CMBS	Civil Servant Medical Benefit Scheme
COA	Certificate of Analysis
COE	Certificate of Entitlement

COMESA	Common Market for Eastern and Southern Africa
COO	Country of Origin
CSDT	Common Submission Dossier Template
CTPM	Contingent Trade Protective Measures
DOH	Department of Health
EAC	East African Community
ECE	Economic Commission for Europe
EPP	Entry Point Projects
ERIA	Economic Research Institute for ASEAN and East Asia
EXP	Export Related Measures
EU-ABC	EU ASEAN Business Council
FDA	Food and Drug Administration
FIA	Food Industry Asia
FTA	Free Trade Agreement
GAD	Department of General Administration
GDP	Gross Domestic Product
GI	Geographical Indication
GMP	Good Manufacturing Practice
GRIPS	National Graduate Institute for Policy Studies
GRP	Good Regulatory Practice
HEV	Hybrid Electric Vehicle
HS	Harmonized System (of tariff codes)
HTA	Health Technology Assessment
IDR	Indonesian Rupiah
INS	Indonesian National Standard
INSP	Pre-Shipment Inspection
IP	Intellectual Property
ISEAS	Institute of South East Asian Studies
ITC	International Trade Centre
ITWG	Interim Working Group for the Common Effective Preferential Tariff
JKN	Jaminan Kesehatan Nasional
KIEP	Korea Institute for International Economic Policy
Lao PDR	Lao People's Democratic Republic
LCGC	Low Cost Green Car

LKPP	Lembaga Kebijakan Pengadaan Barang Jasa Pemerintah or National Public Procurement Agency
LPA	Litres of Pure Alcohol
MAST	Malaysia's National Medicines Policy
MD	Medical Device
MFN	Most Favored Nation
MIC	Myanmar Investment Commission
MNC	Multinational Corporation
MNMP	Malaysia's National Medicine Policy
MOC	Ministry of Commerce
MPV	Multi-Purpose Van
MRA	Mutual Recognition Agreement
MYR	Malaysian Ringgit
NAIA	Ninoy Aquino International Airport
NCE	New Chemical Entities
NEML	National Essential Medicines List
NKEA	National Key Economic Areas
NTB	Non-Tariff Barrier
NTM	Non-Tariff Measure
NTR	National Trade Repository
OIE	Office International Des Epizooties
OMV	Open Market Value
OTH	Other Control Measures
PC	Price Control Measures
PFPWG	Prepared Foodstuff Product Working Group
PHEV	Plug-in Hybrid Electric Vehicle
PHP	Philippine Peso
PHO	Partially Hydrogenated Oils
PhRMA	Pharmaceutical Research and Manufacturers of America
PMK	Peraturan Menteri Keuangan or Minister of Finance Regulation
PO	Procedural Obstacles
PPWG	Product Working Group on Pharmaceutical
PTE	Patent Term Extension
QC	Quality Control Measures
SADC	Southern African Development Community

Satra	Saigon Trading Group
SKD	Semi Knocked Down
SKU	Stock Number or Stock Keeping Unit
SOE	State Owned Enterprise
SPS	Sanitary and Phytosanitary
TIRI	Thailand Industrial Standard Institute
TBT	Technical Barriers to Trade
THB	Thai Baht
TRAINS	UNCTAD's Global Database on Non-Tariff Measures
UNCTAD	United Nations Conference on Trade and Development
UNECE	United Nations Economic Commission for Europe
US/USA	United States of America
USD	United States Dollar
USDA	United States Department of Agriculture
VIN	Vehicle Identification Number
VQS	Vehicle Quota System
WHO	World Health Organization
WTO	World Trade Organization
X.O.	Extra Old

Introduction

For the ten members states of the Association of Southeast Asian Nations (ASEAN), tariff rates have fallen on the pathway to the ASEAN Economic Community (AEC). However, this significant advance has been matched in some markets and sectors by an increase in non-tariff barriers (NTBs) that impede the free flow of goods across the region. Given the importance attached to this objective in the AEC Blueprint 2025 and the relatively limited time remaining before the deadline, the e-READI project and the Asian Trade Centre propose to assist ASEAN members in addressing this critical obstacle to deeper integration in the region.

ASEAN Member States have promised to effectively address NTBs for a long time. As this study indicates, years of repeated actions have had limited results — firms are continuing to report significant challenges to doing business in the region. This year marks the 10th anniversary of the ASEAN Trade in Goods Agreement (ATIGA), which originally included provisions on reducing and eliminating non-tariff obstacles to trade. The promise to do so was picked up and included again in the 2015 ASEAN Economic Community (AEC). It has now been added once more to the 2025 Blueprint — with results this time to be achieved in five years.

Despite repeated commitments, ASEAN has so far not accomplished a key goal in reducing — much less eliminating — non-tariff obstacles to trade.

As the ASEAN Business Advisory Council (ABAC) and the EU ASEAN Business Council (EUABC) have noted, the proliferation of NTBs risks undermining progress and slowing economic growth. Effectively tackling the problem first requires a clear understanding of the extent of the challenge.

Not every trade measure taken by ASEAN Member States automatically constitutes a trade barrier. States have legitimate policy objectives to achieve in protecting public health and safety, for example. But it is possible for such actions to cross over and become barriers to trade or for governments to design measures from the beginning to obstruct trade from foreign firms.

Effectively identifying non-tariff barriers to trade should involve a collective effort bringing together the knowledge of companies operating in specific sectors with trade policy experts and government officials. This combined approach should be better able to sort out non-tariff measures (NTMs) from non-tariff barriers (NTBs) and begin to develop a policy plan to eliminate the latter. ASEAN's internal mechanisms for identifying and addressing NTBs have been rudimentary and are meant to improve under the ASEAN Economic Blueprint.

This report, "Assessment of ASEAN NTBs and Benefits of Elimination," will begin by examining barriers to trade in automotive, agri-food, and health (pharmaceuticals and medical devices) sectors. These industries have been identified as key priority sectors for ASEAN for some time.

There have already been multiple survey instruments and investigations prepared on NTBs within ASEAN by organisations such as the EU-ASEAN Business Council (EU-ABC), the Economic Research Institute for ASEAN and East Asia (ERIA), the Institute

of South East Asian Studies (ISEAS), the International Trade Centre (ITC) and the Asia-Pacific Research and Training Network on Trade (ARTNeT).

This report complements this existing literature by using firm-level interviews to identify specific obstacles to trade in ASEAN. It uses insights collected from the ground to guide the development of practical, ASEAN-level recommendations that take into account best practices identified within the literature as well as ASEAN's own past commitments and institutional framework.

Previous efforts to resolve the problem of NTBs at the ASEAN level have not been effective. Firms continue to report significant challenges to doing business across the region, even in priority sectors. Absent new approaches to tackling NTBs, it is unlikely that ASEAN's Blueprint 2025 efforts will be any more successful than past attempts. Trade in goods will continue to be stuck at significantly lower levels than should be the case for a dynamic and integrated region, with fewer jobs and economic growth for member states.

Study Outline

This report begins with a review of the existing literature on non-tariff measures and non-tariff barriers and the application within ASEAN. It then looks in greater detail at three specific sectors of interest: automotive, agri-food and healthcare.

These three sectors were chosen because they represent areas of significant importance to ASEAN in terms of employment, trade flows, future growth opportunities, and prospects for collaboration with ASEAN's key dialogue partners. In addition, these three sectors provide interesting variations in the types of non-tariff obstacles faced by firms doing business across ASEAN.

Since all three sectors represent significant slices of the economy, the report drills down further in agri-food and healthcare. It divides agri-food into three distinct products: alcoholic beverages, seafood and biscuits. These were assumed to provide variation in the levels of regulatory barriers faced by firms from the most restrictive in alcohol to the least restrictive in biscuits. Healthcare was divided into pharmaceutical products and medical devices.

Interview data by firms was collected and grouped together into types of obstacles, such as labelling or certification procedures. These specific challenges were given a "rating" of red, yellow or green depending on how onerous firms found these obstacles to navigate. As might be expected, firms rarely reported on "green" issues.

Finally, the report concludes with recommendations for tackling the types of barriers identified by firms in the region at the ASEAN level. The project did not explore how individual ASEAN Member States might more effectively tackle specific measures noted by companies, as the objective of the study is to identify mechanisms at the ASEAN level to address such barriers in the future. Without a clear understanding of the types of obstacles that firms report within individual member states, however, it is not possible to create an effective mechanism for tackling such challenges at the regional level. Hence this project looked into individual member state barriers for the purpose of developing ASEAN-wide solutions, rather than to tackle domestic-level issues. Future work may want to explore and examine these topics in greater detail.

Understanding Non-Tariff Measures (NTMs)

Under the global trading regime administered through the World Trade Organization (WTO), states are allowed to take steps to protect local markets in certain defined situations. The clearest examples can typically be found in circumstances where governments can take measures to protect human or animal, plant life or health. No one could reasonably expect governments to accept known lethal products, like infant toys that present an obvious choking hazard, toasters that explode when plugged into the wall sockets, or agricultural items laced with pesticides at levels that kill people.

The difficulty is that such stark examples of patently unsafe items are increasingly hard to find. Instead, governments can be rather creative in defining what constitutes an acceptable “measure” for legitimate reasons and what crosses a line into simple protectionism.

In the past, tariffs served a useful purpose in keeping out unwanted foreign products. As tariffs have fallen, some governments have responded by twisting the definitions of allowable measures to include a wide range of items that push the boundaries of acceptability.

According to the United Nations Conference on Trade and Development (UNCTAD), Non-Tariff Measures (NTMs) can be defined as “policy measures, other than ordinary customs tariffs, that can potentially have an economic effect on international trade in goods, changing quantities traded, or prices, or both.”¹ NTMs include a wide and diverse array of policies that countries apply to imported and exported goods; they can be applied behind-the-border (e.g. distribution restrictions and subsidies), at-the-border (e.g. quotas or prohibitions), and at the border of origin (e.g. pre-shipment inspections).² NTMs can be used as instruments of commercial policy — subsidies and trade defense measures — or for other non-trade policy objectives — like public health, food safety, and environmental protection.³

Given the broad definition of NTMs and the need for comparable, up-to-date data, the international community has launched a major effort to gather and make available data on NTMs across countries.

For consistency, this paper makes extensive use of the ERIA-UNCTAD ASEAN NTM Database, which is part of the Global Database on Non-Tariff Measures (TRAINS) TRAINS, a joint global effort by the African Development Bank, ALADI, ERIA, GRIPS, ITC, KIEP, Tripartite (EAC, COMESA, SADC), UNECE, World Bank, and WTO, coordinated by UNCTAD, to collect NTM data mostly in cooperation with governments.⁴ Thus, UNCTAD is the organization that has developed and maintained the current world standard for NTM classification and collection.

¹ UNCTAD. “Non-Tariff Measures: Evidence from Selected Developing Countries and Future Research Agenda.” United Nations, 2010.

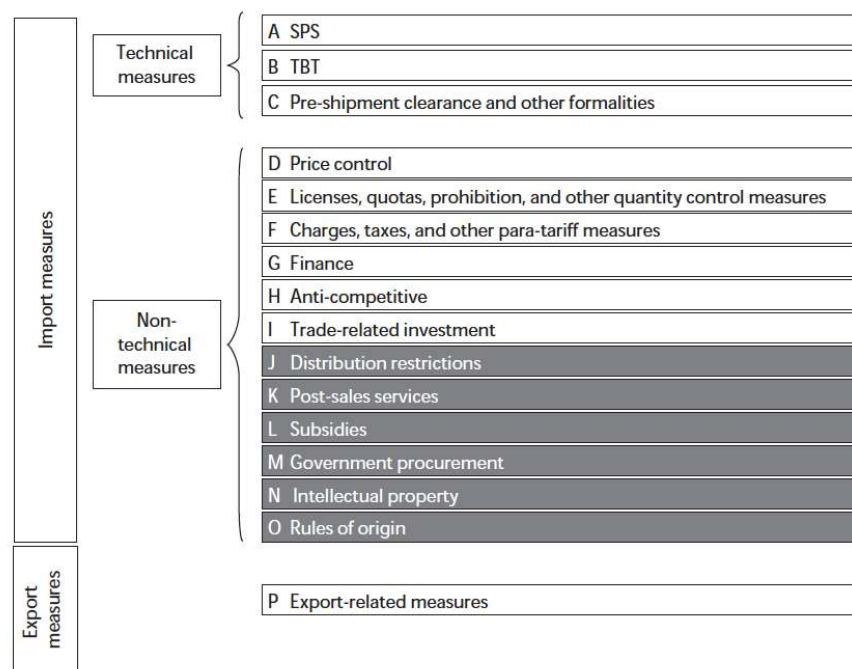
² UNCTAD. “Non-Tariff Measures: Evidence from Selected Developing Countries and Future Research Agenda.” United Nations, 2010

³ Ing, Lili Yan., de Cordoba, Santiago., Cadot, Oliver “Non-Tariff Measures in ASEAN.” Economic Research Institute for ASEAN and East Asia and United Nations Conference on Trade and Development, Feb. 2017.

⁴ UNCTAD. “UNCTAD TRAINS: The Global Database on Non-Tariff Measures User Guide (2017, Version 2).” United Nations, 2018, https://unctad.org/en/PublicationsLibrary/ditctab2017d3_en.pdf. The TRAINS database includes the WTO’s own NTM database, the I-TIP Goods: Integrated analysis and retrieval of notified non-tariff measures. This database includes e-ping notifications. This means that any measures included in the I-TIP goods are also included in

UNCTAD established the Multi-Agency Support Team (MAST) to lead NTM data collection and NTM classification efforts.⁵ The latest MAST classification, adopted in 2010, follows a hierarchical “tree” structure where NTMs are differentiated according to 16 branches, or chapters, denoted alphabetically, with three levels of sub-branches designated by one, two, and three-digit codes (as shown in Figure 1).

Figure 1. UNCTAD Classification of NTMs



To provide a more comprehensive picture of the problems companies face, research initiatives like the International Trade Centre’s NTM survey also include procedural obstacles, defined as practical challenges directly related to implementing NTMs.⁶ These may refer to delays, institutional costs, excessive paperwork and a lack of testing facilities, which may hamper companies from complying with NTMs.

NTMs can increase a business: (i) enforcement costs — cost incurred to show compliance with NTMs — (ii) sourcing costs — the cost incurred when switching from low-grade intermediate to high-grade sources to meet NTM standards — and (iii) process-adaptation costs — changes in capital equipment needed to meet NTM standards.⁷ These increased costs can make products less competitive in the destination market and penalize producers in the exporting country and businesses and final consumers in the importing country. Therefore, the presence of NTMs in supply or value chains can be disruptive.

both the TRAINS database and the UNCTAD-ERIA ASEAN NTM database. In other words, NTMs reported to the I-TIP should be on the UNCTAD-ERIA ASEAN NTM database.

⁵ UNCTAD. "International Classification of Non-Tariff Measures." United Nations Publications, 2012.

⁶ International Trade Centre (ITC). "The Invisible Barriers to Trade – How Businesses Experience Non-Tariff Measures", International Trade Centre, 2015.

⁷ Cadot, Olivier, Mariem Malouche, and Sebastián Sáez. *Streamlining non-tariff measures: a toolkit for policy makers*. The World Bank, 2012.

ASEAN's NTM Guidelines

ASEAN has a long history of attempting to address NTMs. As this paper notes, the focus started well before ASEAN launched the Trade in Goods Agreement (ATIGA) which is approaching its own tenth anniversary. Repeated commitments have not resolved obstacles to doing trade in the region.

The latest effort to do so can be found in the ASEAN NTM Guidelines.⁸ This document, released in August 2018, contains some extremely helpful commitments that — when and if fully implemented — could actually take ASEAN some distance towards addressing NTMs in the region. So far, implementation has been delayed while member states take stock of existing efforts at the domestic level.

The NTM Guidelines are not compulsory, which is perhaps partly why implementation is likely to take time. Without a clear action plan, the useful elaboration of policies embedded in the document is unlikely to assist companies doing business in the region.

However, the existence of the Guidelines does mean that ASEAN members have agreed on some key definitional issues. As an example, the guiding principles call for NTMs that have four characteristics: necessity and proportionality, consultations and engagement, transparency, non-discrimination and impartiality, and periodic review. These commitments are embedded into ASEAN's pledges on Good Regulatory Practices.

The Guidelines include clear timelines for members, as the example of Article 20 shows:

Member States, in introducing or amending NTMs or other trade measures, shall seek to provide advance notifications to the Senior Economic Officials' Meeting (SEOM) and the ASEAN Secretariat. In compliance with Article 11 of the ATIGA, the notifications shall:

- *Be provided 60 days before the action or measure is to take effect;*
- *Provide an adequate opportunity for prior discussions with other Member States, before the adoption of the action or measure; and,*
- *Contain description, rationale, and implementation date and duration of the NTM action or measure.*

⁸ https://asean.org/storage/2018/12/Guidelines_for_the_Implementation_of_ASEAN_Commitments_on_NTMs-July_2018-AEM-AFTAC_32.pdf accessed on March 20, 2019.

Non-Tariff Barriers to Trade (NTBs)

While not all NTMs are pursued with protectionist intent, when countries use them as a means to protect local markets, NTMs can potentially become non-tariff barriers to trade (NTBs). While NTMs may be legitimate measures to achieve a wide range of policy objectives, when poorly designed, they can raise the cost of living and hurt competitiveness by causing delays and extra costs for firms.

NTBs arise when NTMs are:

- enacted specifically to discriminate against imports or foreign firms with the singular purpose of protecting the domestic industry,
- not applied homogeneously across trading partners, or
- include unjustified application of Sanitary and Phytosanitary (SPS) measures and other technical barriers to trade (TBTs).⁹

The rising use of non-tariff issues of all types has the potential to affect and increase costs incurred by firms trading across borders with knock on costs delivered to customers. The business sector is increasingly concerned about NTBs, since these are far less visible, more inconsistent and more complex than tariff measures. From a business perspective, non-tariff measures increase the trade-related costs, making their products less competitive in the destination market. The increase in costs resulting from applying an NTB penalizes not only producers in the exporting country but also businesses and final consumers in the importing country.

Given the impact that trade barriers have on business competitiveness and operational costs, business perceptions and actual experiences of companies can be important additional information that can help identify non-tariff barriers.¹⁰ Exporters and importers are best placed to outline and report on the challenges they face.

Data reported by firms or trading partners has certain advantages over the official data generally used in NTM survey studies. Official data reflects a wide inventory of the measures in place, but typically these data sets do not indicate which measures have the largest impact on trade nor do they disclose measures associated with administrative impediments like slow, non-transparent or corrupt processes.¹¹ Information arising from trader complaints is more likely to give at least a preliminary indication of what measures may cause the most concern for traders.¹² Thus, studies or surveys taking into account business views on NTBs highlight both private-sector demands around the adoption and application of NTBs across countries and clarify the costs incurred by multiple actors across the supply chain as a result of specific measures.

A business perspective is critical to understanding and evaluating the impact of NTBs. At the government level, an understanding of company concerns regarding NTBs

⁹ Austria, Myrna S. "Non-Tariff Barriers: A Challenge to Achieving the ASEAN Economic Community," in *The ASEAN Economic Community: A Work in Progress*, ed. Sanchita Basu Das and Institute of Southeast Asian Studies, 2013.

¹⁰ International Trade Centre (ITC). "The Invisible Barriers to Trade – How Businesses Experience Non-Tariff Measures", International Trade Centre, 2015.

¹¹ Cadot, Olivier, Mariem Malouche, and Sebastián Sáez. *Streamlining non-tariff measures: a toolkit for policy makers*. The World Bank, 2012.

¹² International Trade Centre (ITC). "The Invisible Barriers to Trade – How Businesses Experience Non-Tariff Measures", International Trade Centre, 2015.

helps decision-makers devise and implement appropriate strategies to address policy-induced impediments.

While company interviews are critically important in understanding how barriers to trade impact actual trade flows within ASEAN, firms do not typically understand the difference between NTMs and NTBs. While the former may be technically allowed under World Trade Organization (WTO) and other free trade agreement rules and the latter are not, for companies operating in the region, this distinction is less relevant.

For most firms, an obstacle is an obstacle — justified by health grounds or some other reason or not. *Hence this report does not clearly distinguish between NTMs and NTBs in the material furnished by firms.* If a series of companies have identified a barrier to trade in ASEAN for a particular sector, this is reported in this document.

Governments can wrangle later over whether or not the specific issues identified by firms in this project fit the definition of NTM or NTB. In any case, ASEAN has previously made multiple commitments to address both. ASEAN has pledged to reduce the number of NTMs, because even legitimate NTMs can impede trade, as an example, when standards begin to proliferate. Many legitimate NTMs could be consolidated, for instance, into one clear statement rather than residing in multiple locations managed by different agencies or ministries. ASEAN has also repeatedly promised to eliminate all NTBs.

ASEAN has now, through the NTM Guidelines document, created the following definition of NTMs and NTBs:¹³

- *NTMs, as defined by the United Nations Conference on Trade and Development (UNCTAD), are policy measures other than customs tariffs that can potentially have an economic effect on international trade in goods, changing quantities traded, or prices or both.*
- *NTBs, as defined by the ATIGA, are measures other than tariffs, which effectively prohibit or restrict imports or exports of goods within Member States.*

¹³ August 2018 NTM Guidelines found at:
https://asean.org/storage/2018/12/Guidelines_for_the_Implementation_of_ASEAN_Commitments_on_NTMs-July_2018-AEM-AFTAC_32.pdf Accessed on March 20, 2019.

Business Costs from NTMs and NTBs

It would be ideal, from the perspective of governments, to know exactly how much each individual obstacle to trade “costs” a particular company. Then it would be much easier to prioritize which non-tariff challenges should be addressed first and which can be moved further down the list. All NTMs and NTBs come with associated business costs. Complying with laws, regulations, and rules in markets is expensive.

Getting specific cost data for each NTM or NTB, however, is likely to be a fool’s errand. The quest for such information will simply delay further implementation of the reduction and elimination of barriers to trade.

Why should this be so? In part the problem stems from the differential impact of regulations. Any given rule will affect firms differently. A requirement to put specific information on a label for a can of tuna can be extremely costly for one firm and less costly for another. Firms that have access to inexpensive printers, for example, will find it easier to relabel stock. Companies that trade with only one country could find it less costly to relabel cans than companies that have a global footprint and are only relabeling a tiny portion of the inventory.

Something similar happens for every single obstacle to trade. A day’s delay at customs is clearly costly to firms. The ability to absorb this cost will depend greatly on the firm, the type of product being shipped, the time of year, the capacity of firm, the type of supply chain involved, whether the delay is unexpected or routine, and so forth. Getting a solid cost estimate in hand for what a day’s delay means to a tuna manufacturer is therefore challenging. A day’s delay at customs for tuna could be quite different in cost to a day’s delay for an auto.

Another problem with gathering cost data is that firms themselves do not always have a clear sense of the costs attached to various types of barriers. How much does it cost to not be in a market? If a pharmaceutical product is held up in marketing approvals for 6 or 8 months, how much is this costing the company? If there are no other competitors, it is possible to guess at what the market might ultimately provide in sales, but this can only be a rough ballpark figure.

Even for items that might appear to have a clear cost attached, firms can struggle to get cost figures, such as estimating the costs of higher excise taxes on alcoholic beverages. Calculating the direct costs of paying higher taxes is simple. But the knock-on implications are extremely important and harder for the firm to quantify. Companies with high excise taxes spend a lot more chasing counterfeit products in the marketplace. These costs should be factored into the final estimates. Consumers could decide not to purchase their goods at all but buy lower-priced products or switch to other beverage types entirely. This is clearly an extremely high cost to the firm that also should be factored into estimates.

Hence, while cost estimates would be great to have, they are tough to get. Governments should work with the private sector to discuss the rough values instead of costs associated with each type of obstacle to trade. Firms may not be able to

quantify specifics around a particular NTM or NTB, but they can usually tell whether one is more or less expensive to the company than another.

In the aggregate, these types of assessments are useful for ASEAN because they can direct attention to which NTMs are causing the greatest pain to firms. It may be the case that some aspect of the NTM can be modified to reduce unduly burdensome costs while still maintaining the safety objective of the NTM in the future. Since governments do not always know the full implications and ramifications of every law, rule or regulation once it hits the marketplace, it is necessary to work with industry to understand how the implementation of these rules affects companies in the real world. Objectives can often be effectively met multiple ways. NTMs can be streamlined to manage governmental responsibilities while minimizing costs. NTBs, of course, should be eliminated, with a focus on the most costly.

Methodology

To get at an identification of barriers to trade beyond tariffs, this project interviewed firms across the region in the three key sectors (automotive, agri-food and healthcare). Firms were chosen in close collaboration with the EU-ABC, ASEAN Business Advisory Council, the EU Chambers of Commerce in the region and its partner network of associations and businesses.¹⁴

The interviews were conducted face-to-face due to the complexity of issues related to non-tariff issues. Unlike tariffs, whose effect on trade is certain, the identification of an NTM as a barrier, and its effects, are ambiguous. Face-to-face interactions ensured that respondents correctly understood the purpose and the coverage of the survey, and accurately reported their cases according to predefined products, partner countries and regulatory or procedural obstacles. Thus, the face-to-face interviews investigated which obstacles were perceived as most burdensome, why, what type of obstacles they created for companies and what was the specific role of the related procedural obstacles or the general business environment.

Interviews were conducted against a compressed timetable of months, from September 2018-February 2019. Companies included ASEAN firms as well as businesses from overseas operating across ASEAN borders. While the sample size was adequate, it cannot be viewed as including all possible companies in the sectors under study. In particular, firms were especially difficult to reach in seafood and biscuits.

While it would have been ideal to assign a “cost” to each of these barriers to doing trade, it was not possible to do so. Firms are often uncertain themselves about the costs of each obstacle to trade. Some might be more easily identified, i.e., the cost of an extra day’s delay at customs might be quantified. Others are probably impossible, e.g., the cost attached to having non-transparent procedures in place. Future research might usefully draw out more cost estimates for some of the barriers raised by firms.

Instead, this project developed a “business impact score” to account for the extent of the challenge posed by any particular obstacle reported by firms. The score should be viewed as a “continuum” with a possible range of outcomes from “red” to “yellow” to “green.”

As a simple example of how the continuum works, take excise taxes. In principle, excise taxes could fit anywhere on this spectrum from red to green. Higher excise taxes, however, are more burdensome for firms and cause more difficulties for consumers. This would move the scale from green towards yellow or red, depending on the impact of such excise taxes. Uncertain or arbitrary excise taxes, though, constitutes a “red” impact score. It is not just the tax itself that troubles industry, but the heightened risk attached to sudden shifts in policy that creates a more formidable barrier for firms. Higher excise taxes also increase the incentives for counterfeit products and grey imports, increasing the costs for firms in protecting their own brands and ensuring safety for consumers in the marketplace.

¹⁴ All companies participating in the study were promised complete confidentiality to ensure that they reported on their issues accurately and truthfully.

In each instance, barriers to trade for sectors were added only when multiple firms reported the same types of obstacles to doing trade in a market. A single report of a challenge that was not corroborated by any other firm was not included in the final report.

The report is aimed at ASEAN officials. Hence, although the study collected information at the domestic level from firms operating across borders in the region and presents information from each ASEAN member state, the purpose is not to change regulatory policies within individual ASEAN markets. There is no way to properly understand the regional level implications of policy decisions within ASEAN absent careful examination of business practices inside ASEAN Member States.

Having collected the information at the member state level, the report does not attempt to make recommendations for changes within specific members. Instead, the data was used to consider how ASEAN could more usefully tackle the challenges raised by firms at the ASEAN level. These recommendations were connected to existing ASEAN agreements and institutional frameworks to ensure that ASEAN can quickly and seamlessly begin to tackle these various burdens to companies in the region.

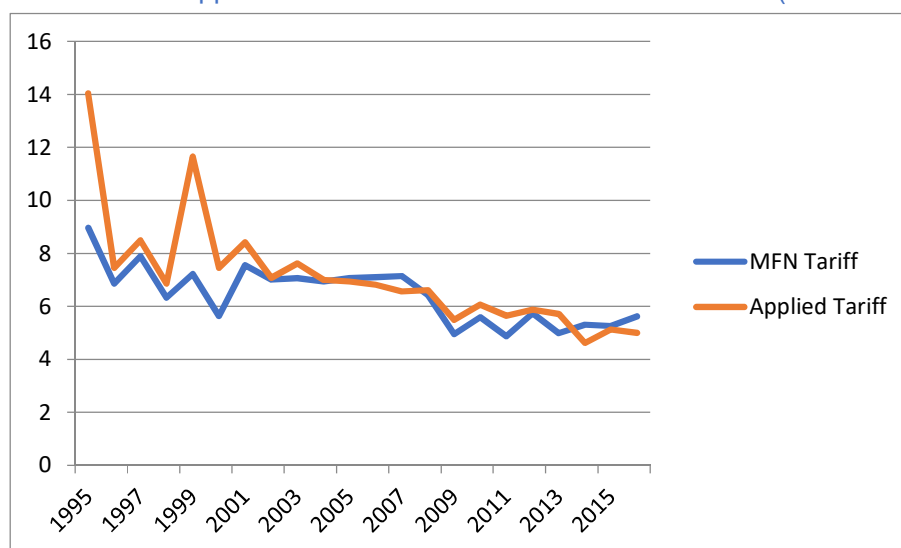
It is clear from the extent and depth of the challenges reported by firms that non-tariff obstacles exist in every ASEAN member state and, most likely, in every sector. Some ASEAN mechanisms for addressing these issues exist, but more work is urgently needed to help fulfil the promise of the ASEAN Blueprint 2025 to create a seamless integrated business region.

The Context: NTMs in ASEAN

Before delving into the specific sectors of this study, it is first important to understand the context of non-tariff issues in ASEAN. After all, without some sense of the overall levels of NTMs in the region, it is not possible to judge whether the concerns of firms expressed in this project are part of a significant problem or simply minor complaints. The data in this section shows, however, that the challenge of NTMs in ASEAN is real and appears to be a growing problem.

The most simple evidence of the scale of the difficulty for ASEAN is the following: while tariffs fell by approximately half over the past 15 years, intra-ASEAN trade increased by only about 5.3%.¹⁵ This suggests that something besides tariffs has constrained firms from trading more across borders. Given years of empirical studies showing that firms traditionally trade more with their neighbours than with more geographically distant locations, the lack of more intra-ASEAN trade after decades of ASEAN tariff liberalization is disheartening.

Figure 2: MFN and Applied Tariff Rates into ASEAN Member States (1995 - 2016)

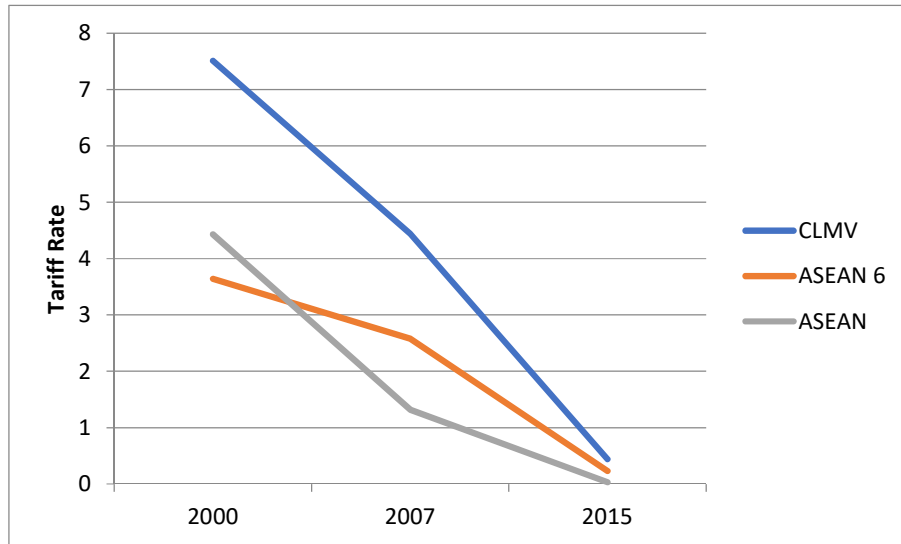


Import tariffs have been successfully reduced through multilateral and regional negotiations, with ASEAN tariffs declining constantly over the past 15 years. Figure 2 shows the decline in external tariffs for goods coming into ASEAN countries. As shown in Figure 3, by 2010, intra-ASEAN tariffs had been eliminated on 98% of product lines in the ASEAN-6.¹⁶

¹⁵ Ing, Lili Yan, Santiago Fernandez de Cordoba, and Olivier Cadot. "Non-tariff measures in ASEAN." (2016).

¹⁶ "World Bank Data Portal." The World Bank, <https://data.worldbank.org/indicator/tm.tax.mrch.sm.ar.zs>

Figure 3: Average Tariff Rates on Intra-ASEAN Imports (2000 – 2015)¹⁷



On the other hand, non-tariff measures (NTMs) have long been used to obstruct trade in Southeast Asia. As early as 1987, surveys noted that in spite of progress being made in lifting formal tariffs through initiatives such as 1977 ASEAN PTA Agreement, companies reported having encountered NTMs while trading in ASEAN.¹⁸

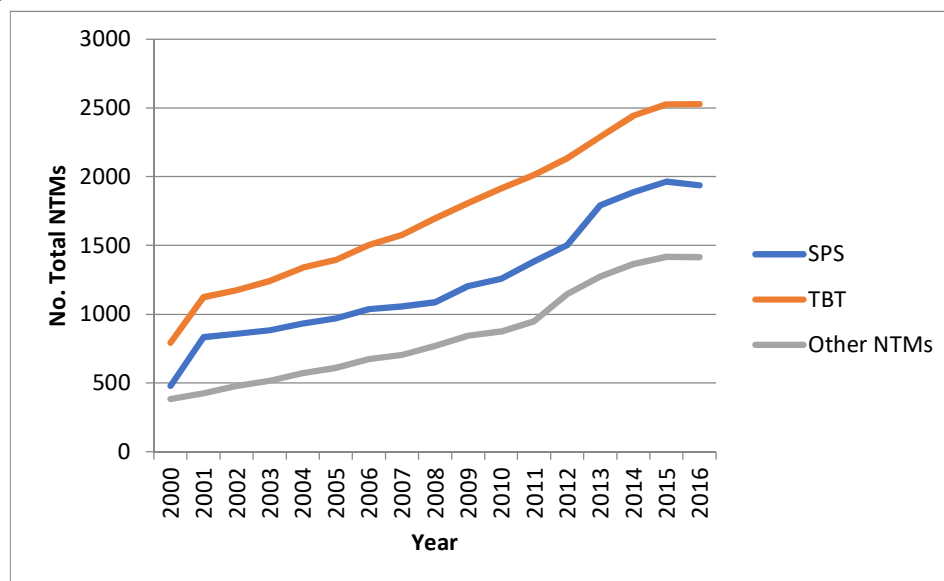
This trend has persisted to this day despite renewed commitment by ASEAN to eliminate NTMs in the signing of the ASEAN Economic Community (AEC) in 2015, which promised the free flow of goods. In fact, according to the Global Database on Non-Tariff Measures (TRAINS), from 2000 to 2015, NTMs in ASEAN rose significantly. Figure 3 shows that the number of sanitary and phytosanitary measures (SPS), technical barriers to trade (TBT) and other types of NTMs increased between 2000 and 2016 by 305, 218 and 266% respectively. This trend is corroborated by other literature. For instance, in a study of nine priority sectors, de Dios found evidence that NTMs remained prevalent despite attempts by ASEAN at NTM-reduction.¹⁹

¹⁷ Figure constructed using data from the “ASEAN Economic Chartbook 2015” and “ASEAN Community in Figures 2013” published by the ASEAN Secretariat.

¹⁸ Ooi Guat Tin, “Non-Tariff Barriers to Expanding Intra-ASEAN Trade,” ASEAN Economic Bulletin, 1987, 97–113.

¹⁹ De Dios, Loreli C. “Non-tariff barriers to trade in the ASEAN priority goods sectors.” Institute of Southeast Asian Studies, 2007.

Figure 4: Total Number of NTMs in ASEAN 2000 - 2016²⁰



In fact, most traded products in ASEAN are today covered by NTMs. A 2015 analysis of NTMs in ASEAN conducted by ERIA shows that “coverage ratios,” or the percentage of imports covered by a measure in a given year, is high across ASEAN.²¹ Table 1 shows that in six of the ten member countries, *all* imports are covered by at least one NTM.

Table 1. Coverage Ratios NTMs in ASEAN 2015²²

Country	NTM Coverage (%)
Brunei	65%
Cambodia	100%
Indonesia	75%
Lao PDR	100%
Malaysia	71%
Myanmar	42%
Philippines	100%
Singapore	100%
Thailand	100%
Vietnam	100%

²⁰ "UNCTAD - Integrated Trade Intelligence Portal - Home Page." Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²¹ Ing, Lily Yan, et al. "Non-tariff Measures in ASEAN: A Simple Proposal." In *Non-Tariff Measures in ASEAN* ed. By Ing, Lily Yan and de Cordoba Santiago Fernandez, Economic Research Institute for ASEAN and East Asia, 2016, 21.

²² Ing, Lily Yan, Santiago Fernandez de Cordoba, and Olivier Cadot. "Non-tariff measures in ASEAN." (2016).

Table 2 shows the breakdown of the types of NTMs. The largest categories are SPS and TBT. Note that this type of data is likely to be skewed since these are the types of NTMs that are generally most requested in survey instruments and so forth. In other words, governments, researchers and even companies are primed to think about SPS and TBT issues when asked about NTMs. Other potential types of NTMs like intellectual property measures that might be restrictions on trade typically do not seem like such obvious or easily identified barriers. Survey instruments like the UNCTAD database can only measure inputs that are included for measurement and therefore miss out on potential obstacles like procedures or slow-moving procedural issues that nevertheless constitute real-world barriers to trade.

Table 2. Number of NTMs in ASEAN by Type²³

NTM by Type	# of NTMs	%
SPS	1984	33.2
TBT	2573	43.1
Pre-shipment Inspection	153	2.6
Contingent Trade Protective Measures	112	1.9
Non-automatic licensing, quotas, prohibitions and quantity control measures other than SPS or TBT reasons	159	2.7
Price control measures including additional taxes and charges	195	3.3
Finance Measures	15	0.3
Measures Affecting Competition	16	0.3
Trade Related investment measures	0	0
Distribution restrictions	2	0
Restriction on post-sale services	0	0
Subsidies	0	0
Government procurement restrictions	0	0
Intellectual property	0	0
Rules of Origin	0	0
Export related measures	766	12.8
Total Coded NTMs	5975	100

Table 3 shows a breakdown of the types of NTMs by member country. In 2018 Thailand adopted the largest number of NTMs across the region.²⁴ In terms of composition, SPS and TBT measures were more prevalent in the Philippines, Singapore, Thailand and Vietnam. By contrast, in Cambodia, Myanmar and Lao, PDR export related measures were more prevalent.

²³ Ing, Lili Yan, Santiago Fernandez de Cordoba, and Olivier Cadot. "Non-tariff measures in ASEAN." (2016).

²⁴ "UNCTAD - Integrated Trade Intelligence Portal - Home Page." Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

Table 3. Number of NTMs in ASEAN by Country and Type (2018)

	CTPM	EXP	INSP	OTH	PC	QC	SPS	TBT	TOTAL
Brunei		46	1		18	2	161	288	516
Cambodia		70	1		12	3	36	121	243
Indonesia	44	74	53	4	5	8	125	321	590
Lao PDR		82	14	1	48	26	38	82	291
Malaysia	24	72	5		12	9	260	331	689
Myanmar		35	2	1	13	5	75	41	172
Philippines	1	146	24	12	23	56	233	360	854
Singapore		49	2		35	1	127	300	514
Thailand	53	128	44	3	21	40	762	562	1560
Viet Nam		57	5	11	7	7	121	122	330
Total	122	759	151	32	194	157	1938	2528	5759

KEY: Contingent Trade Protective Measures (CTPM), Sanitary and Phytosanitary (SPS), Technical Barriers to Trade (TBT), Pre-Shipment inspection (INSP), Quantity Control Measures (QC), Price Control Measures (PC), Other Measures (OTH), Export Related Measures (EXP)

Table 4 shows which product groups are most affect by NTMs in ASEAN by breaking down the number of measures by product category.²⁵ Among the most heavily regulated products are those that are clearly sensitive from a public-health perspective — animal products, foodstuffs and chemicals.

Table 4. Number of ASEAN NTMs by Affected Products (2018)

HS Code	Product description	TBT	SPS	INSP	CTPM	QC	PC	EXP	OTH	Total
	Total	2528	1938	151	122	15 7	19 4	759	32	5881
Sec. I	Live animals and products	277	746	27		21	51	247	8	1377
Sec. II	Vegetable products	414	773	55	2	37	53	252	14	1600
Sec. III	Animal and vegetable fats, oils and waxes	162	321	10		12	29	141	7	682
Sec. IV	Prepared foodstuff;	663	851	24		34	72	201	11	1856
Sec. IX	Wood, cork and articles; basketware	64	65	12		10	21	127	7	306
Sec. V	Mineral products	258	119	19		17	31	102	12	558
Sec. VI	Chemical and allied industries	798	311	35	3	47	74	347	17	1632
Sec. VII	Resins, plastics and articles;	273	35	14	13	18	23	80	9	465
Sec. VIII	Hides, skins and articles; saddlery and travel goods	54	38	4		3	20	69	5	193

²⁵ "UNCTAD - Integrated Trade Intelligence Portal - Home Page." Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

Sec. X	Paper, paperboard and articles	68	14	10	9	12	18	48	8	187
Sec. XI	Textiles and articles	86	87	11	18	12	22	80	5	321
Sec. XII	Footwear, headgear;	63	37	5		2	19	56	6	188
Sec. XIII	Articles of stone, plaster; ceramic prod.; glass	137	13	10	5	7	16	54	7	249
Sec. XIV	Pearls, precious stones and metals; coin	94	28	10		18	20	112	7	289
Sec. XIX	Arms and ammunition	73	35	4		6	17	76	6	217
Sec. XV	Base metals and articles	232	19	14	72	12	21	84	9	463
Sec. XVI	Machinery and electrical equipment	392	5	16		24	37	64	9	547
Sec. XVII	Vehicles, aircraft and vessels	197	3	12		15	30	53	9	319
Sec. XVIII	Instruments, clocks, recorders and reproducers	191	19	7		5	23	91	5	341
Sec. XX	Miscellaneous manufactured articles	163	38	7		10	32	105	6	361
Sec. XXI	Works of art and antiques	35	19	2		6	17	75	5	159

KEY: Contingent Trade Protective Measures (CTPM), Sanitary and Phytosanitary (SPS), Technical Barriers to Trade (TBT), Pre-Shipment inspection (INSP), Quantity Control Measures (QC), Price Control Measures (PC), Other Measures (OTH), Export Related Measures (EXP)

Instruments like business surveys have documented the difficulties that these entail for firms. Consistently, surveys done by UNCTAD, the EU-ASEAN Business Council, the ASEAN Business Advisory Council and the International Trade Centre have shown that businesses: (i) remain affected by burdensome NTMs and (ii) continue to prioritize the identification and removal of NTBs as a means to move forward the ASEAN Economic Community.

Business surveys show that a significant proportion of firms in some of the region's largest markets are affected by burdensome NTMs. For instance, a series of comprehensive business surveys conducted by the International Trade Centre in Thailand, the Philippines and Malaysia, found that a significant portion of firms continue to be affected by NTMs. In a survey with 953 Indonesian companies, the survey found that 27% of importers reported being affected by NTMs.²⁶ A similar survey conducted with 1148 companies in the Philippines showed that three quarters of Philippines exporting and importing firms are confronted with NTM obstacles.²⁷ Finally,

²⁶ International Trade Centre (ITC), "Indonesia: Company Perspectives – An ITC Series on Non Tariff Measures (NTMs)", International Trade Centre, 2016, 15 – 42.

²⁷ International Trade Centre (ITC), "Philippines: Company Perspectives – An ITC Series on Non Tariff Measures (NTMs)", International Trade Centre, 2016, viii - ix.

a survey with 959 companies in Thailand showed that 40% of companies reported facing restrictive regulations and related obstacles.²⁸

Business surveys have also shown that firms in both the agricultural and manufacturing sectors encounter burdensome technical requirements, conformity assessment procedures and associated procedural obstacles. Technical barriers were the most frequently reported barriers to trade in surveys conducted in Thailand the Philippines and Indonesia.²⁹ These measures include product specific technical requirements and SPS conformity assessment procedures. The same surveys also found that procedural obstacles such as inefficiency or obstruction, and arbitrariness or inconsistency are major obstacles encountered by both exporting and importing firms.³⁰

Furthermore, some business surveys have found that unfair competitive practices in ASEAN are of increasing concern to firms. For instance, the 2018 EU-ASEAN Business Council Business survey shows that in ASEAN the number of respondents who reported that they often or occasionally faced unfair competitive practices rose to 62%, up from 48% in 2017.³¹ This usually means that firms are faced with unfair competition from local incumbents or state-owned enterprises. There were large increases in those reporting that they often faced unfair competitive practices for Indonesia, Laos, Malaysia, Singapore, the Philippines and Vietnam.³²

Second, business surveys have also shown that companies continue to prioritize the identification and assessment of burdensome NTMs in the region. Reports by the ASEAN Business Advisory Council to ASEAN Leaders and ASEAN Economic Ministers have all highlighted the need to develop a clear ASEAN roadmap for the removal of remaining NTMs/NTBs hampering trade in the region,³³ especially focusing on barriers within “people-centric” sectors like agri-food, tourism and healthcare.³⁴ For instance, in a 2013 ABAC survey most participants remained unsatisfied with the lack of transparency and progress towards the assessment of Non-Tariff Measures.³⁵ Similarly, the Business Surveys conducted by the EU-ASEAN Business Council in 2016–2018 all have shown that the removal of non-tariff barriers to trade is increasingly

²⁸ International Trade Centre (ITC), “Philippines: Company Perspectives – An ITC Series on Non Tariff Measures (NTMs)”, International Trade Centre, 2016, x - xii.

²⁹ International Trade Centre (ITC), “Indonesia: Company Perspectives – An ITC Series on Non Tariff Measures (NTMs)”, International Trade Centre, 2016, 15 – 42.

International Trade Centre (ITC), “Philippines: Company Perspectives – An ITC Series on Non Tariff Measures (NTMs)”, International Trade Centre, 2016, viii - ix.

International Trade Centre (ITC), “Philippines: Company Perspectives – An ITC Series on Non Tariff Measures (NTMs)”, International Trade Centre, 2016, x - xii.

³⁰ United Nations Conference on Trade and Development, “Non-Tariff Measures: Evidence from Selected Developing Countries and Future Research Agenda.” United Nations, 2010, 74.

International Trade Centre (ITC), “Philippines: Company Perspectives – An ITC Series on Non Tariff Measures (NTMs)”, International Trade Centre, 2016, viii - ix.

International Trade Centre (ITC), “Philippines: Company Perspectives – An ITC Series on Non Tariff Measures (NTMs)”, International Trade Centre, 2016, x - xii.

Medalla, Erlinda, and Mantaring, Melalyn. “Review of Intra-ASEAN Nontariff Measures on Trade in Goods”. Philippine Institute for Development Studies, Discussion Paper Series No. 2017-18, Apr. 2017.

³¹ EU-ASEAN Business Council. “2018 EU-ASEAN Business Sentiment Survey.” EU-ABC, 2017, 33.

³² EU-ASEAN Business Council. “2018 EU-ASEAN Business Sentiment Survey.” EU-ABC, 2017, 33.

³³ ASEAN Business Advisory Council (ABAC), “ASEAN Business Advisory Council Report to ASEAN Leaders.” ASEAN-BAC, 2015, <https://www.asean-bac.org/storage/publication/20180406/FJ1H3QsBCqEq1EcC28zR040620180545.pdf>

³⁴ ASEAN Business Advisory Council (ABAC). “Re-Energizing AEC Towards Prosperity for All: ASEAN BAC Report to ASEAN Economic Ministers.” ASEAN-BAC, Sep. 2017, <https://www.asean-bac.org/storage/publication/20180413/AXqWZZSdtkkookiGQN09g041320180605.pdf>

³⁵ ASEAN Business Advisory Council (ABAC), “ASEAN Business Advisory Council Report to ASEAN Leaders.” ASEAN-BAC, 2014, <https://www.asean-bac.org/storage/publication/20180406/aP5AVV1iwsDIHHPwrtXa040620180541.pdf>

becoming a priority for businesses — topping the list of priorities for businesses in 2018.³⁶ The same survey also shows that NTBs, complex customs procedures and the lack of harmonized standards are all hampering supply chain efficiency within the region.³⁷

³⁶ EU-ASEAN Business Council. "2018 EU-ASEAN Business Sentiment Survey." EU-ABC, 2017.
EU-ASEAN Business Council. "2017 EU-ASEAN Business Sentiment Survey." EU-ABC, 2016
EU-ASEAN Business Council. "2016 EU-ASEAN Business Sentiment Survey." EU-ABC, 2015

³⁷ EU-ASEAN Business Council. "2018 EU-ASEAN Business Sentiment Survey." EU-ABC, 2017.

ASEAN Frameworks for Addressing Non-Tariff Issues

ASEAN Member States have not been oblivious to the challenges of non-tariff issues. While much of the focus over time in the economic pillar has been on the steady reduction of tariffs between members, ASEAN recognized the risk that tariff rate liberalization could be accompanied by the rise of non-tariff obstacles to trade.

As early as 1977, ASEAN leaders explicitly put non-tariff issues on the agenda.³⁸ In general, ASEAN-level commitments have not clearly distinguished between NTMs and NTBs, although a pledge to reduce measures that impede intra-ASEAN trade suggests that the focus was meant to be more on NTBs than NTMs. To be fair, the distinction was perhaps less important in the early days of ASEAN's agenda than it seems to have become in more modern times.

Regardless of nomenclature, it seems clear that ASEAN member governments have taken repeated steps to reduce NTBs in the years since 1977 as Table 5 shows.

Table 5. ASEAN Historical Commitments Towards the Elimination of NTBs³⁹

Year	Commitment
1977	<p>Preferential Trade Agreement</p> <p>Member economies committed to reducing both tariffs and non-tariff barriers by not introducing new or additional non-tariff measures that would impede intra-ASEAN trade and to phase out or eliminate existing non-tariff measures that impeded intra-ASEAN trade</p>
1987	<p>Memorandum of Understanding on the Standstill and Rollback on NTBs among ASEAN Members</p>
1992	<p>Establishment of ASEAN Free Trade Area</p> <p>Established a deadline for the reduction of tariffs to 0–5% and the elimination of NTBs</p>
2004	<p>High Level Task Force on ASEAN Economic Integration (with recommendations regarding NTMs)</p> <ol style="list-style-type: none"> 1. Establishment of ASEAN database on NTMs 2. Set clear criteria to identify measures that were classified as barriers to trade by mid-2005 3. Set a clear and definitive work program for the removal of the barriers by 2005 4. Adopted WTO agreements on TBTs and SPS and Import Licensing and implementation guidelines for ASEAN by the end of 2004
2006	<p>AFTA Roadmap Integration of Priority Sectors</p>

³⁸ Austria, Myrna. "Non-tariff barriers: A challenge to achieving the ASEAN economic community." *The ASEAN Economic Community: A Work in Progress* (2013): 31-94.

³⁹ This table was constructed by the analysis conducted by Austria, *Non Tariff Barriers: A Challenge to Achieving the ASEAN Economic Community*.

	<p>Under the ASEAN Free Trade Area, ASEAN implemented a work programme for the assessment of existing of NTMs and identification of NTMs. The elimination of NTBs would be done in three tranches with reviews done by AFTA Council starting January 2008.</p>
2007	<p>AEC Blueprint for the ASEAN Economic Community (AEC) 2015</p> <p>Committed the region towards the “the full elimination of non-tariff barriers (NTBs).” It included commitments to:</p> <ol style="list-style-type: none"> a. Enhance transparency by abiding by the Protocol on Notification Procedures and setting up an effective surveillance mechanism; b. Abide by the commitment to a standstill and roll-back of NTBs; c. Remove all NTBs by 2010 for ASEAN–5 (Brunei Darussalam, Indonesia, Malaysia, Singapore and Thailand), by 2012 for the Philippines, and by 2015 with flexibilities to 2018 for CLMV, in accordance with the agreed Work Program on NTBs elimination; d. Enhance transparency of NTMs; and e. Where possible, work toward having regional rules and regulations consistent with international best practices.
2009	<p>ASEAN Trade in Goods Agreement (ATIGA)</p> <p>The ATIGA made the following commitments:</p> <ol style="list-style-type: none"> a. Forbidding further use of NTMs within the context of intra-ASEAN trade. Transparency regarding NTMs also required members under Article 40 Clause 2: states must ensure that that such measures were not undertaken with the objective of hindering regional trade. b. Coordinating Committee on the Implementation of ATIGA (CCA): to review and monitor potential NTMs, which were to be immediately eliminated upon being deemed as such (once all 10 ASEAN Member States agreed). c. Database on NTMs was to be updated and deposited in the ASEAN trade repository; states required to go over the database and identify existing NTMs for elimination through the appropriate ASEAN body.
2015	<p>AEC 2025 Blueprint</p> <p>No specific agenda for the elimination of NTBs in ASEAN, but clauses such as:</p> <ul style="list-style-type: none"> • Imposing stringent criteria and sunset clauses on trade-protective NTMs such as quotas and other quantity restriction in imports and exports; and

	<ul style="list-style-type: none"> • Embedding good regulatory practice (GRP) in implementing domestic regulations and practices and thereby minimizing compliance cost of meeting NTM requirements.
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To achieve the agenda noted in Table 5, ASEAN has placed the oversight of NTBs into various specialized bodies. There are at least three institutional bodies, shown in Table 6, that have been developed within ASEAN’s governance structure whose work is directly linked with the identification and assessment of non-tariff issues.

Table 6. ASEAN’s Relevant Institutional Bodies⁴⁰

Coordinating Committee of ATIGA (CCA) ⁴¹	ASEAN Consultative Committee on Standards and Quality (ACCSQ)	Working Group on Sanitary and Phytosanitary (SPS) measures
Previously called ITWG (Interim Working Group for the Common Effective Preferential Tariff), this body has been in charge of reviewing and monitoring potential NTMs, which are to be immediately eliminated upon being deemed as such (upon the unanimous consent of all ASEAN members).	The ACCSQ was tasked to undertake the harmonization process and to implement mutual recognition agreement (MRAs) of laboratory test reports and conformity certifications. It is supported by three working groups and eight product-working groups with their corresponding areas of responsibility.	The Working Group has drawn up a series of action plan to combat NTMs in crops, livestock and fisheries, compiling information on relevant NTMs that limit agricultural trade and developing MRA of SPS standards to free up intra-ASEAN agricultural trade.

Despite its continued efforts and commitment, ASEAN has not been able to meet the commitments and goals it established itself to do.

First, it has failed to keep track of NTMs through the NTB database proposed as early as 2004. The database has not been properly maintained; it is out-of-date and lacks an inventory of eliminated NTBs.⁴² In addition, data is messily coordinated in Excel sheets and there are no channels for stakeholders to report and monitor NTMs. Clearly, insufficient steps have been taken to maintain this interface as a source of timely and accurate information.

⁴⁰ Medalla, Erlinda M., and Melalyn C. Mantaring. "Review of Intra-ASEAN Nontariff Measures on Trade in Goods." (2017).

⁴¹ Note that there is also a parallel body for services, called the Coordinating Committee for Services (CCS). It appears to have a function on non-tariff issues, but since every barrier for services is—by definition—not about tariffs, it is not exactly clear what this body is supposed to have done.

⁴² Austria, Myrna. "Non-tariff barriers: A challenge to achieving the ASEAN economic community." *The ASEAN Economic Community: A Work in Progress* (2013): 31-94.

Even when data has been collected together, as the Coordinating Committee on ATIGA (CCA) has tried to do,⁴³ issues are often listed as “resolved” even if the outcome would not meet the typical definition of the word. Under ASEAN-speak “resolved” means the issue cannot be moved further forward or was removed by the ASEAN state with the offending NTM. To actually “resolve” an NTM requires unanimity of all ASEAN Member States. Hence, of the more than 100 “cases” on the CCA list, none appear to have been successfully concluded with the actual resolution and removal of the barrier in question.⁴⁴ Given the lack of transparency in the process thus far, it is difficult to determine what has actually happened in each case in the system.

The CCA process itself is also cumbersome and ill-suited to the task of efficiently addressing obstacles to trade. Since no barrier can be removed until all 10 member states agree to do so, it is clear that progress is going to be slow even if all parties could quickly reach consensus on each individual point.

Second, ASEAN has also made limited progress in identifying and eliminating NTBs. On the one hand, there is lack of common definitions and approaches in identifying NTBs from among the NTMs because of conflicting perceptions of individual firms across the member countries.⁴⁵ Likewise, the inadequate information on the justification of the NTMs (whether legitimate or not) and their enforcement (whether uniformly across trading partners, etc.) make it also impossible to identify which of the NTMs are barriers to trade (NTBs).⁴⁶ In the absence of this critical information, the NTMs can be easily used to protect domestic industries or applied discriminately; and thus become NTBs.

Third, ASEAN has made some progress in the improvement and harmonization of standards and regulations. ASEAN’s approach has been to align its standards and regulations with international standards acceptable at the multilateral level. Harmonization of standards has been completed for electrical appliances; electrical safety; electromagnetic components; rubber-based products; and pharmaceuticals. Nevertheless, supply side capacity constraints as shown by the differences in the infrastructures for standards and conformance of the member countries, can make the harmonization and alignment of standards and regulations slow, if not difficult, to achieve.⁴⁷

ASEAN’s commitments and specialized bodies for the identification of elimination of NTBs over the past two decades have followed similar blueprints and implementation plans. The AEC Blueprint 2025 had, as its first action item, to complete all elements not already finished in the 2015 AEC prior to the end of 2016. This has clearly not been done, even by 2019. Instead, members added new commitments. More alarmingly, the specific elements where ASEAN has promised to identify and eliminate NTMs have seen ambition levels *lowered* between the AEC’s 2015 and 2025 Blueprints.

⁴³ See the complete matrix here: https://www.asean.org/wp-content/uploads/images/2015/July/Matrix_of_Actual_Cases/Matrix%20of%20Actual%20Cases%20on%20NTMs_Resolved%20Cases%20as%20of%2018th%20CCA.PDF Accessed February 15, 2019.

⁴⁴ The ATR website can be found at: <https://atr.asean.org/read/non-tariff-measures/44>

⁴⁵ Austria, Myrna. "Non-tariff barriers: A challenge to achieving the ASEAN economic community." The ASEAN Economic Community: A Work in Progress (2013): 31-94.

⁴⁶ Austria, Myrna. "Non-tariff barriers: A challenge to achieving the ASEAN economic community." The ASEAN Economic Community: A Work in Progress (2013): 31-94.

⁴⁷ Austria, Myrna. "Non-tariff barriers: A challenge to achieving the ASEAN economic community." The ASEAN Economic Community: A Work in Progress (2013): 31-94.

Some scholars have suggested that the slow progress and weak commitment stem perhaps from a fundamental contradiction between ASEAN's operating principles and that of regulating regional trade.⁴⁸ For instance, monitoring functions (e.g. NTM database and identification) exercised by supranational bodies contradict ASEAN's commitment to national sovereignty and non-interference.⁴⁹ Thus, little progress has been made on abolishing NTMs due to the reservations of national governments. Furthermore, ASEAN diplomacy, which tends to revolve around confidence-building measures, and non-binding declarations of intent, has resulted in regional initiatives deferring to the lowest common denominator.⁵⁰ As a result, ASEAN's institutional culture may not be ideal for managing economic integration.

In conclusion, while the commitments ASEAN has made imply a strong commitment towards combating restrictive NTMs, they do not guarantee that NTMs will be effectively eliminated in accordance with the ATIGA and the AEC 2025 Roadmap. On the one hand, those commitments have been vague and do not outline concrete measures that must be taken to eliminate existing NTBs. On the other hand, there are no common definitions or approaches to identify NTBs from NTMs, since there are still conflicting perceptions of an NTM's justification — whether legitimate or not — and enforcement — whether uniformly across trading partners — across the member countries.

Repeated promises to monitor, track and eliminate NTMs and NTBs — now dating back to at least 2004 — have been only partially implemented or are simply ignored completely. The system itself needs significant reform and member states will need to renew their commitments to successfully reach the Blueprint 2025 objectives for NTMs and NTBs.

⁴⁸ Aggarwal, Vinod K., and Jonathan T. Chow. "The perils of consensus: how ASEAN's meta-regime undermines economic and environmental cooperation." *Review of International Political Economy* 17.2 (2010): 262-290.

⁴⁹ Pitakdumrongkit, Kaewkamol. "Beyond The Secretariat: Addressing Governance Issues In Asean Economic Community." *The Singapore Economic Review* 62.03 (2017): 741-759.

⁵⁰ Pitakdumrongkit, Kaewkamol. "Beyond The Secretariat: Addressing Governance Issues In Asean Economic Community." *The Singapore Economic Review* 62.03 (2017): 741-759.

Drilling Down: Non-Tariff Issues in Three Sectors

ASEAN officials have, as noted, made repeated pledges to address non-tariff issues. These promises have been given institutional weight by placing them into specific bodies within the ASEAN structure. While repeated surveys of businesses in the region show on-going concerns over the extent and depth of non-tariff challenges in ASEAN, the existing material does not make it easy to determine exactly how specific firms find doing business across borders in ASEAN today.

Of particular importance, past work does not help structure ASEAN-level recommendations about which barriers are viewed as most problematic and which are less of an issue to firms doing business. As a simple example, the current ASEAN frameworks are skewed towards addressing barriers in standards, with a heavy focus on drafting and managing Mutual Recognition Agreements (MRAs)⁵¹ and using the ACCSQ as the key mechanism for handling NTM and NTB issues.

If, however, firms do not see standards as the primary obstacle to doing business in ASEAN or do not believe that MRAs will create satisfactory solutions in the future to specific challenges on the ground, then these efforts might be better directed towards alternative pathways and institutions.

To get a better handle on what firms see as key challenges, this project builds on existing survey data from ASEAN. It has chosen three sectors as particularly important for understanding the range and types of NTBs that might be present across all business activities in the region: automotive, agri-food and healthcare. Careful interviews with a wide selection of firms doing business in the ASEAN Member States has revealed that challenges do, indeed, go far beyond standards. In fact, as the following sections show, standards are actually not the primary obstacle to doing business in the region. Hence, the ASEAN-level recommendations that conclude the paper include relocating responsibility for NTBs to higher-level ASEAN bodies.

It may also be worth noting that, although this study is about non-tariff issues, companies repeatedly raised tariffs as obstacles to trade in some areas. Future research may want to explore why firms continue to face tariff challenges in a region that is meant to be tariff-free under the ASEAN Economic Community.

⁵¹ MRAs can be very time consuming to negotiate, but firms often are satisfied with the final result. The difficulty in ASEAN has been uneven implementation of MRAs.

I. The Automotive Sector

Case Study in the Automotive Sector – Importing a 2.0 Litre CBU Passenger Car into Malaysia

Malaysia's vehicle production in 2017 accounted for 12% of all the vehicles built in ASEAN. Vehicle exports from Malaysia to markets beyond ASEAN have been modest. Its domestic automotive industry is dominated by two domestic "national car" champions — Proton and Perodua — and shaped by a complex web of vehicle import permits, approved import valuations, customs tariffs, high excise taxes and local content tax incentives. This case study explores the ways in which these measures could act as barriers for foreign automotive manufacturer importing a 2.0-litre CBU passenger vehicle into Malaysia. This analysis is based on issues raised by ASEAN based firms who participated in the study "Assessment of ASEAN NTBs and Net benefits of elimination" under the Enhanced Regional EU-ASEAN Dialogue Instrument (E-READI) cooperation programme.

Restrictive Import Quotas:

The number of imported CBU passenger vehicles is first limited by Malaysia's Approved Permits (APs) system, which controls the number of imported cars based on local vehicle production. The total number of APs each year is limited to 10% of the number of locally-assembled cars in the preceding year.⁵² For instance, under Malaysia's 2017 total production value of 459,558 passenger vehicles, APs were limited to 45900 in 2018.⁵³ The imposition of such quotas represents a significant barrier to trade since it limits the number of imported cars in a given year and distorts market production and prices in favour of local manufacturers, who may not be able to meet production needs or consumer demand.

Furthermore, imported passenger cars are also subject to price control measures that both increase the costs and limit the competitiveness of imported vehicles.

Inconsistent and Non-Transparent Valuation Process:

First, a CBU imported vehicle must undergo a gazetted import valuation — a system where the value of imported vehicles is established and approved by the Malaysian government.⁵⁴ The gazetted valuation process can be time consuming, which increases the carrying costs of inventory and stock costs for automotive importers. Moreover, the gazetted valuation process is not readily transparent and inconsistent with transaction-based methodologies not different from WTO valuation codes.

⁵² United States Department of Commerce International Trade Administration. "Compilation of Foreign Motor Vehicle Import Requirements." Office of Transportation and Machinery, Dec. 2015, <https://www.trade.gov/td/otm/assets/auto/TBR2015Final.pdf>

⁵³ ASEAN Automotive Federation. "AFF Statistics." 2017, http://www.asean-autofed.com/files/AAF_Statistics_2017.pdf

⁵⁴ Minister of Finance Malaysia. "Customs Act 1967: Customs (Values of Imported Completely Built-Up Motor Vehicles) (New) Order 2006." 22 Mar. 2006, <http://paultan.org/media.paultan.org/pricelist.pdf>

High and Discriminatory Taxation:

Second, the importer is subject an import duty of 30% — if the manufacturer operates outside of ASEAN — and excise rates, which fall between 75 and 105% — the highest in ASEAN. For a 2.0 litre CBU vehicle, the excise will amount to 90% of the gazetted value.⁵⁵ This means that an imported car must pay bear a high excise duty based on a non-transparent vehicle valuation procedure. The high excise tax and unique valuation systems raise the price, and as a result reduce the competitiveness of imported vehicles in the Malaysian market.⁵⁶

Third, the competitiveness of imported CBU cars is further affected by tax incentives that are exclusively granted to local automotive manufacturers. The “national car” champions are often able to use their local content levels to receive significant tax exemptions. For instance, under the new Energy Efficient Vehicle programme, a 50% exemption on excise duty is given to locally assembled/manufactured energy efficient vehicles.⁵⁷ The application of excise rates in a discriminatory manner creates an uneven playing field, distorts prices, limits production and negatively impacts the prices, margins and competitiveness of automotive imports.

Complex and Discriminatory Conformity Assessment Procedures:

Finally, importers of passenger vehicles are confronted by complex conformity assessment procedures and the inconsistent and discriminatory application of product requirements. Within the customs clearance process, a passenger car is subject to a high level of physical vehicle inspection, which can be time-consuming and delay the removal of vehicles from the waterfronts. While these types of costs will vary depending company specific factors, delays in the removal of vehicles from the water front can increase a firm’s inventory carrying costs and create inventory stock outs that lead to sales losses. Companies that participated in the study also reported inconsistencies in the application of UNECE standards. Locally manufactured vehicles are allowed a phase-in period while the same concession is not granted to imported vehicles. The discriminatory application of standards creates an uneven playing field and negatively impacts the margins and competitiveness of automotive imports.

According to companies interviewed under this study, the cumulative impact of the various NTMs/NTBs more than doubles the Free on Board (FOC) price of the two-litre imported vehicle. The barriers faced by imported passenger vehicles into Malaysia are consistent with non-tariff measures found across ASEAN. Controls in the form of:

- quotas and non-automatic licensing,
- complex conformity assessment procedures, often combined with unique national standards

⁵⁵ “Malaysia: Duties & Taxes on Motor Vehicles.” Malaysia Automotive Association, 1 Sept. 2018, http://www.maa.org.my/pdf/duties_taxes_on_motor_vehicles.pdf

⁵⁶ “Guide on: Automotive Industry (Excluding Commercial Vehicle).” Royal Malaysia Customs Department Sales & Service tax Division Putrajaya, 23 Aug. 2018, [http://mysst.customs.gov.my/assets/document/Guide%20On%20Automotive%20Industry%20\(Excluding%20Commercial%20Vehicle\).pdf](http://mysst.customs.gov.my/assets/document/Guide%20On%20Automotive%20Industry%20(Excluding%20Commercial%20Vehicle).pdf)

⁵⁷ Ministry of International Trade and Industry. “Review of National Automotive Policy.” Official Portals of the Ministry of International Trade and Industry, 28 Oct. 2009, <https://www.miti.gov.my/index.php/pages/view/1449>

- high taxation levels and
- national or green car policy programs.

These continue to be impediments to trade flows of both vehicles and components across ASEAN.

ASEAN Automotive Overview

Governments usually view the automotive sector as a key pillar for industrialization and economic growth. In ASEAN, the sector — which includes finished vehicles, parts and components — has thrived in recent years. Significant growth has been the result of a myriad of favourable government policies targeting both domestic and foreign markets, coupled with strong economic growth in the region.

Key ingredients in the industry's capability of becoming a more significant player on the global stage will be determined by how ASEAN governments and industry firms play to their potential strengths and how the sector will be able to address the inevitable competitive challenges that will emerge from new powerhouse automotive economies like China and India. There is a "window of opportunity" for ASEAN producers before China and India become critical global players.

The emergence of tariff-free automotive trade within ASEAN represents an important step in the pursuit of stronger economies of scale. This scale and greater integration in global industry supply chains will be a critical element in arming the ASEAN industry to be a strong competitor well into the future.

While the emergence of tariff-free automotive trade within ASEAN represents an important step in the pursuit of stronger economies of scale, the ASEAN automotive industry is still heavily protected with both high MFN tariffs for non-ASEAN imports and a broad suite of NTMs and NTBs that currently interferes with the creation of a genuinely integrated automotive industry across ASEAN.

For the automotive sector as a whole, ASEAN automotive issues encompass broad areas including taxation, safety and environmental standards, customs procedures, certification processes, inspection and testing arrangements, and the incentivization of specific types of vehicle under "green" or "national champion" initiatives. Each of these measures adds cost to the automotive industry and to consumers, delays the delivery of new technologies, and frustrates the creation of a genuinely-competitive global industry. Unless a way is found to understand the implications of NTMs and to deal them, the ASEAN automotive industry will increasingly operate at a sub-optimal level.

A failure to effectively address unjustified, difficult, and costly NTBs will increasingly negate much of the competitive advantage that can be expected to emerge from the growing economies of ASEAN. In essence, it risks being a case of "two steps forward and one step backwards."

This report complements existing work identifying and assessing NTMs and NTBs affecting the automotive sector within and outside ASEAN. It does this by identifying a range of the NTMs in the automotive industry that exist throughout ASEAN, highlighting their impact on a wide range of ASEAN industry participants and

encouraging the pursuit of greater regional integration through a series of ASEAN level recommendations.

Identifying, assessing and eliminating NTBs within the automotive sector will not be easy in many individual economies. But the work is essential if the ASEAN automotive industry is to be able to address the inevitable headwinds that will be encountered ahead, to secure the benefits of true regional integration, and to successfully grow into a formidable global competitor.

Automotive Industry Outlook

The groundwork for an automotive sector in the ASEAN region started with Thailand in the 1960s leading the way by encouraging a domestic manufacturing base. Malaysia and Indonesia followed suit some 20 years later. These government initiatives catapulted the ASEAN automotive industry to be the fifth largest automotive market in the world and a global production hub, boasting three million auto sales and producing approximately four million cars and trucks per year.⁵⁸ With the inclusion of automotive parts and accessories, as well as other types of automotive classes, the contribution to the sector would undoubtedly be higher. According to Oxford Economics, the gross output of the motor vehicles and parts sector in ASEAN in 2014 was nearly \$125 billion. Furthermore, it generated around 5.3% of global value-added output in the sector.⁵⁹

A major catalyst for the growth in the automotive sector was, in part, due to governmental policies aimed at increasing domestic input. Coupled with strong economic growth in the region, the automotive industry continues to sustain strong demand, due to a rapidly growing consumer demand and a booming construction industry. This was further supported by data highlighting a general increase in vehicle sales from 2014 till 2017.⁶⁰

Despite strong growth in the economic front, much of the ASEAN region still exhibits relatively low GDP, particularly when compared to advanced economy standards. Consequently, the vehicle penetration rate in ASEAN remains low, with an estimated 75 cars per 1000 inhabitants across the region as compared to the world average of 170 cars.⁶¹

However, real GDP is forecast to grow by 4.6% per annum, increasing as household disposable income rises. As such, the average number of cars per 1000 inhabitants in ASEAN could rise to as much as 220 by 2030.⁶² Coupled with the fact that ASEAN is strategically located between two of the world's largest and fastest growing automotive markets, it is predicted that compound annual growth rate (CAGR) of automotive production by the ASEAN-5 countries⁶³ will reach 3.7% by 2020, with nearly half of the world of all new cars in the registered in the world in either China or India by 2030.⁶⁴

⁵⁸ "ASEAN Automotive: A Huge Potential" Ipsos, 7 Sep. 2016, <https://www.ipsos.com/en/asean-automotive-huge-potential>.

⁵⁹ Oxford Economics. "Non-tariff measures on the automobile industry: Quantifying the impact on the ASEAN economy." Oxford Economics, Aug. 2015.

⁶⁰ "ASEAN vehicle sales up over 4% in 2017 – ANALYSIS", Just Auto, 30 Jan 2018, https://www.just-auto.com/analysis/asean-vehicle-sales-up-over-4-in-2017-analysis_id180969.aspx,

⁶¹ Oxford Economics. "Non-tariff measures on the automobile industry: Quantifying the impact on the ASEAN economy." Oxford Economics, Aug. 2015.

⁶² Oxford Economics. "Non-tariff measures on the automobile industry: Quantifying the impact on the ASEAN economy." Oxford Economics, Aug. 2015.

⁶³ Malaysia, Indonesia, Thailand, Vietnam and the Philippines

⁶⁴ Tikon L, "ASEAN Automotive Outlook", LMC Automotive, 2016, <http://data.thaiauto.or.th/iu3/images/stories/PDF/aiu59/seminar%20AIU59%20-8-7-2016.pdf>

These high growth figures might not be achievable, however, as factors threaten to reduce growth of vehicle ownership in the region such as congestion, poor infrastructure, or a continued pace of urbanization and increasing population density leading to an increased use of public transport.

The automotive industry in ASEAN is also making an increasingly significant contribution to regional economies and to the broader global industry. As Table 7 shows, production in 2017 exceeded 4 million motor vehicles or 4.2% of global production.

Table 7: A Global Automotive Industry Comparison⁶⁵

	2017 Production
ASEAN	4,047,196
China	29,015,434
European Union	18,717,845
India	4,782,896
Japan	9,693,746
Korea	4,114,913
North America	17,458,189
Total global production	97,302,534

The sector has also become a large employer in economies like Thailand, Indonesia and Malaysia, where production reached 3.8 million — 92% of total regional production — in 2017. Similarly, in 2017 sales in those three countries amounted to 2.5 million — 75% of total regional sales as shown in Table 8. Overall, the sector has the potential for strong growth well into the future as per capita incomes grow, economies develop, new investment flows and export markets open.

Table 8: ASEAN Automotive Industry⁶⁶

	2017 Production	2017 Sales
Brunei	0	11,209
Indonesia	1,216,615	1,079,534
Malaysia	499,639	576,635
Myanmar	4,930	8,225
Philippines	141,252	425,673
Singapore	0	116,148
Thailand	1,988,823	871,650
Vietnam	195,137	250,619
Total	4,047,196	3,339,693

⁶⁵ International Organization of Motor Vehicle Manufacturers. "2017 Production Statistics." 2018, <http://www.oica.net/category/production-statistics/2017-statistics/>

⁶⁶ ASEAN Automotive Federation, "2017 Statistics." 2017 http://www.aseanautofed.com/files/AAF_Statistics_2017.pdf

Analysis of Automotive NTMs and NTBs in ASEAN

ASEAN automotive NTMs encompass broad areas including taxation, safety and environmental standards, customs procedures, certification processes, inspection and testing arrangements, and the incentivization of specific types of vehicle under “green” or “national champion” initiatives. As noted earlier in this paper, as firms do not make a clear distinction between “measures” which are allowed and “barriers” which are not, this project does not do so either.

For the purposes of this paper, automotive products will be defined as HS code 87: *Vehicles Other than Railway or Tramway Rolling Stock, and Parts and Accessories Thereof*. An analysis of existing data shows that NTMs affecting ASEAN’s automotive industry mainly fall under the same TBT category as conformity assessment procedures and limitations/prohibitions of imports. Globally, UNCTD’S database reveals a total of 2828 reported NTMs that affect the automotive sector, with majority identified as TBT measures, reflecting a variety of standards and technical requirements.⁶⁷

The automotive industry in the ASEAN region has seen an increase in the use of NTMs in recent years. In fact, the ASEAN 5 have all, in recent times, enacted new policies with the direct goal of boosting domestic production and exports. The main policies that have been utilized have been excise tax policies to support domestic firms. Excise tax policy can be used to implicitly — or explicitly — discriminate against imports. This discrimination can be carried out through different methods, such as the application of differential rates or via reference to different tax bases. The main premise in defence of such NTMs has been that the government has to protect their own “infant” automotive industry.⁶⁸ Given the scale of operations by market leaders, they would be able to benefit from economies of scale. Thus, local firms would find it hard to compete on an equal footing.

The total number of NTMs affecting the automotive industry in ASEAN as registered with UNCTAD account for 244 (of 2828).⁶⁹ The Philippines leads the list with the highest number of NTMs followed by Singapore and Indonesia. Figure 5 shows Malaysia and Myanmar imposed the least number of NTMs in automotive products.⁷⁰

As with all basic “counts” of NTMs from the database, these figures may need to be viewed cautiously. It is not the total number of NTMs that always matters, but *what*, concretely, each NTM does to the business environment. It is possible to imagine that a country could have only one NTM, but this measure is so restrictive as to make trade entirely unviable. The country would look much better on a chart like Figure 5, but in reality, the business climate would be abysmal.

Alternatively, a country might do an excellent job of actually being transparent about all NTMs. Thus, the figures look abnormally high relative to others that are less

⁶⁷ “UNCTAD - Integrated Trade Intelligence Portal - Home Page”. Asean.I-Tip.Org.

<https://trains.unctad.org/Forms/ProductViewNew.aspx?mode=modify&action=search>

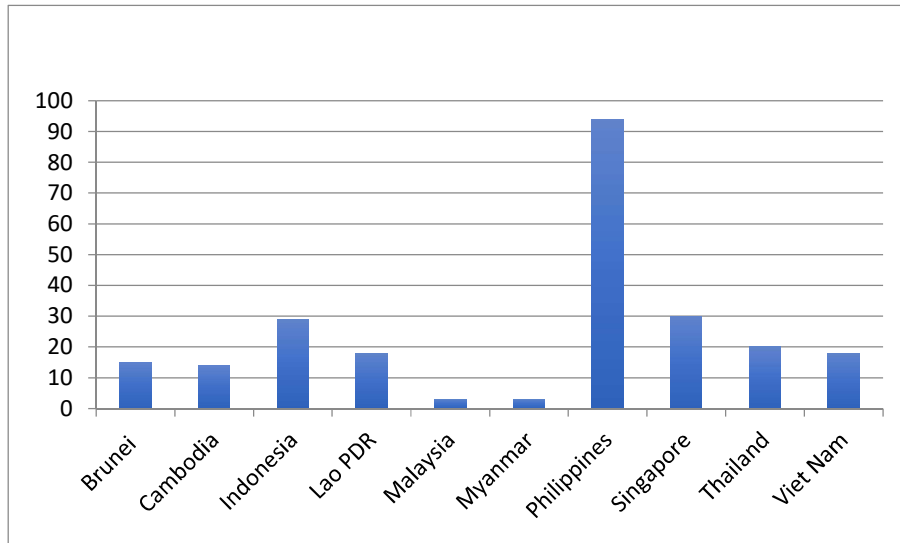
⁶⁸ Nehru, V. “Modern industrial policy: Lesson from Malaysia’s auto industry.” International Economic Bulletin 22 (2012), <https://carnegieendowment.org/2012/03/22/modern-industrial-policy-lessons-from-malaysia-s-auto-industry-pub-47625>

⁶⁹ “UNCTAD - Integrated Trade Intelligence Portal - Home Page”. 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

⁷⁰ “UNCTAD - Integrated Trade Intelligence Portal - Home Page”. 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

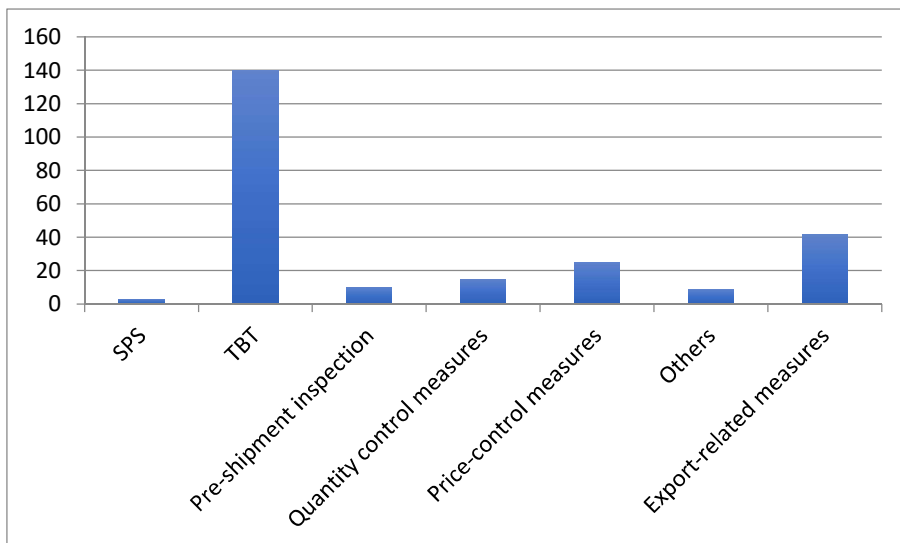
meticulous about recording all possible NTMs into the database. In short, while it can be useful to examine the total number of NTMs and compare them to one another or compare NTMs in one sector to another, it is also important to remember that such blanket figures can disguise many things.

Figure 5: Number of NTMs by Country (ASEAN HS Code 87)



Reflecting global trends, the most commonly identified NTMs in UNCTAD's database for ASEAN's automotive sector are TBT measures as seen in Figure 6.⁷¹ Most of these NTMs fall under conformity assessment procedures and prohibitions or restrictions of imports.

Figure 6: Number of NTMs by Barrier (ASEAN HS Code 87)



⁷¹ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

These NTMs cover most of automotive and its corresponding parts. A 2013 study found that over 70% of imports of automotive and corresponding parts and accessories in Indonesia, Singapore, Malaysia, Philippines and Thailand were subjected to some form of NTMs.⁷²

⁷² Austria, Myrna. "Non-tariff barriers: A challenge to achieving the ASEAN economic community." *The ASEAN Economic Community: A Work in Progress* (2013): 31-94.

Interview Findings with Automotive Industry Participants

The following section is based on the results of a series of interviews conducted in September and October 2018 in key ASEAN markets with industry players in automotive manufacturing, parts and components. Interview candidates included ASEAN companies as well as foreign players. It does not cover all ASEAN markets, nor highlights all potential issues — only those explicitly raised by interview subjects.

As noted earlier, the “impact scoring” of red/yellow/green was not developed by the firms directly. It was derived from company interviews and by the extent to which a particular barrier was repeatedly raised by firms as well as by how much of an obstacle any specific barrier poses to doing business. The impact score should be viewed as a continuum from red to green, rather than a clear shift from one category to another. As might expected, the charts below reflect few “green” impact scores, as firms typically did not spend time discussing issues that were not viewed as problematic. If viewed across time, however, some of the listed items could very well decline from red to yellow to green or the reverse.




Indonesia

Indonesia’s automotive manufacturing industry is the second-largest in ASEAN. It accounted for 30% of ASEAN’s 2017 motor vehicle production and is largely focused on supporting domestic sales demand. Indonesia’s industry is highly protected and in recent years has been focused on a *Low Cost Green Car* (LCGC) Program with significant tax concessions provided for cars of certain emission levels, price thresholds and local content.⁷³ In addition, its approach includes high MFN tariff and taxation levels and a focus on quantitative import restrictions for key components as well as audit, certification and product testing requirements.


Technical Barriers to Trade

Category	Description	Impact
Labelling Requirements	<u>Complex Labelling Requirements</u> Labelling requirements surround component and parts importation in Indonesia. Labels are required to be in Bahasa Indonesia and to incorporate a range of safety, health and importer information.	 Yellow
National Product Requirements	<u>Unique National Standards:</u> Indonesian National Standards (SNI) requirements surround importations in Indonesia. The coverage of mandatory standards includes tyres, safety glass and windshields. Under SNI standards an Economic Commission for Europe (ECE)/ASEAN compliant vehicle would not meet the requirements for local approvals.	 Yellow


⁷³ Sigr, Daihatsu “Low Cost Green Car to Boost Indonesia’s 2016 Car Sales.” Indonesia-Investments, 13 August 2016, <https://www.indonesia-investments.com/news/todays-headlines/low-cost-green-car-to-boost-indonesia-s-2016-car-sales/item7092?>

Conformity Assessment	<p><u>Inflexible and Complex Homologation⁷⁴ Process:</u> A new complex process for new vehicle model homologation has been put in place that does not follow UNCE standards and makes it difficult to certify a new car. It is of special concern because of its inclusion criteria. For instance, companies claimed that a new-model-year vehicle with no regulatory component of performance change, but with a new Vehicle Identification Number (VIN), would be subject to the Homologation procedure.</p>	
Procedural Obstacle – Implementation	<p><u>Regulation Implementation:</u> Multiple participants raised concerns about inconsistencies in the interpretation of regulations. There seem to be no guidelines or explanations guiding the implementation of regulations.</p>	
Procedural Obstacle – Certification Process	<p><u>Lack of infrastructure and manpower</u> Companies raised concerns about the lack of infrastructure and manpower skills, both of which cause delays and problems.</p>	

Pre-Shipment and Other Formalities


Category	Description	Impact
Pre-Shipment Inspection	<p><u>Inconsistent Import Licencing Procedure</u> Pre-shipment inspection must be done by Indonesian customs officers. In some cases, companies need to fly an (or their) audit team over to the overseas manufacturing plant for them to conduct tests. The process can be lengthy and costly for manufacturers.</p>	

Import Licencing




Category	Description	Impact
Licensing for Economic Reasons	<p><u>Inconsistent Import Licencing Procedure</u> Import licencing programme where approved importers require approval to import CBU vehicles. Approvals can be slow to obtain and are subject to variations that coincide with Indonesia's time-to-time policy initiatives to address balance-of-payments and associated economic concerns.</p>	

⁷⁴ Homologation is a widely used term in the automotive industry. It refers to the process of certifying that either vehicles or vehicle components have met and satisfied all the requirements set by various statutory regulatory bodies to be exported.


Trade Investment Related Issues

Category	Description	Impact
Local Content Requirements	<p><u>High Local Content Requirement</u></p> <p>There is a 60% local content requirement that some participants claimed is almost impossible to meet by foreign companies, making it difficult for them to operate in Indonesia.</p>	


Price Control Measures

Category	Description	Impact
Tariff	Non-ASEAN participants raised concerns about an MFN tariff of 40% for imported passenger cars.	
Taxes	<p><u>Import Tax:</u></p> <p>Value Added Tax is as high as 150% for some vehicles.</p>	
	<p><u>Variable and Inconsistent Taxes:</u></p> <p>There are also regional variations to tax rates and different applications depending on the type of vehicle. For example, multi-purpose-vans (MPVs) attract a lower tax rate than passenger sedans and consequently make it very difficult for sedans outside of the LCGC to compete.</p>	

Measures Affecting Competition

Category	Description	Impact
Green Car Initiative (LCGC)	<p><u>Discriminatory Green Car Initiative</u></p> <p>This program offers significant tax concessions and rebates in return for the local production of cars achieving certain emission levels, price thresholds and local content levels.</p> <p>It was introduced in 2013 and is a domestically focused initiative designed to produce an affordable entry car for first time auto buyers. The pricing point of cars in this programme has a significant distortive impact on the broader market and the prospects for sale success of smaller cars outside of the programme.</p>	

Others

Category	Description	Impact
Private Sector Engagement	<p><u>Lack of transparency and consultation in the design and implementation of regulations:</u> Participants raised concerns about the lack of private sector engagement and participation in the design and implementation of policies.</p>	 Yellow


Malaysia


Two “national car” champions, Proton and Perodua, with a domestic market focus, dominate Malaysia’s automotive industry. Malaysia’s production in 2017 accounted for 12% of all the vehicles built in ASEAN. This passenger car focus has been built on high levels of protection including import quotas, local content arrangements, gazetted import valuations and high excise taxes.

Malaysia’s domestic industry is supported by a complex web of complete build up (CBU) import permits, approved import valuations, customs tariffs, high excise taxes and local content tax incentives. Vehicle exports from Malaysia to markets beyond ASEAN have been modest. In recent years, Malaysia has sought to become a regional hub for the production of energy efficient vehicles and high technology vehicle components.


The Mahathir government, sworn in on May 10, 2018, has canvassed the prospect of a new “national car” initiative, but few details have been forthcoming.

Technical Barriers to Trade




Category	Description	Impact
Conformity Assessment	<p><u>Excessive Inspection Assessment:</u> Customs clearances for imported motor vehicles involve a high level of physical vehicle inspection. Used cars attract even higher levels of inspections.</p>	 Yellow
	<p><u>Delays from Procedural Obstacles:</u> These inspections can be time-consuming and delay the removal of vehicles from the waterfront. These delays add to costs.</p>	

Procedural Obstacle – Product Requirements	<p><u>Inconsistent and Discriminatory Application of Product Requirements</u></p> <p>Malaysia adopts and applies a large range of UNECE technical standards. However, there are reported inconsistencies in the application of new regulations. This can lead to locally-manufactured vehicles being allowed a phase-in period while the same concession has not been granted to imported vehicles.</p>	
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Quantity Control Measures


Category	Description	Impact
Permanent Quotas	<p><u>Permanent Quotas:</u></p> <p>An import quota system applies where the volume of imported cars is limited to 10% of the previous year's market production.</p> <p>Import permits and importer approvals are part of the quota system.⁷⁵</p>	

Price Control Measures


Category	Description	Impact
Valuation	<p><u>Non-Transparent Valuation Process</u></p> <p>Gazetted valuation involves a valuation system where the value of imported Completely Built Up (CBU) motor vehicles needs to be established and approved by the government. This approved value then forms the basis on which all duties and associated charges are calculated. This process is time-consuming, inconsistent with transaction-based methodologies, not readily transparent and varies from WTO valuation codes.</p>	
Taxation	<p>High excise tax rates for passenger cars of between 75% and 105% (versus 0 for commercial vehicles).</p>	
Customs Duty	<p>Non-ASEAN participants raised concerns about the current MFN tariff. The MFN tariff for passenger cars and commercial vehicles is 30% (0% for ASEAN-sourced cars).</p>	

⁷⁵ Malaysia has recently revised its policies on the Approved Permit (AP) system for vehicles and motorcycles to ensure that only Bumiputera entrepreneurs are allowed to obtain APs. See the March 14, 2019, press statement at: <https://ongkianming.com/2019/03/14/media-statement-miti-aims-to-be-fully-transparent-on-the-issuance-of-open-approved-permits-aps-for-vehicles-and-motorcycles/> accessed on March 20, 2019.

Trade Related Investment Measures

Category	Description	Impact
Local Content Measures	<u>Local Content Tax Liability</u> . This provides significant protection for locally produced passenger cars, which are further able to use their local content levels to achieve discounts on their tax liability.	 Red

Measures Affecting Competition


Category	Description	Impact
Green Car Initiative	<u>Customized incentive packages for National Companies:</u> A new automotive policy framework seeks to encourage the local development of energy efficient vehicles. This new programme is still being finalized and is somewhat opaque in that incentive packages can be negotiated on a company-by-company basis and include a suite of investment incentives, tax incentives, infrastructure support and duty concessions. There is also a risk of different interpretations by different government ministries.	 Red




Singapore

Singapore does not have a domestic motor vehicle manufacturing industry. However, it has sought to limit the volume of vehicles on its city roads via a series of policy initiatives including import quotas and very high taxation/registration charges. It also requires the local certification of new vehicle models and specific safety/emissions components.




Singapore's automotive trade barriers are designed to control congestion in the city-state as opposed to the primary objective of other ASEAN economies of protecting emerging domestic manufacturing industries.

Technical Barriers to Trade


Category	Description	Impact
Registration Requirements for Importers	<u>High Registration Fees:</u> The most burdensome fee is the additional registration fee (ARF). A car with an open market value (OMV) of S\$75,000 incurs an ARF liability of S\$107,000.	 Yellow


Product Quality Standards	<p><u>Safety Standards</u></p> <p>New cars are required to comply with recognised global safety standards covering 52 items including fuel economy and emissions standards.</p>	
Conformity Assessment	<p><u>Long Inspection and Certification Process:</u></p> <p>Vehicles are also subject to inspection. The certification and inspection process required for homologation can be time consuming with the process requiring up to four months for a vehicle importer.</p>	
	<p><u>Repeated testing and homologation:</u></p> <p>Cars are required to be re-tested and re-homologated again and again. This process may take up to four months.</p>	

Price Control Measures

Category	Description	Impact
Taxation	<p><u>High Excise Duty:</u></p> <p>Excise duty of 20%.</p>	
	<p><u>Tiered Registration Fee</u></p> <p>Additional registration fee, tiered rate, ranging from 100% for the first 20,000 SGD to 180% above 50,000 SGD.</p>	
	<p><u>Tax for Used Cars</u></p> <p>In addition to other taxes, a used car surcharge of S\$10,000 per used car is payable.</p>	

Quantity Control Measures

Category	Description	Impact
Import Quotas	<p><u>Volume Restraint and Certificate of Entitlement</u></p> <p>A volume restraint is applied at the point of vehicle ownership to limit vehicle growth. In recent years, a vehicle quota system (VQS) has tightened annually. It is now 0.25% per annum. Furthermore, a person must have a certificate of entitlement (COE) to be able to register a new car. A COE can be bought at auction and give the right to ownership and road use for 10 years. A quota premium must be paid after 10 years if an owner wishes to keep the car.</p>	

Restriction of Imports	<u>Restrictions of Imports</u> Used Cars: Only used cars that are less than three years old can be imported and registered.	
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Thailand






Thailand is regarded as having the strongest automotive industry in ASEAN. Its production in 2017 accounted for nearly half of all vehicles built in the region.

Thailand has built its industry on the foundation of high protection (both tariffs and NTMs), free trade zones and strong foreign investment encouragement. It has attracted global vehicle manufacturers and parts suppliers. An initial focus on pick-up trucks has seen Thailand become a regional production hub for these vehicles. This early emphasis has now been complemented by an Eco Car Program designed to encourage the development of smaller, fuel-efficient passenger cars. The Eco Car Program has prescriptive local content and production volume elements. The production volume element has the capacity to be viewed as a significant export incentive as it is unlikely that the Thai domestic market will be able to absorb the required vehicle production volumes of the approved manufacturers.




Thailand also holds high MFN tariff and taxation levels, unique mandatory technical standards for key components and unique type approval process for vehicles.

Technical Barriers to Trade


Category	Description	Impact
Product Requirements	<u>National Standards</u> Use of national technical standards related to emissions, seat-belts, glass and tyres.	
Certification Requirement	<u>Lengthy Certification Process</u> Certification of these components can be time consuming in that it requires Thai and/or Thai-witnessed testing in overseas facilities.	
Labelling Requirements	<u>Additional Labelling Requirements</u> Eco stickers: Vehicles sold in Thailand must display eco stickers at the point of sale. These labels include information related to fuel consumption and safety features.	


<p>Authorization Requirements</p>	<p><u>Complex Approval Procedure</u></p> <p>To secure approval for the eco stickers, the approval of three different government agencies (Excise Tax, Thai Industry Standards Institute and the Office of Industrial Economics) and a re-confirmation of some test results must be sequentially obtained.</p>	
<p>Conformity Assessment</p>	<p><u>Lengthy and Inconsistent Homologation Process</u></p> <p>A lengthy vehicle-type approval process by the Department of Land Transport that can include unclear approval criteria with reliance on officer discretion.</p> <p>It is common for industry participants to regularly encounter complex regulations and unclear processes across a wide spectrum including customs, and technical and regulatory approvals for vehicles, production components and spare parts.</p>	
	<p><u>Lengthy Customs approval process:</u></p> <p>Complexity of customs free zone operations and slow approval processes for vehicle release. It includes a very tedious documents check by Thai Customs for FTA imports, zero tolerance for even the smallest mistakes in documents, e.g. even for obvious typing errors. Very low acceptance of other countries' interpretations of the rules make it difficult (oftentimes impossible) to find a compromise between the exporting country's authorities and Thai Customs.</p>	
<p>Standards (Automotive Parts)</p>	<p>Thailand Industrial Standard Institute (TIRI) safety standards for:</p> <ul style="list-style-type: none"> • Safety glass: UN Certified products are not accepted, and importers must re-test their products. • Tyres: These require labels which might force manufacturers to change the materials of the tyres. 	
<p>Conformity Assessment (Automotive Parts)</p>	<p>Homologation for</p> <ul style="list-style-type: none"> • Safety belts, with no local testing facilities. • Homologation for tyres before and after being assembled into the vehicle. 	

Price Control Measures

Category	Description	Impact
Customs Duty	<p><u>High MFN Tariff</u></p> <p>Non-ASEAN participants raised concerns about an 80% tariff levied on imported vehicles. This is the highest among automotive manufacturing economies in ASEAN and is up to double the MFN tariff rate of the other major automotive production economies in ASEAN – Malaysia and Indonesia.</p>	
Valuation	<p><u>Complex and Difficult Valuation Process</u></p> <p>Complex valuation demands and processes for imported vehicles and parts. Some participants claim it is hard to argue more than 2% difference with the declared value.</p>	
Taxes and Charges for Sensitive Product Categories	<p><u>High Excise Tax</u></p> <p>Participants expressed concerns about the way in which excise taxes are calculated using a CO2 emission formula. Excise tax varies between 20-50%.</p>	

Measures Affecting Competition

Category	Description	Impact
Eco Car Program	<p><u>Eco-car program:</u> The eco-car phase two program offers significant investment and tax concessions for cars that meet certain emissions levels, incorporate specific locally-produced components and meet minimum production thresholds. Eight manufacturers have received investment approvals under the program. The volume requirements (800,000 units pa if all 8 producers achieve the threshold) will place significant export pressure on the Thai industry and make it very difficult for any similar imported cars to compete in the market.</p> <p>The eco-car tax rate is 12%–14% versus 25%–30% for conventional passenger cars (or 40% for larger-engine cars).</p>	

<p>Selective Tax Rates</p>	<p>Special tax rates available under specific local production programs. These include:</p> <ul style="list-style-type: none"> • A 50% tax reduction for locally-produced HEV/PHEV electric vehicles. • A further reduction to 2% for BEV electric vehicles produced in Thailand under board of investment programs. • A concessional tax rate for e85 and natural gas fuelled vehicles. 	
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
Vietnam

Vietnam’s automotive industry is at a delicate stage. It is relatively small when compared to the more mature industries of Thailand, Malaysia and Vietnam. Its production in 2017 accounted for 4.8% of ASEAN motor vehicle production.




The Vietnamese Government is seeking to develop the industry, including a local vehicle company, as part of the country’s development and industrialization. To cushion its domestic industry from the zero tariffs for ASEAN, Vietnam has introduced a series of contentious non-tariff measures that signal out imported vehicles for complex and time-consuming emissions and safety testing. Furthermore, as tariffs for ASEAN-sourced vehicles were reduced, Decree 116 emerged which required lot-by-lot emission testing and safety inspections of imported vehicles (versus a 36-month requirement for locally-produced vehicles). This resulted in a significant reduction in imported vehicles into the marketplace.

Technical Barriers to Trade


All TBT related concerns raised by participants involve Decree 116. They claimed that this Decree represents a serious challenge to the flow of imported CBU motor vehicles because of its complex, cumbersome and time-consuming demands, including:

Category	Description	Impact
<p>Certification Procedures</p>	<p>Complex vehicle-by-vehicle homologation and certification documentation demands including lot-by-lot paperwork.</p>	
	<p>Complexity of providing documentation certifying an imported vehicle to a lower ‘Euro 4’ standard when source country certification level is ‘Euro 6’.</p>	
<p>Inspection Procedures</p>	<p>Lot-by-lot random safety and emissions testing for each shipment versus a 36-month requirement for locally-produced vehicles.</p>	
<p>Procedural Obstacle</p>	<p><u>Infrastructure:</u> Lack of laboratory and testing capability beyond Hanoi to accommodate the expected volume of imported CBU motor vehicles.</p>	


Price Control Measures

Category	Description	Impact
Customs Duty	<p><u>High MFN tariffs:</u> Non-ASEAN participants showed concerns about MFN tariffs applied to motor vehicles: Motorcycle tariff levels are 50%. Vehicle tariffs levels are 70%.</p>	
Internal Tax	<p>High taxation including on-going ownership and fuel taxes. Special consumption taxes of up to 150%.</p>	
Special Tax	<p>A used imported CBU motor vehicle attracts a special tax of US\$10,000 per vehicle.</p>	


Quantity Control Measures

Category	Description	Impact
Prohibition	<p><u>Ban on used parts:</u> An import ban on used parts has the effect of eliminating the potential use of remanufactured parts in the local automotive manufacturing industry.</p>	

Measures Affecting Competition

Category	Description	Impact
National Car	<p>Decree 125 provides significant assistance through a delayed refund payment mechanism for the domestic automotive industry that is not available to CBU imported motor vehicles.</p> <p>The Decree includes:</p> <ul style="list-style-type: none"> (i) tariff exemptions for imported parts used in the local assembly of motor vehicles with an engine capacity of less than 2.5 litres provided annual production volume thresholds are achieved and (ii) excise tax exemptions for imported parts used in the local assembly of motor vehicles. 	


Finance Measures

Category	Description	Impact
Regulation on Official Foreign Exchange Allocation	All money remitted out of Vietnam must be supported by a contract and must be pre-approved by the Bank of Vietnam. A series of regulatory requirements impede ready foreign exchange flows and trading activity.	 Yellow


The Philippines

The Philippines has long struggled to develop its own automotive manufacturing industry with a variety of policy mixes tried over the decades. It is the smallest of the ASEAN motor vehicle producers with production in 2017 accounting for 3.5% of the vehicles produced in ASEAN. Its industry has been undermined by used car imports and its current taxation arrangements are seen to favour imported small cars and pick-up trucks. In spite of its difficulties in establishing a strong vehicle manufacturing industry, the Philippines has been more successful in building a parts manufacturing industry with a focus on supplying key labour-intensive components like wiring harnesses.


Measures Affecting Competition

Category	Description	Impact
Manufacturing Incentives	As part of a strategy of seeking to become a regional hub, primarily for parts manufacture, a range of government incentives are available in a bid to double domestic manufacturing capacity by 2022. Model eligibility for the “cars program” is based on a minimum 200,000 units of local production over six years.	 Red

Price Control Measures

Category	Description	Impact
Excise Tax	<u>High Excise Tax</u> The automobile excise tax is based on a net selling price. It ranges from 4% for the first p600,000 to 50% above p4,000,000.	 Red

Measures Affecting Competition


Category	Description	Impact
Tax	<p><u>Differential Taxation</u></p> <p>There are significant discounts for alternative fuel cars and commercial vehicles including pick-up trucks. Hybrid vehicles attract a 50% discount and electric vehicles are tax exempt. Commercial vehicles are also tax exempt.</p>	 Yellow

CLM Countries

The automotive markets in the remaining ASEAN countries are not significant. However, firms are still facing a number of non-tariff issues while operating in these markets. In most cases, these barriers are the tools for governments to encourage more investment into local production and manufacturing. In some other cases, the NTBs are the consequences of a lack of regulations or an incomplete regulatory framework. The listed issues were raised by multiple firms.


Cambodia

Price Control Measures

Category	Description	Impact
Taxes	<p>Cambodia creates the cost base for special tax liability, which can range from 30% to 70% depending on the vehicle type and engine capacity, on an MFN duty-paid basis. This has the effect of disadvantaging ASEAN-sourced vehicles, which lose, for tax purposes, the advantage of the import tariff exemption they receive.</p>	 Red


Laos

Price Control Measures

Category	Description	Impact
Taxes	<p>Laos has a zero MFN duty rate but has high levels of taxation with motor vehicle consumption tax rates ranging from 25% to 90% depending on vehicle engine capacity.</p>	 Red

Myanmar

Measures Affecting Competition

Category	Description	Impact
Market Access	<p><u>Incentives to discourage manufacturing of CBU vehicles.</u></p> <p>CBU cars cannot be registered in the city of Yangon and must pay a registration fee of 83.3%.</p> <p>This is a result of a push to produce SKD vehicles, which enjoy several market benefits. The policy limits consumer choices to roughly 10 models.</p>	 Red

Automotive Sectoral Recommendations

While this project is not specifically about making recommendations in each of the three sectors under study, it would be a missed opportunity to take the feedback from myriad automotive companies and fail to provide specific sectoral recommendations to help resolve some of the issues raised by firms. These suggestions for improvement are not designed for individual ASEAN Member States, but for the region as a whole.

Taken collectively, the study has raised a number of automotive-specific non-tariff issues that are worthy of addressing at the regional level. It seems clear from the interview processes that existing ASEAN approaches to resolving some of these concerns have, thus far, failed to effectively tackle these barriers to trade in the region. Given ASEAN's own objective of creating an integrated production platform for vehicles and parts, many issues should be resolved as quickly as possible.

The first, most important recommendation for the sector is that ASEAN cannot build the integrated production base for the sector until and unless member states begin to "Think ASEAN." Increasingly, members seem to be moving down the track of pursuing individual country objectives, resulting in a highly fragmented sector that is damaging the growth prospects of every single ASEAN member state. On their own, each market is simply too small to be viable.

ASEAN has taken steps towards the harmonization of standards and conformity assessment processes for automotive products, but the interview data shows firms find the results — even in this limited area — unsatisfactory thus far.

ASEAN has an Automotive Product Working Group (APWG), which ought to be driving work towards resolving many of the non-tariff issues discussed above. Instead, much of the focus seems to have been around the development of multiple mutual recognition agreements (MRAs), which focus around the harmonization of standards. These MRAs clearly do not guarantee the reduction of NTBs.

APWG has undertaken the harmonization of automotive products by developing agreements to align national standards or technical requirements with the United Nations Economic Commission for Europe (UNECE) Regulations of the 1958 Agreement.

As part of its mandate, the APWG:

- undertakes the exchange of information on standards, rules and regulations;
- reviews and analyses those regulatory regimes;
- identifies areas for possible harmonization and MRAs;
- develops sectorial MRAs; and
- identifies technical infrastructure needs in conformity assessment.⁷⁶

As part of its work, the APWG is currently developing the ASEAN MRA on Type Approval of Automotive Products, which provides a mechanism to recognize the

⁷⁶"ACCSQ Structure." Association of Southeast Asian Nations, 18 Oct. 2012, https://asean.org/?static_post=accsq-structure.

testing, and inspection results of the product from the source country in ASEAN by the importing member states.⁷⁷ Under the MRA, states will also commit to ensure that no re-testing is required for components and systems that are already compliant with UNECE regulations according to the MRA's requirements.⁷⁸ Out of 32 UNECE regulations proposed initially, ASEAN has agreed to harmonize 19 of those regulations for the initial phase of implementation of the MRA.⁷⁹ After making commitments to implement the MRA in 2016,⁸⁰ there is no evidence that it has been successfully put in place.

The APWG lacks the capacity to address many of the issues raised by participant companies in the study. First, there are no guarantees that the development of an MRA ensures that conformity assessment procedures and standards are recognized and that re-testing requirements are eliminated. Similarly, the APWG does not have a mandate that allows it to identify, assess and eliminate other types of barriers. For instance, issues around licensing, taxation and national car initiatives cannot be addressed by the APWG as it is currently set up.

The issues that are specific to automotive may need to be handled directly by a body like APWG, but ASEAN as a whole will need to ensure that the harmonization of standards and certification procedures and related commitments are appropriately developed and, more urgently, actually implemented. There is still divergence in standards and conformity assessment procedures across multiple markets within the region and there are no mechanisms or bodies in place to monitor or ensure that member states actually follow those commitments. It is important that the APWG not only develop MRAs, but track their effectiveness and implementation.

Second, it is important that ASEAN develops an institutional mechanism or body that would allow it to tackle NTMs that are not related to technical and conformity assessment standards. Currently, none of ASEAN's commitments or bodies has the capacity to assess or report on some of the measures identified by this report as priority within the automotive sector. At the moment ASEAN has no specialized mechanism to address concerning issues around taxation, national car initiatives and non-compliant conformity assessment procedures — the issues at the top of the list for automotive companies operating within the region.

Therefore, it is essential that as a regional body, ASEAN develops mechanisms that ensure that dialogue with private sector stakeholders is constant and that there is an institutional body capable of acknowledging and addressing these priority issues.

For the automotive sector specifically, ASEAN should address: 1) controls in the form of quotas and licensing that can limit the ability of firms to import autos to meet market demands or growth; 2) the use of unique technical standards and type approvals that

⁷⁷ "Automotive Products." ASEAN, Oct. 2015, https://asean.org/?static_post=trade-in-goods

⁷⁸ "11th Draft ASEAN Mutual Recognition Agreement on Type Approval for Automotive Products." 6 May. 2014.

⁷⁹ Land Transport Departments Ministry of Communications Brunei "Press Release: Brunei hosts the 23rd ASEAN Consultative Committee on Standards and Quality (ACCSQ) Automotive Product Working Group (APWG) Meeting." 3 May. 2016. =, http://mtic.gov.bn/ItD/SiteAssets/Site%20Pages/Land%20Transport%20Department/Services/Press%20Release%20of%2023rd%20Meeting%20of%20the%20ACCSQ%20APWG%20Opening%20Ceremony/Press%20Release_23rd%20APWG%20Opening%20Ceremony_020516.pdf

⁸⁰ Land Transport Departments Ministry of Communications Brunei "Press Release: Brunei hosts the 23rd ASEAN Consultative Committee on Standards and Quality (ACCSQ) Automotive Product Working Group (APWG) Meeting." 3 May. 2016.

seem to be proliferating in the region, including complex homologation processes even down to the level of vehicle-by-vehicle approvals with frequent re-testing procedures; 3) the rise of national, green or eco-car initiatives that could be used as a mechanism to distort prices and competition, including unfair taxation policies and other direct subsidy schemes that privilege domestic firms over foreign players; and 4) high taxation and other price control measures that distort the market.

II. The Agri-Food Sector in ASEAN

The Agri-Food sector is very important for the ASEAN economy. Beyond feeding citizens, the sector is important for many ASEAN Member States for shoring up food security, ensuring economic and social growth, and as an important source of export earnings. Beyond the direct employment in the sector, the food and beverage industry as a whole contributed US\$108 billion in sales in ASEAN in 2015. This is projected to rise to US\$164 billion by 2020, with increasing demand for processed and packaged food items.⁸¹

The trade of agri-food products remains a priority for ASEAN, which relies on the sector for growth.⁸² Food Industry Asia notes that the food and beverage sector in ASEAN continues to grow with total values of sales to rise to US\$164 billion in 2020.⁸³ Nevertheless, intra-ASEAN trade in products like pre-packaged foods has been more limited than would be expected — under half the value of extra ASEAN trade.⁸⁴ As a result, there is considerable potential for further agri-food trade within the ASEAN region.

Since tariffs are now zero for nearly all agri-food items crossing borders within ASEAN, the gap between the actual and projected size of the ASEAN markets, particularly for processed and packaged food and beverage items, could be explained by the existence of NTMs that have become NTBs.

Across ASEAN, UNCTAD data shows agriculture continues to exhibit the highest number of recorded NTMs.⁸⁵ Partly this is a function of the method of record keeping, since NTMs are noted specifically in sanitary and phytosanitary (SPS) areas, which map precisely to agri-food sectors. This makes it somewhat easier to note issues in the sector than in some other sectors or industries that cross between measurable NTMs (such as between SPS and TBT complaints) and trade challenges in areas not easily captured (or captured at all) by existing data collection (such as speed of procedures).

Agri-food is an interesting sector, of course, because governments have an important role to play in ensuring that human, animal and plant life and health are not compromised. Hence there are a wide range of allowable measures (NTMs) that governments can legitimately take to regulate for safety. Such distinctions have been codified in trade agreements from the World Trade Organization's SPS rules and

⁸¹Australian Department of Foreign Affairs and Trade. "Why ASEAN and why now? Insights for Australian Business." AusCham Vietnam, 2017, <https://auschamvn.org/why-asean-and-why-now-insights-for-australian-business-launched-by-australian-trade-minister/>

⁸²OECD/FAO. "OECD-FAO Agricultural Outlook 2017-2026." OECD Publishing, 2017, <http://www.fao.org/3/a-i7465e.pdf>

⁸³ Food Industry Asia (FIA), "Removing Non-Tariff Barriers in ASEAN through Regulatory Convergence and Mutual Recognition in the Food Sector." FIA, 2018, 8. <https://foodindustry.asia/documentdownload.axd?documentresourceid=30842>

⁸⁴ Food Industry Asia (FIA), "Removing Non-Tariff Barriers in ASEAN through Regulatory Convergence and Mutual Recognition in the Food Sector." FIA, 2018, 8. <https://foodindustry.asia/documentdownload.axd?documentresourceid=30842>

⁸⁵ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

picked up in ASEAN's own agreements and embedded into ASEAN trade agreements signed with other dialogue partners.⁸⁶

While NTMs are allowed for agri-food, such appropriate actions do appear to have slipped across into non-tariff barriers (NTBs) for many specific practices outlined by firms in this project.

As noted elsewhere, however, since firms do not always recognize the difference between NTMs and NTBs, this project simply reports on all non-tariff issues as relayed by interviewed firms.

Firms operating in the agri-food sector frequently report facing regulatory and technical constraints that create delays, impose costs, increase risks and add unnecessary complexity. Overall, a lack of harmonized regulatory requirements for agri-food products in the region represents significant costs for trading businesses and as a result presents a significant negative impact on trade, especially intra-regional food sector trade. Assessing the extent of these costs is not possible in the scope of this current study.

The agri-food sector is very large, containing products as varied as live animals to processed frozen foods and beverages. To effectively survey NTBs in the sector required narrowing down the scope. This project therefore identifies and assesses barriers in three different agri-food subsectors: alcoholic drinks, seafood and biscuits. All three are produced and consumed in most ASEAN Member States, traded across borders, and imported from abroad. These three sub-sectors were chosen because they should vary greatly in the extent to which firms face regulatory barriers to trade.

Alcohol is one of the most highly regulated products in ASEAN. Biscuits ought to face limited sector-specific obstacles to trade. Seafood sits in the middle. Hence this project was designed to interview companies in these three sectors to highlight the NTBs that were perceived to be the most burdensome for firms.

⁸⁶ See the WTO's SPS rules and other materials at https://www.wto.org/english/tratop_e/sps_e/sps_e.htm, ASEAN's SPS information at <https://atr.asean.org/read/sanitary-and-phytosanitary-sps-measures/62>, and a sample of an ASEAN FTA under the ASEAN/Australia/New Zealand FTA Chapter 5 at <http://aanzfta.asean.org/trade-in-goods/sanitary-and-phytosanitary-sps/>. All websites accessed on February 1, 2019.

A. Alcoholic Drinks

Case Study Alcoholic Drinks Sub-Sector- Importing a Spirits Bottle into Thailand

The total size of the Thailand alcoholic beverage market in 2016 was approximately 3.1 billion litres. Thailand is ranked 72nd for alcohol per capita consumption in the world. Consumption is dominated by beer and spirits, which make up 73 and 26% respectively of the total alcohol consumed. The Thai spirits market offers opportunities for both low-cost local and imported premium spirits. Nevertheless, there are a series of existing regulations that make it costly and increasingly difficult to import alcoholic drinks into Thailand. This case study explores some of those barriers from the perspective of an alcoholic drinks company trying to import a bottle of a spirits into Thailand. The analysis is based on issues raised by ASEAN based firms who participated in the study “Assessment of ASEAN NTBs and Net Benefits of Elimination” under the Enhanced Regional EU-ASEAN Dialogue Instrument (E-READI) cooperation program.

Thai Specific Standard Certification Requirements

Imported alcoholic beverages first need to comply with Thai-specific standards to obtain an import permit. Beginning on September 2019, the Thai Government will require that all importers of alcoholic beverages submit a Certificate of Analysis (COA) for importation. This requires importers to submit specific documentation or samples for COA testing to obtain an import license. Under the requirement, Importers will incur additional costs by having to use a Thai industry specific format, content and methodologies that are inconsistent with COA from the country of origin, and thus have the potential to significantly increase their compliance costs. Overall, the COA requirement does not follow international standards and represents a significant barrier to alcohol importers that incur additional costs and time to demonstrate compliance.

Strict and Costly Labelling Requirements

Furthermore, imported alcoholic beverages must meet strict and costly labelling requirements to ensure they can be sold in the Thai market and do not incur risks of penalization.

The Procedure and Condition for Labels of Alcoholic Beverages 2015 prohibits the use of quality claims like “premium” or “deluxe” or cartoon images in alcoholic drinks labelling; and disregarding any evidence, trademark, geographical indicators or international standards associated with those labels.⁸⁷ The lack of guidelines specifying the messages permitted or prohibited and inconsistent interpretations of those guidelines, may also create uncertainties for importers under the risk of trade

⁸⁷ European Association for Business and Commerce (EABC) “2018 European Business Position Paper.” EABC Thailand, 2018.

disruption as a result of non-compliance.⁸⁸ If found non-compliant, alcoholic beverages importers using quality claims or any figures or drawings on their labels, will be restricted from entering the Thai market. This may lead to additional transportation costs to return non-compliant products, increase stock and inventory carrying costs and lead to sales losses. Moreover, if the importer wants to mitigate the risk of non-compliance, it needs to ensure that its labels do not use any quality claims or drawings. To do so, importers of alcoholic drinks will have to incur significant costs to create entirely new and separate labelling processes for their Thai inventory.

Alcohol importers may also incur significant cost as a result of the proposed Graphic Health Warning Law, which seeks to impose a tobacco-style pictorial health-warning graphic covering a substantial area of the labels and packaging materials.⁸⁹ The proposal requires all alcohol distributors to use four-selected colour Graphic Health Warnings in every batch of liquor they sell. The measure will create additional labelling costs for alcohol manufacturers, who need to modify their labelling procedures to ensure that every label has a colour pictorial health warning. Moreover, the measure will not only create additional costs for alcohol importers, but also damage the trademark value of alcoholic drinks sellers.

Costly, Inconsistent, Complex and Discriminatory Taxation

In addition, alcohol importers are also subject to a costly, inconsistent and complex taxation system. Thailand implements a hybrid taxation system where an excise tax is levied on alcohol quantity and an ad valorem tax is levied on the value of the product — determined by the products' Expected Retail Price.⁹⁰ Under the tax reform, the company is subject to a 20% ad valorem tax based on the bottles suggested retail price and 255 THB (\$8.14 USD) excise tax per litre of pure alcohol. In addition, earmarked taxes of 17.5% are imposed on alcohol excise taxes for allocation to causes like communities, activities and public health funds. The imposition of high ad valorem, earmarked and excise taxes are inconsistent with international best practices and create an uneven playing field. While imported liquors experienced substantial price increases, locally produced and lower-priced liquors such Lao Khao are favoured by the reforms. The disproportionate imposition of high excise, ad-valorem and earmarked taxes distort competition between local and foreign firms and make it increasingly costly to import alcoholic beverages into Thailand.

Illicit and Counterfeit Trade

Last, imported alcoholic beverages need to operate in an environment where illicit trade threatens their brand and price competitiveness. High and irregular excise taxation does not only make it difficult to import alcoholic drinks into a market, but it creates incentives for the proliferation of illicit trade.

⁸⁸ European Association for Business and Commerce (EABC) "2018 European Business Position Paper." EABC Thailand, 2018.

⁸⁹ Adcock, Alan. and Le Marquer, Aaron "Graphic Health Warning Thailand." *Managing Intellectual Property*, 24 Sep. 2015, <http://www.managingip.com/Article/3491896/Thailand-New-alcohol-labelling-and-message-requirements.html>

⁹⁰ Preece, Rob. "Excise taxation of non-alcoholic beverages in Thailand: products, approaches, rates and administration." *International Network of Customs Universities*, [http://worldcustomsjournal.org/Archives/Volume%206%2C%20Number%202%20\(Sep%202012\)/07%20Preece.pdf](http://worldcustomsjournal.org/Archives/Volume%206%2C%20Number%202%20(Sep%202012)/07%20Preece.pdf)

Currently, counterfeit alcohol is often produced and sold as “duty free goods” mostly through stores along the borders and on social media platform such as LINE, Facebook and Instagram.⁹¹ The presence of this illicit trade is not only connected to a lack of enforcement, but to high taxation.⁹² This means that foreign brands, subject to higher taxation, are the most impacted from illicit alcohol activities.⁹³ According to some of the study’s participants, the prices of imported wine and spirits through legal channels could be double the price of counterfeit and other illegally imported products. Therefore, firms must incur significant additional costs as a result of a loss of market share — consumers switch and buy lower priced products or switch to other beverage type entirely — and constant surveillance efforts to detect and eliminate counterfeit products.

Thailand’s policies concerning the importation of alcoholic drinks are consistent with practices found across ASEAN, where high and discriminatory levels of taxation, often associated with counterfeit trade, complex licensing procedures and increasingly burdensome labelling requirements continue to be impediments to trade flows for alcoholic beverages.

⁹¹ European Association for Business and Commerce (EABC) “2018 European Business Position Paper.” EABC Thailand, 2018, 120.

⁹² “High Tax, Incentive for Illicit Alcohol.” Spirits Europe, <https://spirits.eu/taxation-economy/high-tax-incentive-for-illicit-alcohol>

⁹³ European Association for Business and Commerce (EABC) “2018 European Business Position Paper.” EABC Thailand, 2018.

Alcoholic Drinks Market Outlook

The alcoholic drinks sector is a rapidly expanding one as consumption around the world increases. ASEAN is heavily involved both as a producer and a consumer. A rising middle class and the recent growth in alcoholic sales and consumptions across ASEAN provide significant opportunities for alcoholic drinks manufacturers selling their products across the region. A dynamic consumer market, solid economic growth and the establishment of middle-and upper-income groups in countries like Malaysia, Singapore and Thailand, have all underpinned the steady growth of ASEAN's alcoholic drinks sector.

However, such opportunities could be undermined by policies and regulations that continue to make it time consuming and costly to sell alcohol in certain regional markets. ASEAN's alcoholic drinks industry is still heavily protected by high MFN tariffs, high excise taxes and a broad suite of technical requirements that make it costly for manufacturers to sell across the region.

Therefore, a failure to effectively address unjustified, difficult, and costly NTBs will increasingly negate much of the growth and opportunities within the alcoholic drinks sector.

ASEAN is involved in production across a range of alcoholic beverage categories. It has producers of spirits operating in a number of countries. On the one hand, most manufactured spirits are traditional products, such as rice-based drinks, or at times a range of international products produced in the Philippines or Vietnam.⁹⁴ On the other hand, countries often import spirits from the European Union or the United States.⁹⁵

ASEAN is also a major producer of beer, which dominates the local markets with high market shares and broad-based product portfolios. Some international brands like Carlsberg or Heineken have large operations in the region.⁹⁶ There are also local breweries with strong market shares in Thailand, Vietnam and the Philippines.⁹⁷

The only countries producing grape-based wine in ASEAN are Thailand and Vietnam, although production is very small and mainly focused on supplying their local markets.⁹⁸

Note that, unlike many products, alcoholic beverages are often covered by geographical indications (GIs), which is a type of intellectual property protection. Under GIs, some products, like Scotch whiskey, can only be supplied from Scotland, as any other product that might otherwise appear to be similar would be missing some essential elements embedded in the production of the beverage that is unique to whiskey made in Scotland. This means that many alcoholic beverages must be

⁹⁴ Shanton, Emms and Sia, "The ASEAN Regional Market for Alcoholic Drinks: A Senior Management Briefing", March. 2011, <http://www.bacchuscult.com/images/docs/old/The-ASEAN-Regional-Market-for-Alcoholic-Drinks.pdf>

⁹⁵ Shanton, Emms and Sia, "The ASEAN Regional Market for Alcoholic Drinks: A Senior Management Briefing", March. 2011, <http://www.bacchuscult.com/images/docs/old/The-ASEAN-Regional-Market-for-Alcoholic-Drinks.pdf>

⁹⁶ Shanton, Emms and Sia, "The ASEAN Regional Market for Alcoholic Drinks: A Senior Management Briefing", March. 2011, <http://www.bacchuscult.com/images/docs/old/The-ASEAN-Regional-Market-for-Alcoholic-Drinks.pdf>

⁹⁷ Jitpleechheep, Pitsine. "ThaiBev riding ASEAN acquisition wave." Bangkok Post, 23 Feb 23. 2018, <https://www.bangkokpost.com/business/news/1416719/thaibev-riding-asean-acquisition-wave>

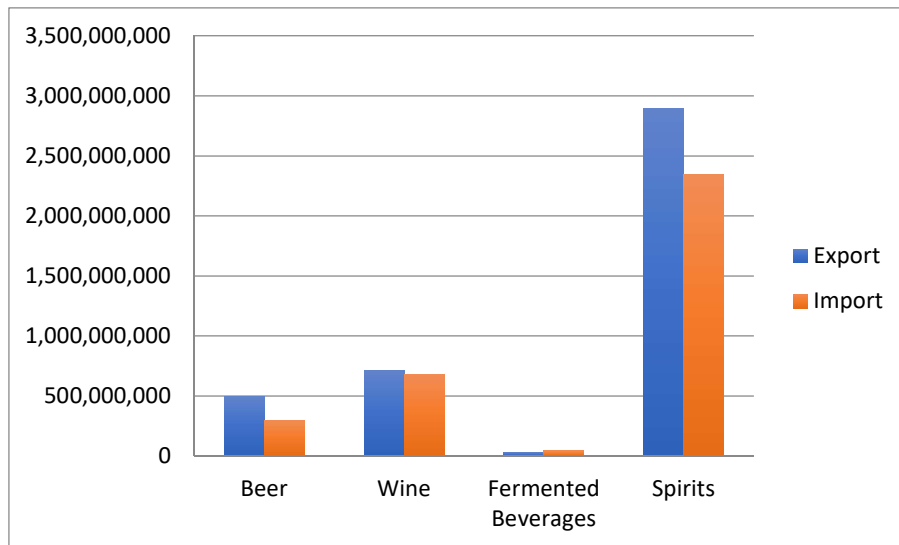
⁹⁸ Shanton, Emms and Sia, "The ASEAN Regional Market for Alcoholic Drinks: A Senior Management Briefing", March. 2011, <http://www.bacchuscult.com/images/docs/old/The-ASEAN-Regional-Market-for-Alcoholic-Drinks.pdf>

imported from abroad, since it is impossible to craft a Scotch whiskey, as an example, in ASEAN.

The importance of GIs to the alcoholic beverage trade is therefore an interesting wrinkle to the NTB story in the region. Since Scotch whiskey has to be imported from Scotland and cannot be crafted locally, it will never compete directly with a local Scottish whiskey brand. It could certainly be in competition with other spirits, but since the driving motivation behind many NTBs is protection of local competitor products, such incentives might be assumed to be reduced for alcohol.

When breaking down trade by the type of drink, as shown in Figure 7, spirits composes the largest majority of ASEAN imports and exports, followed by wine and beer.⁹⁹

Figure 7: Exports and Imports: Alcoholic Beverages in ASEAN (in USD)



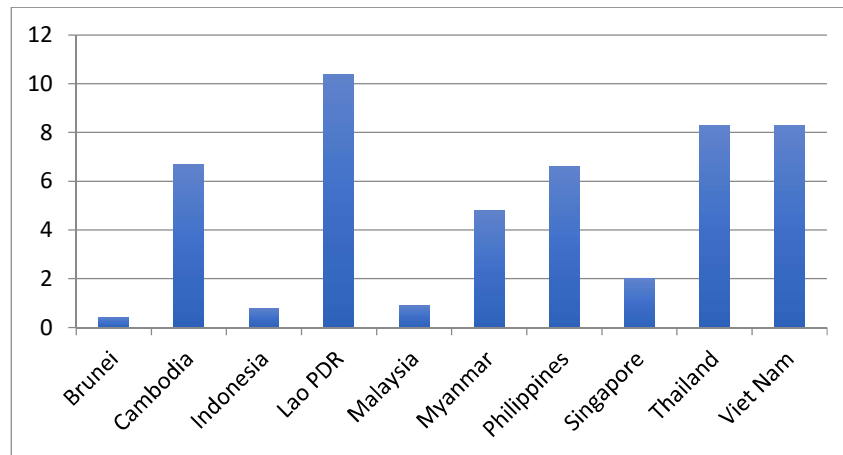
Alcohol consumption in ASEAN has increased substantially. ASEAN's consumption per capita in 2016 was 4.97 Litres of Pure Alcohol (LPA), a 37% increase from 2010.¹⁰⁰ When broken down by country, Laos consumes the most, as shown in Figure 8, followed by Thailand, Vietnam and Cambodia.¹⁰¹ Alcohol consumption was the lowest in countries with stringent drinking laws like Singapore and majority-Muslim countries like Malaysia and Indonesia.

⁹⁹ "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

¹⁰⁰ Shanton, Emms and Sia, "The ASEAN Regional Market for Alcoholic Drinks: A Senior Management Briefing", March, 2011, <http://www.bacchuscult.com/images/docs/old/The-ASEAN-Regional-Market-for-Alcoholic-Drinks.pdf>

¹⁰¹ World Health Organization (WHO). "Global status report on alcohol and health 2018." World Health Organization, 2018).

Figure 8: Alcohol Consumption in Litres Per Capita (2016)



Furthermore, import and export market trends continue to show that ASEAN imports most of its liquor. As shown in Figure 9, imports of alcoholic beverages in 2017 to ASEAN economies were valued at US\$1.97 billion while exports were at US\$357 million.¹⁰² While the growth rate of the ASEAN alcoholic beverages imports was almost 66% between 2005 and 2009, import growth has slowed.¹⁰³

Figure 9: Exports and Imports: Alcoholic Beverages ASEAN (USD)

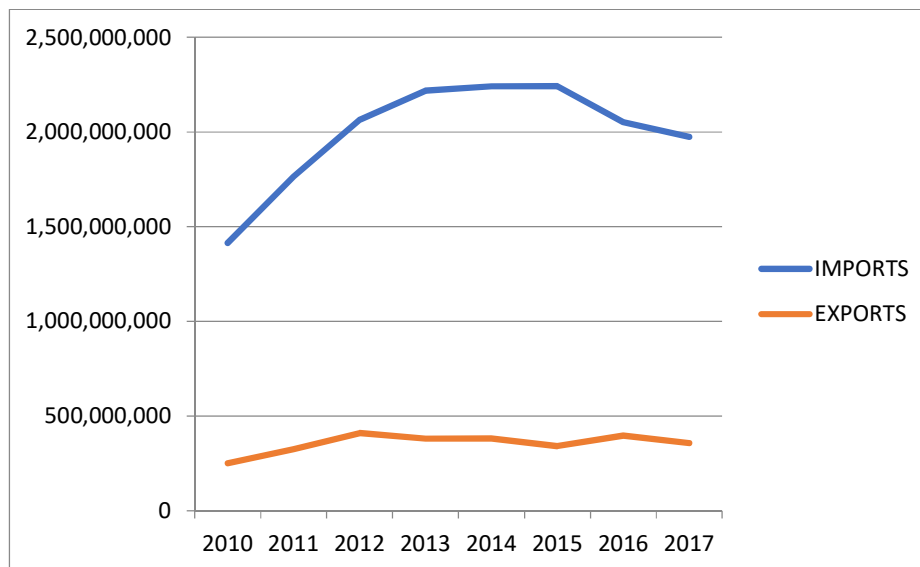


Figure 10 illustrates the current breakdown of alcoholic beverage trade and consumption in ASEAN.¹⁰⁴ In particular, Singapore stands out as the biggest importer

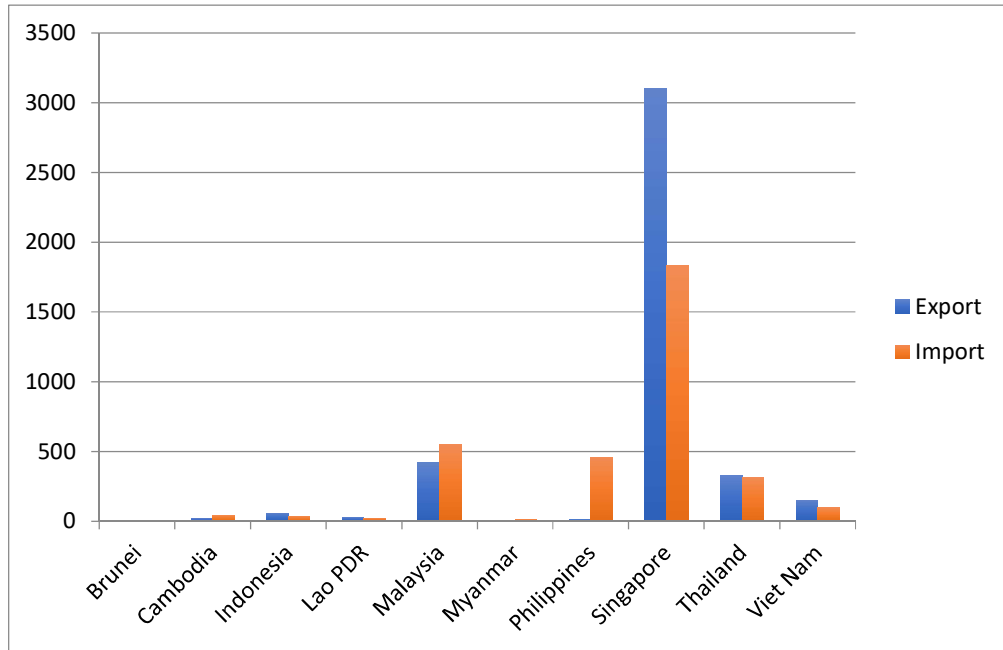
¹⁰² "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

¹⁰³ Shanton, Emms and Sia, "The ASEAN Regional Market for Alcoholic Drinks".

¹⁰⁴ "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

as well as the biggest exporter. This might be because Singapore, which has very small population and consumes relatively little alcohol, is a major re-export base for foreign products.

Figure 10: Imports and Exports: Alcoholic Drinks in ASEAN 2017 (USD Millions)



ASEAN's market for imported alcoholic drinks has an unusual structure in terms of the characteristics of the target markets. In terms of imports, Malaysia is in second, while Philippines, Thailand and Vietnam are in distant third, fourth and fifth place. In terms of exports, Malaysia and Thailand are in distant second and third places. This might be the result of strong local alcoholic drinks industries, especially in the Philippines and Thailand.¹⁰⁵

¹⁰⁵ World Health Organization (WHO). "Global status report on alcohol and health 2018." World Health Organization, 2018).

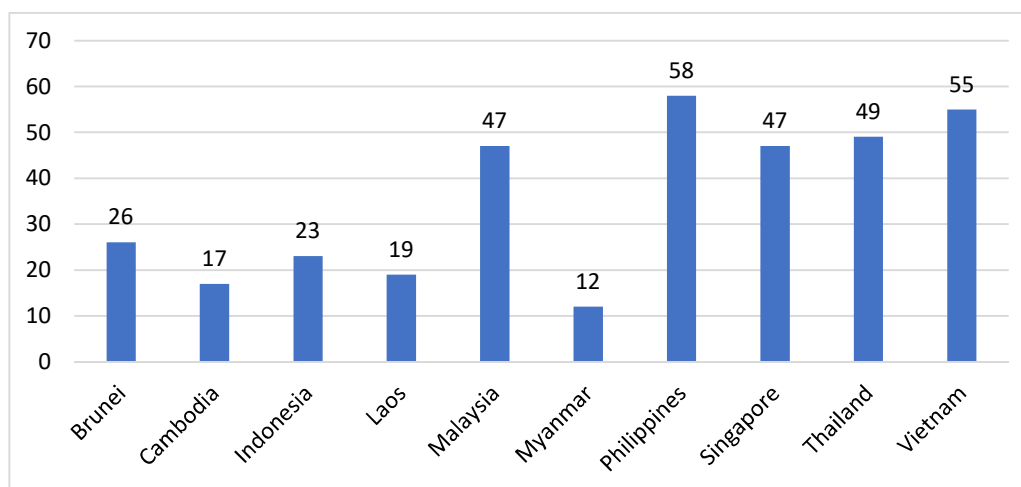
NTBs in ASEAN’s Alcoholic Beverages Sector

ASEAN alcoholic drinks NTBs encompass broad areas including taxation, safety and environmental standards, customs procedures, licensing, inspection and testing arrangements, and restrictions on marketing and advertisements. An analysis of existing data shows that NTMs affecting ASEAN’s alcoholic drink sector are mainly product identity requirements, labelling and packaging, and conformity assessment measures.

Using the UNCTAD study, 2982 NTMs have been reported globally for the alcoholic drinks sector with the majority identified as TBT and SPS measures, reflecting a variety of standards and technical requirements and product safety concerns.¹⁰⁶ Literature assessing NTMs within the alcoholic beverages sector has highlighted trade restrictions of alcoholic beverages in comparison to other traded goods. More specifically, even among the consumables/foods sector, alcoholic beverages experience some of the highest numbers of NTMs. Assessments of NTMs in ASEAN, particularly a very comprehensive one done by ERIA in 2016, have concluded that alcoholic beverages shows the fourth-highest number of NTMs imposed within the food sector.¹⁰⁷

The UNCTAD survey of NTMs for ASEAN’s alcoholic drinks sector shows a total of 244 measures. Figure 11 notes that Philippines, Vietnam, Thailand, Malaysia/Singapore (tied) impose the greatest number on alcoholic beverages.¹⁰⁸

Figure 11: Number of NTMs by Country (HS Codes 2203-2208)



Like the rest of the world, most of the NTMs noted by UNCTAD for ASEAN also fall within the SPS (139 entries) and TBT (134 entries) categories.¹⁰⁹ These are shown in

¹⁰⁶ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>. For the purposes of this paper, alcoholic drinks products have been defined as HS codes 2203-2208: Beer, wine of fresh grapes, vermouth and other wine of fresh grapes, other fermented beverages, like cyder, sherry, mead, undermatured ethyl alcohol of an alcoholic strength above and below 80%.

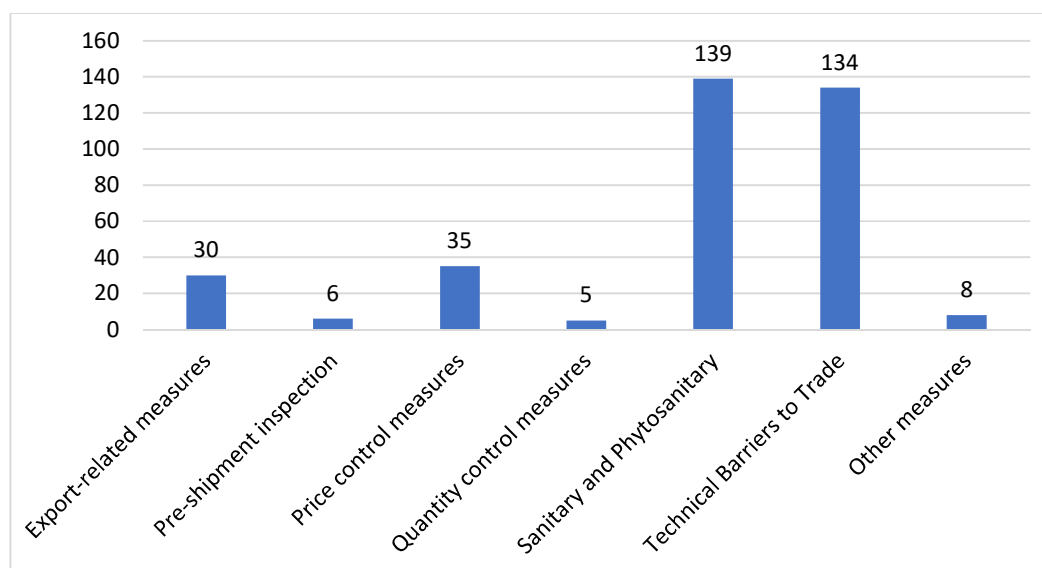
¹⁰⁷ Ing, Lili Yan, Santiago Fernandez de Cordoba, and Olivier Cadot. "Non-tariff measures in ASEAN." (2016).

¹⁰⁸ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

¹⁰⁹ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

Figure 12 and the majority of the ASEAN measures fall under product identity requirements, labelling and packaging, and conformity assessment measures.

Figure 12: Number NTMs by Measure, HS Codes 2203-2208



Position papers have singled out individual countries in ASEAN for imposing NTMs on imported alcoholic beverages. For example, the 2016 ERIA report notes that Thailand imposes type F9 (price control measures, n.e.s.) on imported alcoholic beverages.¹¹⁰ Industry position papers, such as one prepared by the EU-ASEAN Business Council, have also highlighted countries such as Vietnam, who have a number of non-tariff measures that have been introduced on imported alcohol and other sectors.¹¹¹

Other studies have focused attention on just excise tax structures. The ASEAN Excise Tax Reform white paper broke the category of excise tax on alcoholic beverages into five further subcategories, explained the factors shaping trade policies on excise tax, and made five specific policy recommendations, as well as possible mechanisms or models to make such transitions and policy reforms possible.¹¹²

While most goods are subject to tax liabilities, the alcohol sector has particular challenges. Excise taxes on beverages in ASEAN range from high to extremely high. Clearly, companies may prefer to pay lower taxes over higher taxes. But the issue is not just a matter of the overall tax bill. What is particularly challenging for the industry to navigate is uncertainty over tax collection, uneven policies in collection, and the incentives created by particularly high tax policies.

Uncertainty or unevenness in tax collection could be easily addressed, but these are primarily issues for domestic authorities. They do impede business and have trade implications.

¹¹⁰ Ing, Lili Yan, Santiago Fernandez de Cordoba, and Olivier Cadot. "Non-tariff measures in ASEAN." (2016).

¹¹¹ EU-ASEAN Business Council, "Promoting Trade & Investment between ASEAN & Europe." EABC, Aug. 2014.

¹¹² As noted in the Asia Pacific Tax Forum, "ASEAN Excise Tax Reform: A Resource Manual." Mar. 2014.

ASEAN should focus more heavily on the incentives created by high tax regimes. Having extremely high excise taxes creates opportunities for a range of activities that can have spill-over effects on neighbouring countries. To avoid expensive legal trade in alcohol, illicit trade in counterfeit products typically soars,¹¹³ along with greater manufactured quantities of completely unregulated and patently unsafe goods¹¹⁴ that are often transported and sold across ASEAN borders.

Improved policies on taxation could, as the OECD notes, also help ASEAN governments drive criminal entrepreneurs out of business, reduce incentives to enter illegal markets, and help governments sustain legitimate markets.¹¹⁵

¹¹³ For more information, a useful source is the OECD Task Force on Countering Illicit Trade. Website at <http://www.oecd.org/gov/risk/oecdtaskforceoncounteringillicittrade.htm> accessed on March 19, 2019.

¹¹⁴ A recent example includes "More than 80 Dead from Drinking Bootleg Alcohol in Indonesia," *CNN*, 12 April 2018, accessed at: <https://edition.cnn.com/2018/04/12/health/indonesia-fake-alcohol-intl/index.html> on March 19, 2019.

¹¹⁵ See the OECD metrics and mapping tools available at <http://www.oecd.org/gov/risk/oecdtaskforceoncounteringillicittrade.htm>

Alcoholic Drinks Interview Findings


The following section is based on the results of a series of interviews largely conducted between November 2018 and January 2019 in key ASEAN markets with industry players in the alcoholic beverages sectors. Interview candidates included ASEAN companies as well as foreign players. It does not cover all ASEAN markets, nor highlight all potential issues — only those explicitly raised by interview subjects.

As noted earlier, the “impact scoring” of red/yellow/green was not developed by the firms directly. It was derived from company interviews and by the extent to which a particular barrier was repeatedly raised by firms as well as by how much of an obstacle any specific barrier poses to doing business. The impact score should be viewed as a continuum from red to green, rather than a clear shift from one category to another. As might be expected, the charts below reflect few “green” impact scores, as firms typically did not spend time discussing issues that were not viewed as problematic. If viewed across time, however, some of the listed items could very well decline from red to yellow to green or the reverse.

Cambodia

Cambodia has a moderate per capita consumption of alcohol: around 6.7 litres per capita in 2016.¹¹⁶ According to a report by the Asia Foundation, the country has limited alcohol regulations and a particularly weak policy framework for the regulation of alcohol.¹¹⁷ There is no minimum drinking age, and no limitations on sales and advertising. Large local producers and large importers, who have strong affiliations with the dominant political party, are the main players in Cambodia.¹¹⁸

Technical Barriers to Trade


Category	Description	Impact
Customs Clearance	<p><u>Lengthy Customs Clearance</u></p> <p>One of the documents required for exporting is the Customs clearance form, which is only valid within a specific time period (e.g., 15 days for Vietnam). The delay at Cambodia’s border is often longer than 15 days. Firms often need to request an extension of the customs clearance form. The cost of keeping one container at the Cambodia border is US\$500-700/month.</p>	

¹¹⁶ World Health Organization. “Global Status Report on Alcohol and Health 2018”. Geneva: World Health Organization. 2018. Licence CC BY-NC-SA 3.0 IGO.

¹¹⁷ Shea, Nathan, and Williams, Nicola. “The Alcohol Industry in Cambodia: A Study of Taxation, Regulation, Distribution, and Consumption of Alcohol.” The Asia Foundation, Jun. 2017. asiafoundation.org/publication/alcohol-industry-cambodia-report/.

¹¹⁸ Shea, Nathan, and Williams, Nicola. “The Alcohol Industry in Cambodia: A Study of Taxation, Regulation, Distribution, and Consumption of Alcohol.” The Asia Foundation, Jun. 2017. asiafoundation.org/publication/alcohol-industry-cambodia-report/.


Licensing

Category	Description	Impact
Non Automatic Import License	<p><u>Challenging Import Licencing Process</u></p> <p>Getting import licenses for alcoholic drinks is a challenging process for importers. To apply for an import license, importers need to have:</p> <ul style="list-style-type: none"> • a Certificate of Origin form D (original version), • a commercial invoice, • a packing list, • a Bill of Lading, and • possible additional documents. <p>Importers are required to submit import licenses for customs clearance. This requires ASEAN exporters of alcoholic drinks to prepare all documents before shipping.</p>	 <p>Yellow</p>

Indonesia

Indonesia's alcohol consumption stands at 321.7m litres in 2018 or 1.2 litres per capita per year.¹¹⁹ Considering Indonesia is the largest market in ASEAN, the consumption level is low. Nonetheless, the level of consumption is expected to grow at 6.2% per year, which is relatively high among ASEAN countries. The consumption is dominated by beer at 92% of the market, followed by proportions of regular wine, spirits and cider, sherry and rice wine.¹²⁰ The revenue from alcohol beverages is US\$1,341 million or US\$5.17 per capita, which is the lowest among ASEAN countries.¹²¹

Trade Environment


Category	Description	Impact
Illicit and Counterfeit Trade	<p><u>Counterfeit Trade</u></p> <p>There is a high percentage of counterfeit wine and spirits as well as parallel imports in the Indonesian market.</p> <p>The prices of imported wine and spirits through legal channels could be double the prices of counterfeit and other illegally imported products, which induces demand for the illegal imports.</p>	 <p>Red</p>

¹¹⁹ "Alcoholic Drinks - Indonesia, Statista Market Forecast." Statista, Statista, www.statista.com/outlook/10000000/120/alcoholic-drinks/indonesia.


¹²⁰ World Health Organization. "Global Status Report on Alcohol and Health 2018". Geneva: World Health Organization. 2018. Licence CC BY-NC-SA 3.0 IGO.

¹²¹ "Alcoholic Drinks - Indonesia ", Statista Market Forecast." *Statista*, Statista, www.statista.com/outlook/10000000/120/alcoholic-drinks/indonesia.



Licensing

Category	Description	Impact
Non-automatic import license	<p><u>Multiple Licenses</u></p> <p>There is a need to obtain different types of licenses from different authorities, from importing to retailing. Licenses for distribution come from the Ministry of Trade. Other licenses come from local authorities, like the licence to sell which comes from the local mayor or Governor of Jakarta. Food and beverages must be certified by The National Agency of Drugs and Food Control before it can be sold in the local market.</p>	 Yellow

Price Control Measures

Category	Description	Impact
Import Duty	<p><u>Increased Import Duties</u></p> <p>Companies raised concerns about the increases in taxes for alcohol. For instance, under the Finance Ministry Regulation PMK No. 158/PMK.010/2018, concerning the Tariff for Excise on ethyl alcohol drinks, the import duty for drinks with alcohol content of 5–20% and drinks with alcohol content of more than 20%, are to be raised to 90% and 150% respectively.</p>	 Red





Distribution Restrictions

Category	Description	Impact
Restrictions on Sales	<p><u>Distribution and Sales Restrictions</u></p> <p>Only restaurants, cafes and liquor stores can apply for a license to sell wine and spirits. There are no clear and transparent guidelines for the distribution of wine and spirits. Such products cannot be sold in mini-marts.</p>	 Yellow
Marketing	<p><u>Restriction on Marketing:</u></p> <p>Wine and alcoholic drinks are not allowed to be advertised in mass media in Indonesia, except for Bali.</p>	 Red

Laos

Laos has a high per capita consumption of alcohol: around 10.4 litres per capita per year in 2016.¹²² Until 2015, Laos had not placed any restriction on both sales and consumption of alcohol.¹²³ According to Euromonitor, the alcoholic beverages industry is dominated by locally produced rice whisky called Lao-lao, and imported beers and spirits.¹²⁴

Technical Barriers to Trade

Category	Description	Impact
Conformity Assessment	<u>Custom clearance procedure:</u> A lengthy certificate of analysis process may take up to four weeks. This is a lengthy delay when compared to ten working days for Singapore.	
	<u>Traceability information Requirements:</u> Firms need to show proof of chemicals for their products and they are required to pay a deposit bond to customs officers.	
	<u>Inspection:</u> According to the standard procedure, customs officers have to open the shipment to examine the goods. Firms who do not want to go through this hassle pay customs officers to clear the products.	
Labelling Requirements	<u>Language Requirements</u> Labels must all be translated into the Lao language.	

Malaysia

Malaysia's alcohol consumption stood at 23.4 million litres in 2016 or 0.9 litres per capita per year.¹²⁵ Alcohol is prohibited in Malaysia for Muslim consumers and is not as widely available compared to other ASEAN countries. The country also has the third-highest alcohol duty in the world.¹²⁶ The majority of alcohol consumed is beer — 95% of the beer market share is taken up by Tiger Beer Singapore and Carlsberg.¹²⁷

¹²² World Health Organization. "Global Status Report on Alcohol and Health 2018". Geneva: World Health Organization. 2018. Licence CC BY-NC-SA 3.0 IGO.

¹²³ "Laos to restrict alcohol sale." *Asia One*, <https://www.asiaone.com/health/laos-restrict-alcohol-sale>


¹²⁴ "Alcoholic Drinks in Laos." *Euromonitor*, Euromonitor International, 2018, www.euromonitor.com/alcoholic-drinks-in-laos/report.

¹²⁵ "Malaysia: per Capita Alcohol Consumption 2015 | Statista." *Statista*, Statista, www.statista.com/statistics/691016/malaysia-per-capita-alcohol-consumption/.




¹²⁶ "Liquor Control Bill: How Other Countries and Cities in Asia Tackle Drinking." *The Straits Times*, 19 Jan. 2016, www.straitstimes.com/singapore/liquor-control-bill-how-other-countries-and-cities-in-asia-tackle-drinking.

¹²⁷ Cheang, Michael. "6 Things You Need To Know About Beer In Malaysia." *Star2.Com*, Star2.Com, 26 Nov. 2018, www.star2.com/food/food-news/2015/10/17/6-things-you-need-to-know-about-beer-in-malaysia/.


Trade Environment

Category	Description	Impact
Illicit and Counterfeit Trade	There is high percentage of counterfeit wine and spirits as well as parallel imports in the market.	 Red


Technical Barriers to Trade

Category	Description	Impact
Labelling Requirements	Every new label or change in label must be submitted for approval, which takes a considerable amount of time.	 Yellow
Requirements	Every month, all importers must submit hard copy returns covering: <ul style="list-style-type: none"> • quantity, • volume, • sold, and • tax stamps applied for. 	 Yellow
Procedural Obstacles – Customs Procedures	Inventories can be held up at customs for prolonged period. No explanations have been given.	 Yellow


Licensing

Category	Description	Impact
License	<u>Repeated Import Licence</u> Importers must apply for an import licence every year.	 Yellow




Price Control Measures

Category	Description	Impact
Excise Tax	<u>High Excise Taxation:</u> High taxation: 295% per litre of alcohol.	 Yellow
	<u>Discrimination of Excise Duty on Same Products:</u>	



	Locally produced liquor was subjected to a much lower excise tax. Compound hard liquor, locally produced, has an excise that is lower than the excise charged to drinks like whiskies, rum, gin and vodka.	
	<u>Unjustified Differential Excise Duty:</u> Sparkling wine attracts a high tax in comparison to still wine: 450 Ringgit vs. 60 Ringgit.	

Quantity Control Measures

Category	Description	Impact
Quota	<u>Quota for import license:</u> Limited import quotas make it nearly impossible for firms to export alcoholic drinks to Malaysia.	
Import Ban	<u>Import ban (temporary):</u> Alcoholic drinks are banned from import into Malaysia during some periods within a year.	
	<u>Malaysia Food Regulation of 1985:</u> Regulations are not up to date and do not apply to the current context. Flavouring in liquor is not mentioned in the 1985 Food Regulation, which means that products like flavoured liqueur may be taken off the market.	




Myanmar

Alcohol consumption in Myanmar is listed at 0.7 litres per capita in 2015.¹²⁸ This is despite the fact that most of the consumption is unrecorded according to the World Health Organization (WHO).¹²⁹ Alcohol is traditionally perceived to be a luxury in Myanmar and is not accessible outside the major cities. Nonetheless, popular local beers exist. These are Myanmar, Dagon and Mandalay beers. Popular local spirits are Myanmar Rum, Mandalay Rum and Grand Royal Whisky.


¹²⁸ "Myanmar - Total Alcohol Consumption per Capita (Liters of Pure Alcohol, Projected Estimates, 15 Years of Age)." Trading Economics, tradingeconomics.com/myanmar/total-alcohol-consumption-per-capita-liters-of-pure-alcohol-projected-estimates-15-years-of-age-wb-data.html.

¹²⁹ World Health Organization, "Myanmar - Global Status Report on Alcohol 2014." World Health Organization, 21 Sept 2014, www.who.int/substance_abuse/publications/global_alcohol_report/profiles/mmr.pdf.




Technical Barriers to Trade

Category	Description	Impact
Non-automatic import license for alcoholic drinks	<p><u>Complex Import License approval:</u></p> <p>Different types of licenses are required i.e. licenses for:</p> <ul style="list-style-type: none"> • production, • warehousing, • distribution and • sales. <p>Licenses issued by the Ministry of Trade are valid for one year.</p>	
Import licenses for ingredient and material imports	<p><u>Lengthy Waiting Time</u></p> <p>The process takes about three months and has a lot of uncertainties. As a result, companies need to stock up on inventory and undergo a high wastage ratio and high financial costs.</p> <p><u>Involvement of Multiple Authorities</u></p> <p>The licensing application process involves multiple agencies and licences including:</p> <ul style="list-style-type: none"> • FDA approval, • MIC letter of import recommendation, • MOC import licenses. In addition, the Ministry of Industry gets involved in imports that are deemed as containing chemicals. 	
Standards	<p><u>Documentation Standards</u></p> <p>Specific documentation styles are required but are inconsistent with ASEAN standards. There are no clear written guidelines for companies to follow.</p>	

Quantity Control Measures

Category	Description	Impact
Import License	<p><u>Cap on Import Licences:</u></p> <p>Import licenses are required to import alcoholic drinks into Myanmar but no new licenses have been granted within the past few years which makes it impossible for companies to enter the market.</p>	

Others

Category	Description	Impact
Lack of Transparency and Consultation	<p><u>Sudden changes in laws and regulations</u></p> <p>Change in laws and regulations that do not conform to standardisation: Laws and regulations are changing fast. Companies are not well informed and not engaged in the policy making process. The implementation of new laws and regulations is within a short period of time. There are no standards and mechanisms in place, which makes it difficult for companies exporting to Myanmar to adjust to new regulations.</p>	
Transit Pass	<p><u>Lengthy Transportation Application Requirement</u></p> <p>Required for companies to transport products manufactured from one region to another. For example, companies who manufacture products in Bago need to apply for a Transit pass from the GAD in Bago to ship their products from Bago to other regions in Myanmar.</p> <p>In the application, companies must list all the trucks that will be used for the transportation, vehicle numbers, and stock numbers or SKUs. This makes for detailed documentation requirements.</p> <p>Companies often have one staff dedicated to following up with the Authority to get each transit pass approved</p> <p>The application could take one, two or three weeks.</p> <p>Application for new products could take up to six months.</p>	
Grey Market and Illegal Imports	<p><u>Grey market and illegal imports:</u></p> <p>No regulations or actions have been taken by the government concerning illegally imported alcoholic drinks. Illegal imports accounted for up to 40% of the market volume.</p>	

The Philippines

The Philippines' alcohol consumption is at 6.6 litres per capita in 2016.¹³⁰ The consumption is dominated by beer and spirits, which make up 98% of total alcohol consumed, with beer at 65%. In total, the country's revenue stands at US\$6,774 million, which is the highest among ASEAN countries, despite consumption levels only coming in third.¹³¹ This is due to the significantly higher proportion of spirit consumption and price per unit of both beers and spirits when compared to other ASEAN members.

¹³⁰ World Health Organization. "Global Status Report on Alcohol and Health 2018". Geneva: World Health Organization. 2018. Licence CC BY-NC-SA 3.0 IGO.

¹³¹ World Health Organization. "Global Status Report on Alcohol and Health 2018". Geneva: World Health Organization. 2018. Licence CC BY-NC-SA 3.0 IGO.


In interviews, firms did not report on specific issues in the Philippines. This does not mean that no issues are present in the market — It may simply be a function of the interview subjects and locations. Future research is needed to clarify the status of possible issues in the Philippines for this sector.

Singapore

Singapore’s alcohol consumption stood at 140.0 million litres in 2018, which amounts to 24.2 litres per capita per year. This consumption is largely dominated by beer, which makes up over 86% of total consumption followed by regular wine and spirits.¹³² Singapore has one of the highest alcohol taxes in the world, resulting in a price per unit of US\$7.26, which is more than twice the level in Malaysia, the second highest in ASEAN. This allows Singapore to collect revenue of US\$992 million or US\$176.10 per capita per year, which is more than twice the level of the country with the second-highest revenue per capita in ASEAN.¹³³

The beer market is dominated by Asia Pacific Brewery, which brews Tiger Beer. The brewery accounted for 51% of the beer market in 2013. The remaining share is occupied by imported beers like Heineken, Guinness, Baron’s and Anchor.¹³⁴ Wine is mostly imported from Australia, France and Chile, by volume. It holds a significant market share in the alcoholic beverages industry as indicated by the 117 wine wholesalers in the city-state.¹³⁵

Technical Barriers to Trade

Category	Description	Impact
Import Restriction	<p><u>Storage and transport conditions:</u></p> <p>Forced to transfer from IBC tanks to stainless steel tanks. Since these tanks are \$3000-4000 each, they are a significant expense for alcohol importers.</p>	 <p>Yellow</p>


¹³² World Health Organization. “Global Status Report on Alcohol and Health 2018”. Geneva: World Health Organization. 2018. Licence CC BY-NC-SA 3.0 IGO.

¹³³ “Alcoholic Drinks - Singapore | Statista Market Forecast.” *Statista*, Statista, www.statista.com/outlook/10000000/124/alcoholic-drinks/singapore#market-volume.


¹³⁴ “Specialty Beer in Singapore.” Flanders Investment & Trade Market Survey, www.flandersinvestmentandtrade.com/export/sites/trade/files/market_studies/402150529084129/402150529084129_1.pdf

¹³⁵ Crystal Gilliam “A Quick Guide to Wine Distribution in Singapore.” *Inventory Management Software*, TradeGecko Blog, www.tradagecko.com/blog/a-quick-guide-to-wine-distribution-in-singapore

Price Control Measures

Category	Description	Impact
Excise Tax	<u>High excise tax on alcohol:</u> Excise tax is \$88 per litre of alcohol. For some high alcohol content products, it can be taxed \$30-40 a bottle.	 Red

Market Access

Category	Description	Impact
License	<u>Ambiguous distillation licensing requirement:</u> There are no clear guidelines for setting up a distillery in Singapore although there is a framework in place for microbreweries.	 Yellow

Thailand

Thailand's alcohol consumption was 2,673.5 million litres in 2018.¹³⁶ Consumption is dominated by beer and spirits, which make up 73% and 26% of the total alcohol consumed. The remaining 1% is shared between regular wine and cider, perry and rice wine. Although beer almost triples spirits in consumption level, spirits sales are higher in revenue at US\$2,637.7. Beer revenue was US\$2,533.1 in 2018. Nonetheless, the two beverages still make up over 97% of the total revenue. In comparison to ASEAN countries, Thailand has the third-highest alcohol revenue of US\$5,318 million and the second-highest in consumption per capita (38.2 litres) and in alcohol revenue per capita, with an average of US\$76.55 per year.




The beer market is dominated by the two breweries, Boon Rawd and ThaiBev, which produce Singha and Chang beers respectively. In 2017, these two brands made up 90% of the market share despite a growing imported beer and craft beer market.¹³⁷ The spirits market is a mix of local and imported premium spirits imported from France and the UK. ThaiBev also produces the two-most popular local spirit, Ruang Khao and Hong Thong, which ranked second and eighth among top spirit brands in 2018.¹³⁸

¹³⁶ "Alcoholic Drinks - Thailand | Statista Market Forecast." *Statista*, Statista, www.statista.com/outlook/10000000/126/alcoholic-drinks/thailand#market-arpu.




¹³⁷ "Microbrewers take on Thailand's big beer." *Straits Times*, Jul 7, 2017, <https://www.straitstimes.com/asia/se-asia/microbrewers-take-on-thailands-big-beer>

¹³⁸ Micallef, Joseph "The International Spirits Market Is Remarkably Local." *Forbes*, 11 July 2018, www.forbes.com/sites/joemicallef/2018/07/11/the-international-spirits-market-is-remarkably-local/#47b22b77651d.


Technical Barriers to Trade

Category	Description	Impact
Certificate of Analysis	<p><u>Unique National Standards</u></p> <p>The COA Requirement for the importation of alcohol does not follow international standards but Thailand's own standards. The standards are not up-to-date, are inconsistent with international standards and do not engage private sector stakeholders. Businesses must incur both a time and administrative cost to demonstrate that they comply with the standard.</p>	
Labelling Requirements	<p><u>Procedure and Condition for Labels of Alcoholic Beverages 2015.</u></p> <p>This regulation prohibits the use of quality or properties claim statements such as "premium," "reserve," "deluxe," and "X.O. (extra old) or cartoon images regardless of whether they are true and factual and supported by evidence, trademarks, geographical indicators or international standards. They may infringe intellectual property rights and impose unduly intrusive and trade restrictive terms for entry in Thailand.</p> <p>This means that alcohol importers in Thailand cannot use any positive message or non-trademarked cartoons, and incur significant costs to modify product labelling for exporting to Thailand.</p>	
	<p><u>Draft Law: Graphic Health Warnings</u></p> <p>A 2009 draft law seeks to impose a tobacco-style pictorial health-warning graphic that covers a substantial area of the labels and packaging materials.</p> <p>A draft of the law requires alcohol distributors to use all four selected colour Graphic Health Warnings in every batch of liquor sent for sale.</p> <p>This would not only incur a significant cost for alcohol importers, but damages brand equity and trademark value. It also encourages illicit alcohol such as smuggled, counterfeit, and products that are trademark-infringed.</p>	


Price Control Measures

Category	Description	Impact
Excise Tax	<p><u>Excise Tax on Alcohol:</u></p> <p>Excise tax is an indirect tax on the sale or use of specific products and services such as automobiles, non-alcoholic beverages, alcoholic beverages and entertainment activities, paid indirectly by the end consumers.</p> <p>Currently, alcoholic beverages have been subjected to heavy excises and are taxed in a hybrid system whereby both specific taxation, levied on alcohol quantity, and ad valorem taxation, levied on value of product (Suggested Retail Price), are applied.</p>	
	<p><u>Inconsistent Excise Tax on Alcohol:</u></p> <p>Excise tax regulations on alcohol change frequently and the Thai government does not enforce the suggested retail prices legislation uniformly; often-favouring local producers.</p> <p>Claims from interviewees indicate that the suggested retail price for local alcohol producers can be lower than the actual price. Concerns were shown regarding the large influence and the lack of enforcement against local alcohol producers.</p> <p>For instance, “Lao Khao” has still been taxed at comparatively lower levels than other liquors.</p>	
Additional Taxes	<p><u>Hybrid Tax System</u></p> <p>Besides excise tax, earmarked taxes of 17.5% are also imposed on alcohol for allocating to communities, social activities and public health funds.</p>	

Distribution and marketing restrictions

Category	Description	Impact
Marketing	<p><u>Restriction on advertising:</u></p> <p>Alcohol advertising in Thailand is regulated by the Alcoholic Beverage Control Act 2008, which states that alcoholic beverages may not be advertised in a manner which directly or indirectly shows the name or trademark and packaging under Section 32 of the Alcoholic Beverage Control Act.</p>	

Others


Category	Description	Impact
Competition	Multiple participants shared concerns about the favourable treatment of local alcohol manufacturers. They claimed that such manufacturers often receive tax concessions or benefits that foreign companies do not.	 Red

Vietnam

Vietnam's alcohol consumption stood at 4,749.7 million litres in 2018. This was the highest among all ASEAN countries. Consumption is dominated by beer, which makes up 88% of total alcohol consumed. The remaining 12% is shared between spirits, cider, perry and rice wine and regular wine that is significantly smaller in percentage. Vietnam's revenue in the alcoholic drinks market amounted to US\$6,670 million in 2018. Currently, Vietnam ranks third in revenue and first in consumption per capita among ASEAN countries, with an average of US\$70.36 and 48.0 litres per year. The market is expected to grow at a steady rate of 5.7%.¹³⁹

The beer market is dominated by Sabeco Brewery, which produces Saigon Beer, 33 Beer; Vietnam Brewery Ltd, a joint-venture of Heineken Asia Pacific and Saigon Trading Group (Satra), which produces Heineken and Tiger. The government aims to raise beer output by 18% to 25%, up from 3.4 billion litres in 2015 to between 4 billion and 4.25 billion litres by 2020, in order to increase beer exports across Southeast Asia.¹⁴⁰ The rest of the alcohol market is dominated by rice wine and spirits imported from China.¹⁴¹

Distribution and Marketing Restrictions

Category	Description	Impact
Sales Restriction	<u>Online Trading Restriction</u> Alcoholic drinks with the alcohol level above a certain threshold (15%) are banned from online trading (e-commerce) and advertising. Even retailers of the imported alcoholic drinks are not allowed to advertise or promote their products.	 Red

¹³⁹ "Alcoholic Drinks - Vietnam | Statista Market Forecast." *Statista*, Statista, www.statista.com/outlook/10000000/124/alcoholic-drinks/vietnam#market-volume

¹⁴⁰ Khanh, Vu Trong. "Vietnam Primed to Share More Beers With Neighbors in Southeast Asia." *The Wall Street Journal*, Dow Jones & Company, 6 Jan. 2016, www.wsj.com/articles/vietnam-primed-to-share-more-beers-with-neighbors-in-southeast-asia-1452071349.

¹⁴¹ "Spirits - Vietnam | Statista Market Forecast." *Statista*, Statista, www.statista.com/outlook/10020000/127/spirits/vietnam.


Technical Barriers to Trade

Category	Description	Impact
Labelling Requirements	<u>Labelling Requirement:</u> Labels and sub-labels must be in Vietnamese to display compulsory content under Vietnam's Regulation on Labels and Decree No. 89/2006/NĐ-C.	Yellow
	<u>Product Seal:</u> The customs seal on imported alcoholic drink bottles can break easily during transportation. Firms need to apply another plastic layer on top of the seals to protect the seals from breaking. This adds to cost.	Yellow

Price Control Measures

Category	Description	Impact
Excise Tax	<u>Excise Tax on Alcohol:</u> There have been several rounds of special consumption tax hikes since 2013, currently at 65%, which reduced consumption and business sales. The nominal tax rates will increase to 75% by 2022. The effective tax rate will be 42.9%.	Yellow
	<u>Inconsistent Excise Tax on Alcohol:</u> Imported alcoholic drinks are subject to high taxes and charges. However, many locally-produced alcoholic drinks such as home-made breweries and small-scale breweries are not paying taxes. Many of these breweries are not registered and might not meet hygiene and health standards.	Red
Additional Tax	<u>Additional taxes/charges:</u> The Ministry of Health is considering special charges for alcoholic drinks in addition to special consumption taxes.	Yellow
Decreed Customs Valuation	<u>Customs valuation:</u> According to Decree 59, customs officers can use a reference list to determine the value of an imported alcoholic drink when the officer thinks the declared price could be wrong. However, there is no transparency on the list process. Firms cannot argue with customs officers' decisions.	Red

Intellectual Property

Category	Description	Impact
Procedural Obstacle – Enforcement	<u>Poor Enforcement</u> The low level of Intellectual Property Rights enforcement provides an avenue for cheap and fake alcohol or illegal products which makes it difficult for firms to market their products to consumers when cheaper products are available.	

Alcoholic Drinks Findings Analysis

The interviews showed that ASEAN's alcoholic beverages market is more limited than it should be as a result of:

- high levels of taxation,
- complex licensing procedures, and
- increasingly burdensome labelling requirements.

A closer analysis points at the prevalence and the drawbacks of these types of policies. Interviews with firms operating across the region show that the alcoholic beverages business face significant market access barriers associated with high and discriminatory taxation and increasingly complex technical standards.

High Taxation

Across most of the ASEAN markets high taxation makes it difficult to import alcoholic drinks. This is even worse when drinks are:

- taxed in hybrid systems that use ad valorem taxes (Thailand),
- taxed at levels that are inconsistent (Thailand), or
- when local manufacturers are excluded officially or unofficially (Vietnam).

High and irregular excise taxation does not only make it difficult to import alcoholic drinks into a market, but it creates incentives for the proliferation of illicit trade.

Illicit Trade

In most of the markets, participating businesses raised concerns about illicit trade. Illicit trade in alcohol seriously damages the legitimate sector, reducing its ability to grow, invest and employ. It also depresses the tax revenues that the government could normally expect to receive. According to some participants, the prices of imported wine and spirits through legal channels could be double the price of counterfeit and other illegally imported products. This encourages demand for illegal imports. Counterfeit and illegal trade is a significant challenge for firms operating across the region, which fact is connected not only to a lack of enforcement, but also to high taxation regimes.

Illicit products are not only an issue of missing tax revenue. They also come with potentially significant health risks, as illicit or counterfeit products may be filled with all manner of contaminated items. For governments that claim NTMs on the basis of protecting human safety, this outcome is particularly perverse.

Licensing and Labelling Requirements

Across most of the markets, import licenses for alcohol remain a difficult procedure that alcohol importers see as a barrier. This might be because there is an import license quota that prohibits sellers from entering the market (Myanmar and Malaysia) or because there are procedural obstacles associated with the process.

Furthermore, there is an increasing concern regarding labelling regulations that involve:

- the use of graphical health warnings and
- increasing limitation in the use of graphics or language in labels (Thailand).

This means that businesses incur significant cost to modify their labels for a particular market.

There are mechanisms that can allow firms to label in local languages to assist local customers chose appropriate products without placing significant burdens on firms. For example, allowing firms the option of using stickers for local language labels is an important solution. This also allows local ASEAN firms, including smaller players, to operate in the region.

Services

Last, there seems to be an increasing concern with new regulations limiting the ability to market alcohol. Participating companies emphasized the importance of marketing and advertising when selling alcoholic products and limitations on marketing (Indonesia, Vietnam and Thailand). These can limit their sales significantly. Such limitations are of special concern when they do not apply to certain types of local importers or manufacturers (Thailand); further distorting competition.

The argument is not that governments should not regulate. It is that governments must regulate in ways that are clear, transparent and predictable. Regulations must apply equally to local and imported products.

B. Seafood

Market Outlook

The seafood sector in ASEAN is a rapidly growing one with a number of countries being heavily involved in the production, processing and export of seafood. Countries like Singapore and Philippines have already seen large jumps in seafood imports and regional consumption is predicted to continue to increase in the next decade.

In 2017, the international seafood market traded an estimated 174 million metric tons of seafood with an estimated market value of US\$153.5 billion at a rate of 20.3kg per person per year.¹⁴² The Asia-Pacific region accounted for 47% of the total trade. Demand for seafood is predicted to grow as a result of a growing middle class and global populations.¹⁴³

However, practices like overfishing are affecting seafood supplies and rising seafood prices. Excessive wildcat fishing has led to dwindling fish stocks and an inability to meet a rising demand. This has already affected major world exporters like China, where seafood prices have gone up.¹⁴⁴

Overall, ASEAN's seafood exports are higher than its seafood imports. According to data from COMTRADE, in 2016 ASEAN's seafood exports exceeded its imports by US\$12 billion as shown in Figure 13. In fact, the ASEAN bloc has become one of the APEC region's largest exporters of seafood predicted to reach 24% of global output by 2030.¹⁴⁵

¹⁴² "World Fish Market At A Glance | GLOBEFISH | Food And Agriculture Organization Of The United Nations". Fao.Org. 2019, <http://www.fao.org/in-action/globefish/fishery-information/resource-detail/en/c/338597/>.

¹⁴³ "Seafood Market By Type (Cephalopods, Crustaceans, Molluscs, Flat Fish, Ground Fish, Salmonids, Tuna, Pelagics, Others (Marine Fish And Aquatic Products)), Retail Market Variety (Ambient, Frozen, And Chilled), And Sales Channel (Retail, Foodservice, And Institutional) - Global Opportunity Analysis And Industry Forecast, 2017-2023". *Allied Market Research*. 2019, <https://www.alliedmarketresearch.com/seafood-market>.

¹⁴⁴ Godfrey, Mark. "Southeast Asia'S Seafood Market Being Reshaped By Chinese Tourists." Seafoodsource.com. N.p., 2018. Web. 29 May 2018.

¹⁴⁵ Chan, Chin Yee, et al. "Fish to 2050 in the ASEAN region." WorldFish Center and Intl Food Policy Res Inst, 2017. pp. 17.

Figure 13: Total ASEAN Global Seafood Imports and Exports USD Million (2016)¹⁴⁶

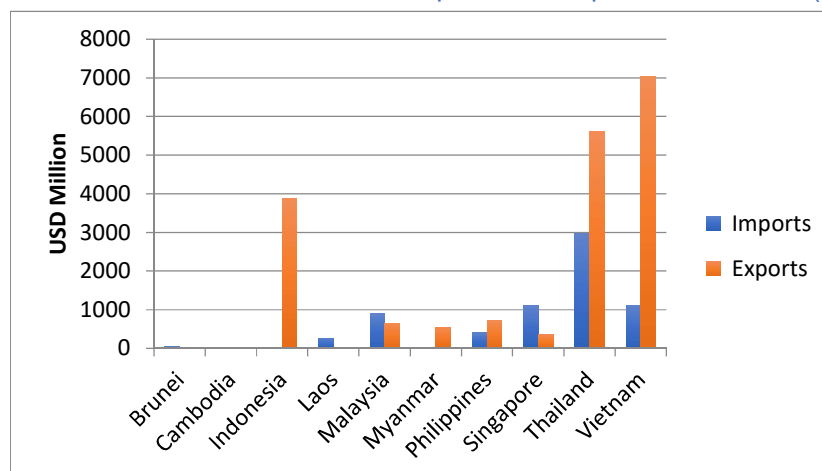


Figure 13 also shows that in 2016, the total seafood exports of the region amounted to US\$18.8 billion. Thailand, Vietnam and Indonesia alone exported US\$6.5 billion of seafood in 2016. Thailand’s seafood imports were US\$3 billion, which were partly a result of Thailand’s well-developed processed seafood sector, much of which was then exported.¹⁴⁷

Seafood does not appear to be moving between ASEAN countries however. In 2016, intra-ASEAN seafood exports of US\$2.2 billion only accounted for 12% of ASEAN’s total seafood exports.¹⁴⁸ Thailand, Vietnam and Indonesia account for 63% of total intra-ASEAN seafood exports as shown in Figure 14. Countries like Singapore, Malaysia and Myanmar, which account for only a fraction of ASEAN’s global exports, do account for 35% of intra-ASEAN seafood exports; indicating that a relatively high share of the exports goes to other ASEAN partners.

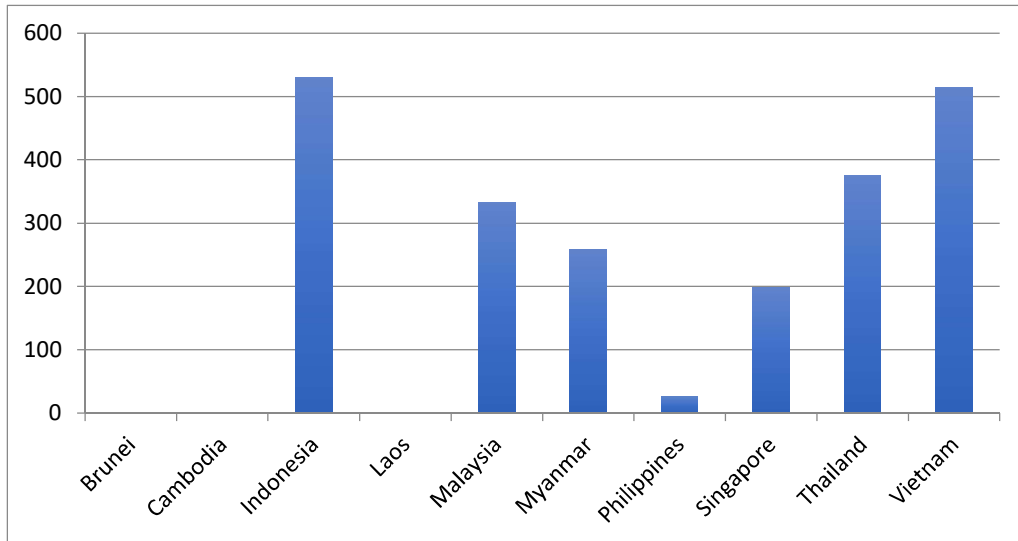
¹⁴⁶ "Download Trade Data | UN Comtrade: International Trade Statistics". 2019. Comtrade.Un.Org. <https://comtrade.un.org/data/>.

¹⁴⁷ Ngamprasertkit, Srisuman. "Seafood Report." USDA Foreign Agricultural Service: Global Agricultural Information Network, 8 May. 2018.

https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Seafood%20Report_Bangkok_Thailand_5-8-2018.pdf

¹⁴⁸ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

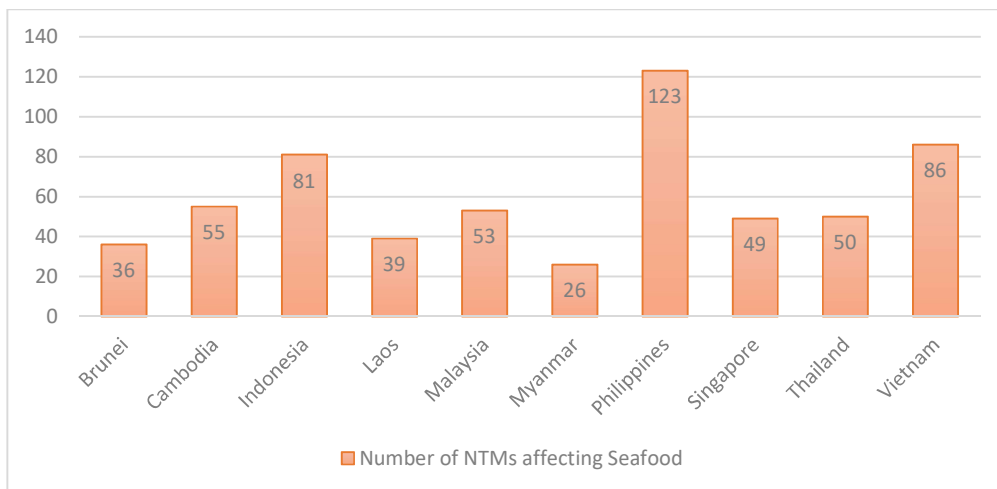
Figure 14: Total Intra-ASEAN Seafood Exports in USD Millions (2016)¹⁴⁹



NTMs in ASEAN's Seafood Sector

The UNCTAD database notes that there are 4359 reported NTMs affecting the seafood industry with the majority identified as SPS and TBT measures.¹⁵⁰ ASEAN has 610 NTMs that affect seafood globally; 595 of these NTMs affect other ASEAN Member States.¹⁵¹

Figure 15: Number of NTMs Affecting Seafood in ASEAN



¹⁴⁹ UN Comtrade: International Trade Statistics". 2019. Comtrade.Un.Org. <https://comtrade.un.org/data/>.

¹⁵⁰ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". Asean.I-Tip.Org. (2019) <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

¹⁵¹ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

Reflecting global trends, the most commonly identified NTMs in ASEAN's seafood sector were SPS and TBT measures. Figure 15 shows that the Philippines imposes the largest number of measures, including 48 in SPS.¹⁵² These NTMs are often issued in the form of regulations by the respective health authorities. According to UNCTAD data, they also appear in the form of restrictions and quarantines on certain food products, pre-inspection testing of radionuclide particles in fish and restrictions on the exportation of imported products.

While SPS measures tended to be more varied across countries, TBTs commonly show up in measures relating to labelling standards reflecting an overall larger trend, where 27% of all TBT measures within ASEAN pertain to labelling.¹⁵³

¹⁵² "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

¹⁵³ S. Devadason, Evelyn. "Regulatory Harmonization In ASEAN: The Case Of The Food Sector". Presentation, ARTNeT Dialogue United Nations Conference Centre, 2017.

Seafood Companies: Interview Findings

The following section is based on the results of a series of interviews conducted between October 2018 – January 2019 in key ASEAN markets with industry players in the seafood sector. Interview candidates included ASEAN companies as well as foreign players. It does not cover all ASEAN markets, nor highlight all potential issues — only those explicitly raised by interview subjects.

As with all agri-food items, governments have an obligation to protect domestic consumers from unsafe products. Seafood can present a particular risk. Hence it may not be surprising that many NTMs have been reported in the seafood sector. How many of these issues cross over into NTBs is more challenging to uncover.

The seafood sector was originally chosen for study because it was assumed to be less regulated than alcohol but subject to tighter controls than biscuits. This assumption is likely to be true. However, getting companies engaged in trade in seafood products within ASEAN proved much more challenging than anticipated.

It may be that companies did not find any particular obstacles to trade in the region and were therefore reluctant to be interviewed in the course of the study. It may be that firms did not wish to highlight specific challenges faced by the sector or to call additional attention to issues in the industry that were not a focus of this study (such as illegal, unreported and unregulated or IUU catch). It could be that seafood firms tend to be smaller and work only in local languages.

Whatever the case, interview responses from seafood firms generally were not strong and did not provide sufficient overview of all ASEAN markets to say with confidence that this study has clearly identified seafood NTBs. More work remains to be done for this sector. Many companies literally said that they do not ship products to other ASEAN markets at all, nor did they know of any firms that sent seafood between ASEAN Member States.

When firms did agree to discuss challenges, these are noted below. As with other sections in the paper, the “impact scoring” of red/yellow/green was not developed by the firms directly. It was derived from company interviews and by the extent to which a particular barrier was repeatedly raised by firms as well as by how much of an obstacle any specific barrier poses to doing business. The impact score should be viewed as a continuum from red to green, rather than a clear shift from one category to another. As might expected, the charts below reflect few “green” impact scores, as firms typically did not spend time discussing issues that were not viewed as problematic. If viewed across time, however, some of the listed items could very well decline from red to yellow to green or the reverse.


Indonesia

Indonesia's seafood imports in 2017 were nearly US\$3 billion, up by 12.9% from 2016.¹⁵⁴ While Indonesia is a major producer of seafood, there is also a large domestic market with seafood consumption targeted to hit 54kg per capita per year in 2019.¹⁵⁵ In 2017, the Ministry of Fisheries and Marine Affairs recorded consumption at 43kg, which is expected to increase to 46kg in 2018.¹⁵⁶


While it does not rely on exports to solely fuel demand, Indonesia is at the same time one of the world's largest seafood processing and canning countries, exporting up to US\$4 billion worth of seafood a year. It is not dependent on exports but has a large domestic market for seafood and aquaculture.¹⁵⁷

According to UNCTAD's NTM list, the majority of SPS measures are composed of health/quality certification or registration procedures. SPS measures also include the prohibition on certain types of shrimp species and also a restriction on their port of entry. The restriction on port of entry also extends to pre-shipment inspection measures. On this point, all fishery products entering Indonesia are required to be cleared only at specified ports of entry.¹⁵⁸

Sanitary and Phytosanitary (SPS)

Category	Description	Impact
Procedural Obstacles – Product Standards	<u>Geographical Inconsistencies in the Application of Standards</u> The devolution of power to local areas in Indonesia has resulted in inconsistent procedures in various parts of the country.	 Yellow

Quantity Control Measures

Category	Description	Impact
Procedural Obstacle – Quotas	<u>Unclear and Inconsistent Quotas Rules and Regulations</u> Quotas, rules and regulations are unclear across different parts of Indonesia. Unofficial rules appear to create an uneven playing field, such as unequal access to quotas.	 Red

¹⁵⁴ "Indonesia - Seafood Trade Intelligence Portal". *Seafood Trade Intelligence Portal*, 2019, <https://seafood-tip.com/sourcing-intelligence/countries/indonesia/>.


¹⁵⁵ "Indonesia Targets 54Kg Of Seafood Consumption In 2019 – Asian Agribiz". *Asian Agribiz*, 2019, <https://asian-agribiz.com/2018/06/07/indonesia-targets-54kg-of-seafood-consumption-in-2019/>.

¹⁵⁶ "Indonesia Targets 54Kg Of Seafood Consumption In 2019 – Asian Agribiz." *Asian Agribiz*. N.p., 2019. Web. 26 Feb. 2019.

¹⁵⁷ "Indonesia - Seafood Trade Intelligence Portal." *Seafood Trade Intelligence Portal*. N.p., 2019. Web. 26 Feb. 2019.

¹⁵⁸ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

Others

Category	Description	Impact
Regulatory Environment	<p><u>Inconsistent and Unpredictable Regulations</u></p> <p>There have been repeated changes in the structure of various regulatory ministries that have resulted in changes in regulation implementation and procedures especially for certificates of origin (COs) and health certificates.</p>	


Malaysia

Malaysia is reportedly among the world's top fish consumers with a consumption rate of 56.6 kg per capita. This far exceeds the world average of 20k per capita. On average, households spend RM 100 or US\$24 per month on varieties of fish.¹⁵⁹ Demand for fish is reducing, as population growth slows.¹⁶⁰

Among ASEAN countries, Malaysia stands out in having more TBT obstacles than SPS.¹⁶¹ According to UNCTAD data, SPS measures for Malaysia include compliance with recognised safety standards but also include special requirements for the “handling, preparing, packing, serving, storing and selling of specific food” which include crustaceans, mollusks and fresh fish.¹⁶² Additional TBT requirements include a provision for the authorities, at their discretion, to require the grading of fish according to type, size and freshness. Export-related measures imposed by Malaysia largely deal with application permits and health certifications.

Given the extent of NTMs reported under UNCTAD, it is likely that Malaysia may have additional NTBs in place for seafood that have not been captured by the firm interviews conducted in this study. Only one issue was explicitly raised.

Quantity Control Measures

Category	Description	Impact
Seasonal Quotas	Malaysia bans export of certain fishes during specific periods of the year, for example, during Chinese New Year	

¹⁵⁹ "Malaysians Eat More Fish Than Japanese, Reveals Study - Nation | The Star Online". 2019. *Thestar.Com.My*, <https://www.thestar.com.my/news/nation/2014/06/19/malaysians-eat-more-fish-than-japanese-reveals-study/>.

¹⁶⁰ "Malaysians Eat More Fish Than Japanese, Reveals Study - Nation | The Star Online". 2019. *Thestar.Com.My*, <https://www.thestar.com.my/news/nation/2014/06/19/malaysians-eat-more-fish-than-japanese-reveals-study/>.

¹⁶¹ Devadason, E.S., V.G.R. Chandran and T.T.Cheong. "Non-tariff Measures in Malaysia." in Ing, L.Y., S. F. de Cordoba and. O. Cadot (eds.), Non-Tariff Measures in ASEAN. ERIA Research Project Report 2015-1, Jakarta: ERIA.

¹⁶² "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/>

The Philippines

The Philippine's seafood imports in 2017 were US\$555 million, up by 30% from 2016.¹⁶³ Consumption of seafood is estimated at 39kg per capita per year, amounting to 50% of their animal protein intake. The country produced a total of 4.2 million metric tonnes of seafood in 2016, accounting for 1.5% of GDP. Over half of the seafood locally produced is exported.

The Philippines leads the ASEAN group in terms of NTMs from the UNCTAD database with 123 in place for the seafood sector, 48 measures of which are related to SPS. Current NTMs under other measures prohibit importers from being covered by financial institutions on a letter of credit unless the importer first pays the import duties in full.¹⁶⁴

The Philippines also have SPS measures that either prohibit or impose restrictions on the import of specific species of prawn or shrimp. Broodstock of Black Tiger Prawns and Pacific White Shrimp, for example, must be from Bureau of Fisheries and Aquatic Resources (BFAR) certified hatcheries and must enter through specific ports of entry such as Manila's Ninoy Aquino International Airport (NAIA). Pacific white shrimp — specifically—are required to be shipped directly from their country of origin. Certain breeds are also required to undergo a period of quarantine before entry into the market. Other SPS measures include health certifications and logistical requirements such as temperature specifications for the transportation for fish. The BFAR also has provisions to conduct inspections at their discretion.¹⁶⁵

No specific issues were reported out by companies in this study for the Philippines. Future research is needed, since the comparatively high levels of NTMs in the UNCTAD database means that some may be viewed as NTBs by firms operating in the region.

Singapore

In 2016, Singapore, a net importer of seafood, imported an estimated US\$1.1 billion or 193,700 metric tons worth of seafood of which US\$447 million came from ASEAN. Singaporeans consume an estimated of 22kg of seafood per person per year. Nearly 95% of Singapore's seafood imports come from the "Coral Triangle," a marine area located in the western Pacific Ocean that includes the waters of Indonesia, Malaysia, Philippines, Pap New Guinea, Timor Leste and Solomon Islands.¹⁶⁶ Singapore is also a middleman for re-export into the region.¹⁶⁷

¹⁶³ "Your Source For Seafood Sourcing Intelligence In The Philippines". 2019. *Seafood Trade Intelligence Portal*. <https://seafood-tip.com/sourcing-intelligence/countries/philippines/>.

¹⁶⁴ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/>

¹⁶⁵ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/>



¹⁶⁶ USDA Foreign Agriculture Service. 2017. "Seafood Report 2017". GAIN Report. USDA Foreign Agriculture Service. https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Seafood%20Report%202017_Singapore_Singapore_11-6-2017.pdf.

¹⁶⁷ "Importing Food Products into Singapore." GuideMeSingapore, www.guidemesingapore.com/business-guides/industry-guides/restaurant-and-food-industry/importing-food-products-into-singapore

According to UNCTAD data, aside from the usual requirements on health certifications and labelling, Singapore has additional NTMs pertaining to specific food products such as smoked fish as well as fishballs/fishcake products.¹⁶⁸

According to a 2016 ERIA report, firms in the Singapore seafood sector found that rules and NTMs in other ASEAN countries were more restrictive and less transparent than in Singapore.¹⁶⁹ UNCTAD's database also reflects similar outcomes, with measures related to food and environmental safety as the most commonly found NTMs within the seafood sector.¹⁷⁰

Sanitary and Phytosanitary Measures (SPS)

Category	Description	Impact
Requirements on Production Processes	<p><u>Uneven standards and lack of enforcement of glazing regulations:</u></p> <p>Glazing is the process of applying a protective layer of ice to seafood, by spraying or dipping seafood into clean water. A glazing regulation refers to the maximum water content allowed in seafood as a result of the glazing process.</p> <p>While the standard in Singapore is enforced, exporting countries have no common standard. Hence, since pricing differs according to country, uneven standards and a lack of enforcement of glazing regulation creates competition problems.</p>	 Yellow
Tolerance limits for residues and restricted use of substances	<p><u>Ban of certain chemicals:</u></p> <p>AVA regulation bans certain chemicals. Importers can get banned if caught. All imported meat is tested. But every other product is only randomly checked, including seafood.</p>	 Yellow

Thailand

Thailand's seafood exports worldwide amounted to an estimated US\$5.6 billion of which, only US\$3.76 million worth was exported to ASEAN, making up roughly 5% of the region's seafood needs.¹⁷¹ Seafood is a staple of the Thai diet and a sizeable tourism industry with a large number of catering businesses and hotels helps to fuel domestic demand for seafood.

¹⁶⁸ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/>

¹⁶⁹ USDA Foreign Agriculture Service. "Seafood Report 2017". GAIN Report. USDA Foreign Agriculture Service. 2017, www.gain.fas.usda.gov/Recent%20GAIN%20Publications/Seafood%20Report%202017_Singapore_Singapore_11-6-2017.pdf.

¹⁷⁰ Lim, H., A. Widiana and B. Aw (2016), 'Non-tariff Measures in Singapore', in Ing, L.Y., S. F. de Cordoba and O. Cadot (eds.), Non-Tariff Measures in ASEAN. ERIA Research Project Report 2015-1, Jakarta: ERIA, pp.127-139.



¹⁷¹ "International Merchandise Trade Statistics (IMTS)." ASEAN Data, <https://data.aseanstats.org/trade-annually>

As one of ASEAN's main producers of seafood, most seafood is procured locally. Rising income levels however have led to a growing demand for imported seafood like tuna, which is imported from Indonesia, Taiwan, Japan, and the rest of the world.¹⁷²

Thailand also has one the world's largest seafood processing industries. However, locally sourced raw material can only fulfil 40–50% of the industry's needs while the other 50-60% have to be imported. For countries that have not signed FTAs with Thailand, base rates for seafood fall anywhere between 5–30%.¹⁷³

According to UNCTAD data, current TBT measures in Thailand include measures like certificate requirements for yellowfin tuna and yellowfin tuna products that are not applicable domestically. Similar measures include requirements for carp that have to be raised according to OIE (Office International Des Epizooties) rules, but such regulations not applicable domestically. A number of seafood products such as prawns are required to be quarantined before being allowed into the market. Explicit prohibitions on the import of certain kinds of fish such as Puffer fish are also prevalent. Both live seafood and food products have strict contaminant limits.


Sanitary and Phytosanitary Measures (SPS)

Category	Description	Impact
Conformity Assessment	<p><u>Inconsistent Documentation Requirements</u></p> <p>The Department of Fisheries, who operate at the port, ask importers to provide multiple documents, which can include:</p> <ul style="list-style-type: none"> • the catch certificate, • the certificate of origin, • exporting permission and • the health certificates. <p>According to the law, one is enough, but importers often get in trouble when they can only provide one of them. It is difficult for certain importers to get health and catch certificates.</p>	 Red
	<p><u>Hard-to-Obtain Documentation</u></p> <p>Tuna importers are asked for Captain Certificates. However, some SMEs importing into Thailand cannot obtain Captain Certificates, since a lot of the tuna imported is bought from markets where such certificates do not exist.</p>	 Yellow

¹⁷² USDA Foreign Agricultural Service. 2018. "Thailand: Seafood Report". Global Agricultural Information Network. USDA. https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Seafood%20Report_Bangkok_Thailand_5-8-2018.pdf.

¹⁷³ Infofish. "Thailand Seafood Market And Potentials For Peruvian Products." Infofish, Peru Export and Tourism Promotion Board (PROMPERU), 2013. www.siicex.gob.pe/siicex/resources/sectoresproductivos/Thailand%20Report%20Market%20Review.pdf.

Others

Category	Description	Impact
Consumer Preferences	People in ASEAN do not consume canned tuna, since they prefer fresh seafood. As a result, the market share for Thai canned and other seafood processed foods in ASEAN is as low as 1%. Most Thai processed seafood goes to Europe and the U.S. markets.	 Green

Vietnam

Vietnam is currently the fourth largest exporter of seafood with exports hitting US\$7 Billion in 2017 with an 18% increase year-on-year.¹⁷⁴ Seafood imports amounted to an estimated US\$1 Billion in 2016, up four percent from 2015, half of which is imported from ASEAN. The main export of Viet Nam is shrimp, which hit an estimated value of US\$3 Billion in 2016. Consumption is currently at 27kg per capita per year.¹⁷⁵ Besides fishing and aquaculture, Vietnam also has a large seafood processing industry, producing 2,8760 thousand tons in 2016 and 1,798 thousand tons of frozen aquatic products.






According to UNCTAD data, Vietnam has a requirement for the immediate payment of customs duties instead of the usual 275 days, which is applicable to all members unless stated otherwise. Also, as of 2011, Vietnam implemented an NTM to prevent inflows of similar products produced domestically — including seafood products. Other than the usual SPS measures, such as health certifications, current laws also include a requirement for products that are imported to be consumed within the country, causing potential problems for companies looking to re-export seafood products.

Looking across the various NTMs in ASEAN, while the majority take the form of SPSs and TBTs, certain measures like prohibitions and restrictions of particular breeds of seafood imply a different purpose. Furthermore, certification standards that require issuing by the local health authority indicate a lack of harmonisation across the region; especially since a food safety certificate issued by the exporting country might not be enough to exempt an importer from inspections.


¹⁷⁴ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/>.

¹⁷⁵ Wood, Laura. "Assessment Of Vietnam's Seafood Market 2017 - Research And Markets". *Businesswire.Com*. 2017, <https://www.businesswire.com/news/home/20170426006886/en/Assessment-Vietnams-Seafood-Market-2017-Research>.

Sanitary and Phytosanitary Measures (SPS)

Category	Description	Impact
Conformity Assessment	<p><u>Traceability Requirements:</u> The local health regulatory body requires a proper health certificate. Re-exporters cannot provide health documentation which is required as their local government cannot issue it for an imported product.</p>	
Registration requirements for importers	<p><u>Documentation:</u> Importers need to submit documents both online (via the National Platform) and offline (at the port). The process is time-consuming and costly.</p>	
Conformity Assessment	<p><u>PO Customs clearance procedures:</u> Customs clearance procedures at the port are complicated and time-consuming. Firms need to spend additional fees to speed up the process.</p>	
	<p><u>Inconsistent Requirements:</u> Standards requirements for different shipments are inconsistent.</p>	
	<p><u>Testing Requirements:</u> There are no clear and transparent regulations on how many samples the testing authorities can request from importers. In several cases, the amount of goods that are taken away for testing can be significant.</p>	

Trade Related Investment Measures

Category	Description	Impact
Local Presence Requirement	To sell products, a factory has to be registered in Vietnam. Setting up a factory is a lengthy process with registration taking from 3 months up to 2 years. The total number of ASEAN firms that have completed the procedures is limited.	

C. Biscuits

While alcoholic beverages are heavily regulated and seafood could be, biscuits should be an agri-food category with minimal impediments to trade. Like all food products, governments have the right to ensure that citizens are prevented from consuming clearly unsafe biscuits. But the extent and reach of government regulations for the sector should — on the face of it — be relatively modest.

Biscuits are a useful category for investigation into NTBs in agri-food for ASEAN, however, because member countries are involved as both producers and consumers. Nearly every ASEAN country has at least one local firm in the sector and many products are regionally available.

By product type, the biscuits market is segmented into sweet biscuits, savoury, crackers, filled/coated, wafers, and others. In 2017, the global biscuits market was worth US\$76.38 billion. The market is expanding at a compound annual growth rate of 4.70% and is forecasted to reach US\$109.95 billion in 2025.¹⁷⁶

Factors like the change in consumer preferences toward more convenient snacks or products, the increase in per capita food consumption and the expanding demand for healthy snacks are driving the growth of the global biscuits market.¹⁷⁷ Many companies are working towards healthier snacks to stay relevant in the 21st century.¹⁷⁸

The Asia-Pacific region is expected to be the fastest-growing market in the near term, which can be attributed to shifts in consumer preferences and increasing disposable incomes.¹⁷⁹

ASEAN follows this trend. Over the past decade, the trade volume of biscuits has steadily grown. Figure 16 shows how both imports and exports have grown by 20 and 30% respectively.¹⁸⁰ The same graph shows that exports have not only grown but have remained much larger than imports, which points to the dominance of local manufacturers.

¹⁷⁶ Globenewswire, "Global Biscuits Market is expected to be valued US\$109959.9million by 2025". 6 July. 2018 <https://globenewswire.com/news-release/2018/07/06/1534154/0/en/Global-Biscuits-Market-is-expected-to-be-valued-US-109-959-9-Million-by-2025-Transparency-Market-Research.html>

¹⁷⁷ Mordor Intelligence. "Biscuits Market – Growth, Trends and Forecast (2018 – 2023)". (April 18, 2018) <https://www.mordorintelligence.com/industry-reports/biscuits-market>

¹⁷⁸ Business Insider Singapore. "These famously unhealthy companies are taking extreme measure to get customers back". 16 Jan. 2018) <https://www.businessinsider.sg/unexpected-new-players-in-healthy-snacks-2016-1/?r=US&IR=T>

¹⁷⁹ Magazinebbm. "World Biscuit Market and Trends". <http://www.magazinebbm.com/english/?p=1547>

¹⁸⁰ "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

Figure 16: ASEAN Imports and Exports of Biscuits 2004 – 2017 USD Million¹⁸¹

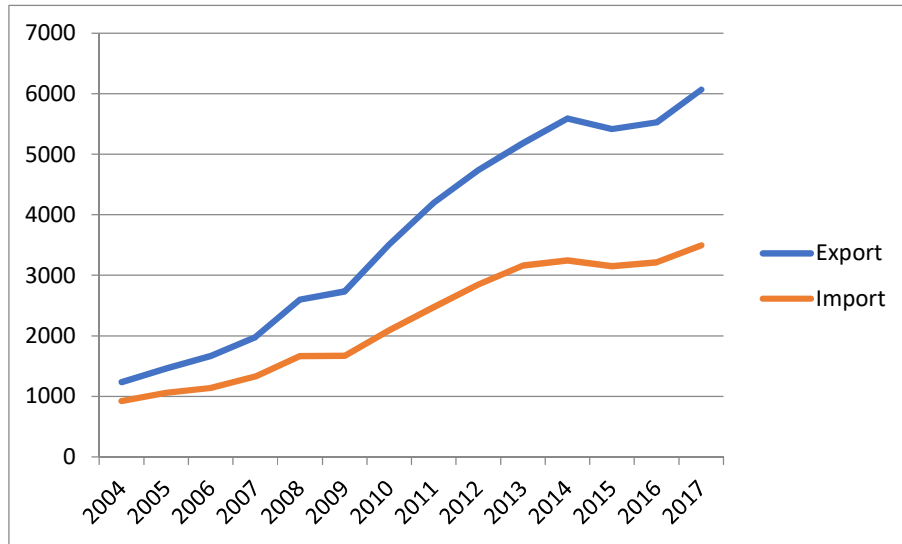
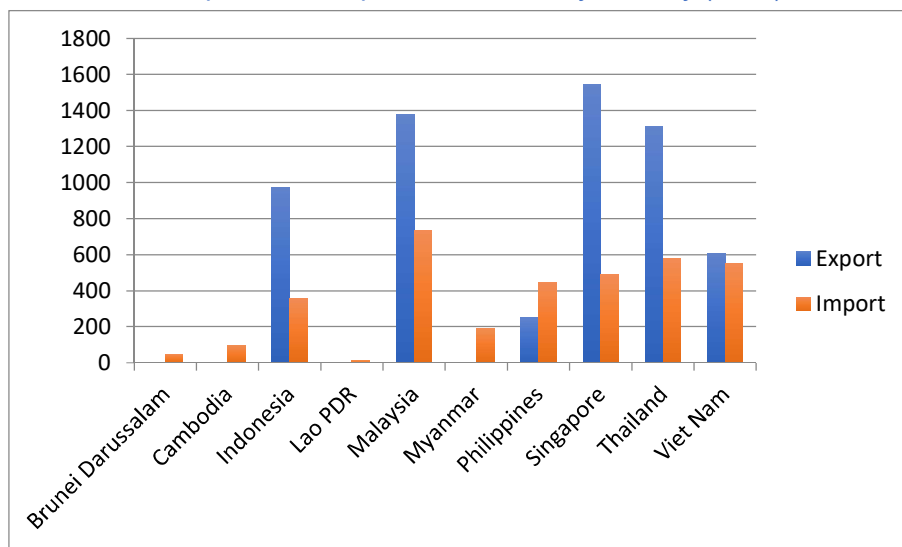


Figure 17 highlights the strength of national biscuit markets, since most ASEAN major markets (except the Philippines) export more than they import. Singapore, Malaysia and Thailand are the top three biscuits exporters, while Malaysia, Thailand and Vietnam are the top three importers.¹⁸²

Figure 17: ASEAN Imports and Exports of Biscuits by Country (2017) USD Million¹⁸³



¹⁸¹ "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

¹⁸² "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

¹⁸³ "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

NTMs in ASEAN's Biscuit Sector

Overall, ASEAN imposes 244 NTMs in the biscuit sector, 12% of the total NTMs applied to biscuit products around the world according to the UNCTAD database.¹⁸⁴ Figure 18 shows that Thailand, followed by Vietnam and the Philippines, impose the most NTMs, accounting for 54% of regional biscuit NTMs.¹⁸⁵ As a whole, ASEAN's average number of NTMs on biscuit products per country — 24.4 — is below Asia's regional average — 28.9 — but higher than Africa's — 17.8 — and Latin America's — 16.4. This means that while ASEAN countries on average do not impose more NTMs on biscuits than their Asian counterparts, they do impose more NTMs on biscuits than other comparable regions like Africa and Latin America.

Figure 18: Number of NTMs in ASEAN for the Biscuit Sector (2018)¹⁸⁶

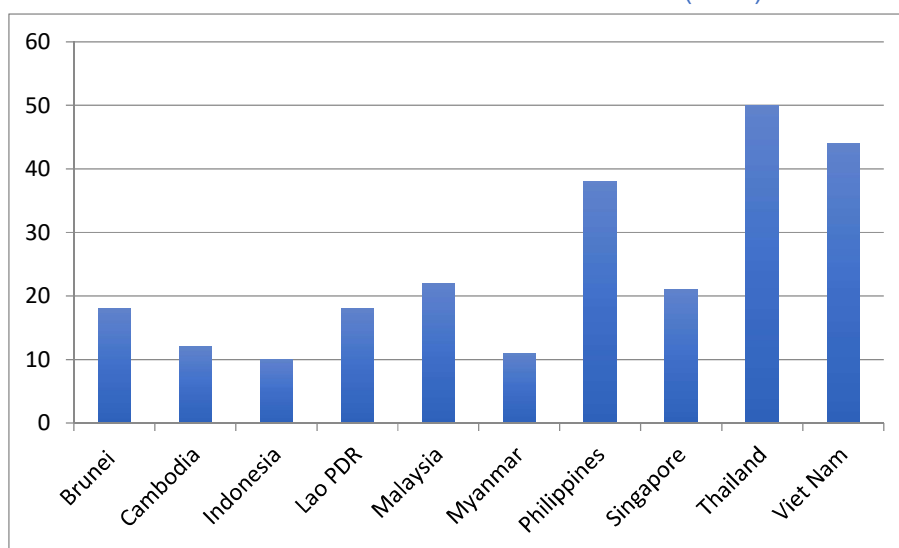


Figure 19 shows that TBT and SPS measures account for most of the NTMs affecting the biscuit sector in ASEAN in the UNCTAD data. Countries with the most regulations on technical barriers to trade are Thailand and Malaysia. Countries with the most SPS measures are Thailand and Vietnam.¹⁸⁷

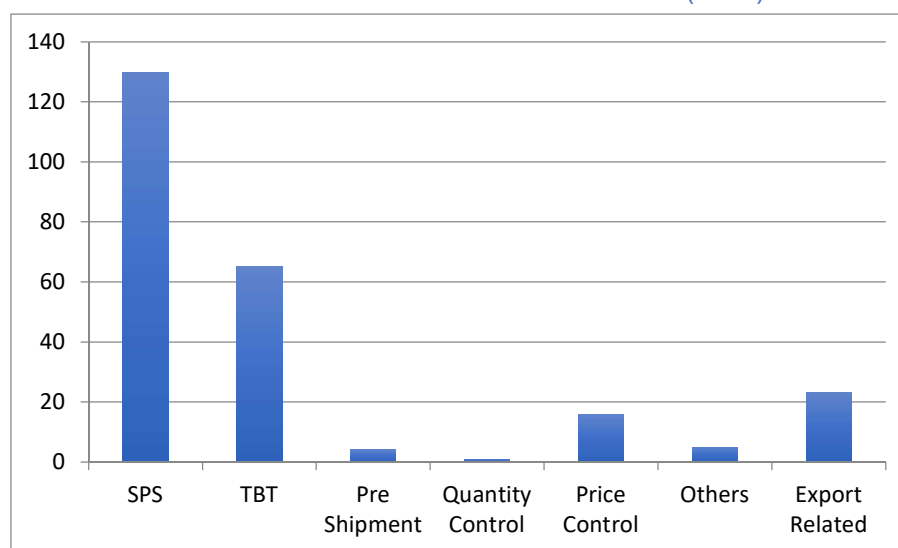
¹⁸⁴ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

¹⁸⁵ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

¹⁸⁶ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

¹⁸⁷ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

Figure 19: Number of NTMs in ASEAN for the Biscuit Sector (2018)¹⁸⁸



Surveys within the pre-packaged food industry have consistently shown that the most challenging TBTs in the region can be found in diverging nutritional claim rules. These are generally the result of different labelling standards across member states.

For instance, surveys conducted by Food Industry Asia (FIA) have revealed that nutrition claims and nutrition reference values are more complex than the Codex Benchmark¹⁸⁹. Such inconsistencies persist even in established markets like Malaysia, Thailand and Indonesia.¹⁹⁰ The same surveys also cite incoherency and a lack of transparency in the development and implementation of regulations as one the major sources of complexity for regulations in the region.¹⁹¹ Thus, diverging nutritional labelling standards and associated procedural obstacles, such as inconsistency and a lack of transparency, are likely to pose obstacles to trade for biscuit businesses in the region.

Furthermore, a similar survey conducted by FIA found that packaged food exporters around the region face increasing barriers as a result of regulatory convergence and harmonization. Barriers relevant to the biscuits sector included:

- Halal certification, which lacks a unified standard and certification framework;¹⁹²

¹⁸⁸ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

¹⁸⁹ ASEAN Food Beverage Alliance (AFBA) "Nutritional Labelling in Prepackaged Food: Impact on Trade in ASEAN." Food Industry Asia and University of Malaya, 2018, 3.

Food Industry Asia (FIA) "Removing Non-Tariff Barriers in ASEAN through Regulatory Convergence and Mutual Recognition in the Food Sector." FIA, 2018, 15.

¹⁹⁰ ASEAN Food Beverage Alliance (AFBA) "Nutritional Labelling in Prepackaged Food: Impact on Trade in ASEAN." Food Industry Asia and University of Malaya, 2018, 3.

¹⁹¹ ASEAN Food Beverage Alliance (AFBA) "Nutritional Labelling in Prepackaged Food: Impact on Trade in ASEAN." Food Industry Asia and University of Malaya, 2018, 34.

¹⁹² Food Industry Asia (FIA) "Removing Non-Tariff Barriers in ASEAN through Regulatory Convergence and Mutual Recognition in the Food Sector." FIA, 2018, 16.

- Premarket registration, which can be complex, costly, delay product market access and reduces supply chain efficiency;¹⁹³
- Import and export certification, which requires different information, documentation and process requirements across member countries; and¹⁹⁴
- Authorization of food ingredients and additives, which lacks a standard common approval process. Firms need to obtain multiple authorizations with significant variations in registration requirements and timelines for risk.¹⁹⁵

Overall, the lack of regulatory divergence and harmonization of nutritional labelling and product registration certification standards across ASEAN is very likely to act as a barrier to trade for biscuit companies. These requirements may add unnecessary complexity and increase the costs of products, and thus limit trade in the ASEAN market.

¹⁹³ Food Industry Asia (FIA) "Removing Non-Tariff Barriers in ASEAN through Regulatory Convergence and Mutual Recognition in the Food Sector." FIA, 2018, 17.

¹⁹⁴ Food Industry Asia (FIA) "Removing Non-Tariff Barriers in ASEAN through Regulatory Convergence and Mutual Recognition in the Food Sector." FIA, 2018, 19.

¹⁹⁵ Food Industry Asia (FIA) "Removing Non-Tariff Barriers in ASEAN through Regulatory Convergence and Mutual Recognition in the Food Sector." FIA, 2018, 18.

Biscuit Interview Findings

The following section is based on the results of a series of interviews conducted between October 2018-January 2019 in key ASEAN markets with industry players in the biscuits sector. Interview candidates included ASEAN companies as well as foreign players. It does not cover all ASEAN markets, nor highlight all potential issues — only those explicitly raised by interview subjects. All NTM details are tabulated from the UNCTAD Integrated Trade Intelligence Portal.

While the study made every effort to interview firms in the biscuit sector about specific challenges to doing business in ASEAN, firms were reluctant to respond to requests. Total interview numbers were smaller, and the number of issues raised were limited. Firms were especially reluctant to draw attention to possible NTBs in individual ASEAN Member States.


As with seafood, it is certainly possible that ASEAN has limited NTBs in the sector. As a possible check on this option, the following section reports carefully on the UNCTAD data available for NTMs for each ASEAN member state for biscuits. Since many NTMs are likely to be viewed as legitimate government checks on health and safety, as an example, conclusions should not be drawn that every NTM is an automatic NTB for the sector. Nevertheless, there does seem to be evidence from the UNCTAD database, combined with the limited interview results, to suggest that NTBs are present in ASEAN in biscuits. Further study is needed to confirm this finding.

In the meantime, as with other interview sections, the “impact scoring” of red/yellow/green was not developed by the firms directly. It was derived from company interviews and by the extent to which a particular barrier was repeatedly raised by firms as well as by how much of an obstacle any specific barrier poses to doing business. The impact score should be viewed as a continuum from red to green, rather than a clear shift from one category to another. As might expected, the charts below reflect few “green” impact scores, as firms typically did not spend time discussing issues that were not viewed as problematic. If viewed across time, however, some of the listed items could very well decline from red to yellow to green or the reverse.

Cambodia

According to the UNCTAD NTM database, Cambodia has imposed 12 NTMs on biscuit products. Most of these are TBTs and include mandatory labelling requirements for pre-packaged foods.

Technical Barriers to Trade


Category	Description	Impact
Customs Delays	<p><u>Customs clearance:</u></p> <p>Significant delays and waiting times at Cambodian borders. One container of 60 products will need a minimum of two weeks to be cleared. One shipment of 30 types of products will need up to two months of waiting (or dwell) time.</p>	 Red

Indonesia

Biscuits are a staple product in Indonesia, where consumers purchase more than US\$1 billion worth of biscuits each year.¹⁹⁶ Over the years, the Indonesia biscuits category has witnessed an influx of new product launches. The product launches range from healthy biscuits like the Oops 100k, savoury biscuits and crackers, to new and innovative biscuit types, like the Nestle Crunch.¹⁹⁷ The biscuit industry trade has recorded a steady growth over the past years, accompanied by an increase in production of biscuits from year-to-year.¹⁹⁸

According to UNCTAD, Indonesia imposes six NTMs on biscuit products. Most of these are TBTs and include requirements to hold a Circulation permit and obtain approval from the Head of Agency for the importation of food.

Sanitary and Phytosanitary Measures (SPS)



Category	Description	Impact
Product Requirements for Religious Reasons	<p><u>Halal Certification</u></p> <p>Participants raised concerns around the lack of harmonization in newly-enacted halal certification bodies.</p>	 Red

¹⁹⁶ "Indonesia's next top biscuit – made by you?", OMRON Asia Pacific, <https://www.omron.asia/story/indonesias-next-top-biscuit-made-by-you/>

¹⁹⁷ "Indonesian Biscuits market: keeping steady and moderate." Biscuit People, 12 May. 2014, <https://www.biscuitpeople.com/magazine/post/indonesian-biscuits-market-keeping-steady-moderate>

¹⁹⁸ "Biscuits industry in Indonesia." The Free Library, 2013, <https://www.thefreelibrary.com/Biscuits+industry+in+Indonesia.-a0335826701>

Technical Barriers to Trade


Category	Description	Impact
Licensing	<u>Multiple Licenses:</u> Firms need to go to different ministries to get different types of licenses.	 Yellow
Procedural Obstacles – Conformity Assessment	<u>Inconsistent Application of Standards:</u> Many officials lack the necessary knowledge about the industry and the procedures to make appropriate and reasonable decisions. There are Standards of Operating Procedures and guidelines, but these are inconsistently followed. The implementation of the same regulation might vary across authorities.	 Red

Malaysia

Biscuits are a popular snack food in Malaysia. Consumers' rising concerns about their health has pushed biscuit companies in Malaysia towards healthier biscuits.¹⁹⁹ Mondelez, as an example, saw a 7% increase in revenue between 2016 and 2017 and attributed it to changing consumer behaviour through relevant innovations.²⁰⁰

According to UNCTAD, Malaysia imposes ten NTMs on biscuit products. Most of these are TBTs and mainly include particular labelling requirements for food confection content.

Sanitary and Phytosanitary Measures (SPS)

Category	Description	Impact
Product Requirements for Religious Reasons	<u>Halal Certification</u> Participants raised concerns around the lack of harmonization in newly-enacted halal certification bodies	 Red


Myanmar

According to UNCTAD, Myanmar imposes two NTMs on biscuit products. Both are TBTs and include labelling requirements ensuring that food is properly labelled with the information required by a relevant government department or organization.

¹⁹⁹ Australian Food and Grocery Council (AFGC), "AFGC Market Insights: Malaysia." TradeWorthy, 2014 https://www.appma.com.au/wp-content/uploads/2015/02/afgc03268_malaysia_web_140627.pdf

²⁰⁰ "Mondelez Malaysia strengthens biscuits category, launches new breakfast range." MarketingInteractive, 08 Aug. 2017, <https://www.marketing-interactive.com/mondelez-malaysia-strengthens-biscuits-category-launches-new-breakfast-range/>

Sanitary and Phytosanitary Measures (SPS)

Category	Description	Impact
Product Registration Requirement	<u>Difficult FDA registration:</u> Getting a certificate and import license in Myanmar is almost impossible. Samples are required for certification and import license application. Customs officers will not allow samples to be shipped into Myanmar without such certificates or import licenses.	 Red

The Philippines

The strong growth of imports over the years indicates there is a strong demand for foreign biscuits in the Philippines market.²⁰¹ The combined value share of key domestic players is expected to remain significantly higher than their multinational counterparts, because local brands lead in all categories in sweet biscuits and fruit snacks.²⁰²

In terms of market shares, Universal Robina Corp continued to lead sweet biscuits, snack bars and fruit snacks in 2018. Its leadership can be traced to its presence in different categories in sweet biscuits, including chocolate coated biscuits, filled biscuits and wafers.

According to UNCTAD, the Philippines impose four NTMs on biscuit products. These are all TBTs and mainly include labelling requirements for pre-packaged foods.

Singapore

The country relies heavily on food supplied from overseas, which can be shown in the trade balance for biscuits over the years. In 2019 the biscuit market is forecast to have a value of \$51.4 million, which is a 13% decrease from 2014.²⁰³ Kraft Foods (S) Pte Ltd and a local firm, Khong Guan Biscuit Factory (S) Pte Ltd, led sweet biscuits, snack bars and fruit snacks in 2018, with their signature brands of Oreo and Khong Guan respectively.

According to UNCTAD, Singapore imposes nine NTMs on biscuit products. These are all TBTs and mainly include labelling requirements for bakery products and product classification requirements.

Thailand

The Thai biscuit markets has seen significant growth with higher demand for daily baked products growing faster than the overall economy.²⁰⁴ In 2014, Thailand's biscuit

²⁰¹ "Sweet Biscuits, Snack Bars and Fruit Snacks in the Philippines." Euromonitor, Jul. 2018,

<https://www.euromonitor.com/sweet-biscuits-snack-bars-and-fruit-snacks-in-the-philippines/report>

²⁰² "Filipino Consumers Prefer Locally Manufactured Biscuits, Snacks and Dairy Products." Nielsen, <https://www.nielsen.com/ph/en/insights/news/2017/Filipino-consumers-prefer-locally-manufactured-biscuits-snacks-and-dairy-products.html>

²⁰³ "Biscuits segment to see negative growth." Asia Food Beverages, <http://www.asiafoodbeverages.com/admin/pubs/showpg.asp?pg=3054>



²⁰⁴ Larive (Thailand) Co. Ltd. "Business Opportunities Study in Thai Bakery Sector." Embassy of the Kingdom of the Netherlands in Bangkok, Jun. 2013,

market size was US\$150 million. According to the Australian Food and Grocery Council, strong growth is expected in the biscuits category over the short term.²⁰⁵

Thailand's retail market is dominated by imported products such as Oreo (Nabisco), Walkers, and Pocky. Major local brands are Bissin (Thai President Foods) and Gilco Collon in the sweet biscuit segment and Gilco Pretz in the savoury biscuit segment.

According to UNCTAD, Thailand imposes 12 NTMs on biscuit products. These are all TBTs and mainly include FDA registration requirements and labelling requirements for breads.

Sanitary and Phytosanitary Measures (SPS)

Category	Description	Impact
Conformity Assessment	<p><u>POTENTIAL Ban on Partially Hydrogenated Oils (PHOs) in Foods:</u></p> <p>Introduction of new regulation to ban PHOs included in foods. This is detrimental since it is hard for foreign importers to provide information about secondary ingredients. Companies--regardless of the content of their product--will have to test their products to show that they do not contain PHOs. This will entail a significant cost for companies who lack the capacity to meet those testing requirements.</p>	
Product Registration Requirement	<p><u>Lengthy Product Registration</u></p> <p>Products must register under Categories Two and Three of prescribed foods which require that these meet specific qualities or standards or have labels determined by ministers.</p> <p>Registration takes more than half a year and each importer has to prove that their product is safe on their own before they import. Each importer must prove that each product is safe.</p>	

<https://www.rvo.nl/sites/default/files/2013/08/Business%20Opportunities%20Study%20in%20Thai%20Bakery%20Sector.pdf>

²⁰⁵ Australian Food and Grocery Council (AFGC), "AFGC Market Insights: Malaysia." TradeWorthy, 2014, https://www.appma.com.au/wp-content/uploads/2015/02/afgc03268_thai_web_140627-1.pdf

Technical Barriers to Trade


Category	Description	Impact
Packaging	<u>Import Marking Requirements</u> Importers need a specific marking label which must be purchased prior to shipping. It can be difficult to put the sticker on before products arrive to Thailand.	
Labelling	<u>Inconsistent Labelling Requirements</u> Sometimes Customs officials have requested translation of each letter on a package. This leads to uncertainty, since there is no rule on translation requirements, which can change from shipment to shipment.	

Vietnam

The Vietnam market has a population of 95.54 million people. The rise in urbanization, spending power and standard of living are expected to drive the snack market to around US\$1 billion by 2020.²⁰⁶ The Vietnam food and beverage industry is seeing strong growth, which can be accredited to the rising spending power of the citizens and their higher living standard. The industry grew 7% between 2016 and 2017, while biscuits grew by 11.9%.²⁰⁷

According to UNCTAD, Vietnam imposes nine NTMs on biscuit products. These are all TBTs and mainly include requirements on labelling of products to comply with existing regulations and content requirements.

Technical Barriers to Trade

Category	Description	Impact
Procedural Obstacle: Product Declaration	<u>Unreliable Product declaration system:</u> Vietnam has just changed the mechanism for firms to declare imported biscuit products. Before Decree 15/2018, this process was done offline through the central/ministry level. After Decree 15/2018, this process is now done online and at municipal level which is much faster and less costly. However, the quality of the registration website cannot meet the demand. The websites break down quite regularly, causing up to seven days in delay for firms.	

²⁰⁶ Dan, Koushas. "Vietnam's Snack Food Market: Knowing Your Consumers." Vietnam Briefing, 27 Jul. 2018. <https://www.vietnam-briefing.com/news/vietnam-snack-foods-market-knowing-your-consumers.html/>

²⁰⁷ Wan, Lester. "Consumers food trends in Vietnam" Rising incomes offering big opportunities for manufacturers." Food Navigator, 16 Jun. 2018, <https://www.foodnavigator-asia.com/Article/2018/06/26/Consumer-food-trends-in-Vietnam-Rising-incomes-offering-big-opportunities-for-manufacturers>

Conformity Assessment	<p><u>Customs Valuation:</u> Biscuits are under the “risk management product group” so 100% shipments need to be tested and checked. If the declared prices are lower than other firms, customs officers will investigate importers. The investigation process is time-consuming for firms.</p>	Yellow
	<p><u>Traceability Information Requirement</u> <u>FTA usage:</u> To apply for preferential tariff rates, firms need to show commercial invoices for local sourcing. Getting commercial invoices for transactions with farmers and micro/small companies in Vietnam is challenging. Manufacturers need to go through traders or middlemen to source from Vietnamese farmers.</p>	Red

Price Control Measures

Category	Description	Impact
Customs Duty	<p><u>Inconsistent Applied Customs Duty:</u> Importers often debate with customs officers over which HS code should be applied for the imported goods. Customs officers often request an HS code with higher tariff rates.</p>	Red

Analysis of Biscuits Findings

The interview results and analysis of UNCTAD data on NTMs show that ASEAN's biscuit market does not appear to operate in the presence of significant NTBs. These findings need to be corroborated with further research.

Nevertheless, there are some labelling and SPS requirements and procedural obstacles that make it difficult for ASEAN and foreign manufacturers to successfully operate across all ASEAN markets. A closer analysis points at prevalence and drawbacks of these specific types of policies.

SPS restrictions including Halal requirements

Participants raised concerns about the operational difficulties associated with halal standards and certification. At present only Malaysia, Singapore and Indonesia have their own official lists of recognized foreign halal certification bodies. While some level of mutual recognition has been introduced between Singapore, Indonesia, Malaysia and Vietnam, there remains a patchy network of recognition of halal certification bodies across the region.²⁰⁸

Customs Clearance

Participants raised concerns about delays and inconsistencies within the customs clearance process. These include delays in some of the least developed members like Cambodia and Laos, or inconsistent treatment by customs officials who often lack the necessary knowledge and training about the industry (such as Vietnam and Indonesia)

Product Registration

Participants raised concerns about lengthy and complicated product registration processes that make it at times almost impossible to sell certain products in a market (Myanmar, Thailand and Vietnam). Such processes can be complex, costly, delay product market access, tie up resources and reduce supply chain efficiencies.

²⁰⁸ Food Industry Asia (FIA). "Removing Non-Tariff Barriers in ASEAN through Regulatory Convergence and Mutual Recognition in the Food Sector." Food Industry Asia, 2018.

ASEAN Recommendations for Agri-Food

This project has been designed to gather information and provide recommendations to improve ASEAN processes for addressing NTMs and NTBs across all sectors. However, as with the automotive sector, it would be a missed opportunity to provide input on how existing ASEAN sectorial bodies might be better adjusted to focus on solving some NTB challenges for the agri-food sector specifically.

At the sectorial level, ASEAN needs to do at least two things: 1) gather better information about NTMs and NTBs for agri-food and 2) take steps to eliminate NTBs for the sector. While many elements of the data collection and reduction processes will overlap with general steps ASEAN should take in the future, some can be sector-specific, located in existing ASEAN institutional bodies that have the relevant knowledge to best address the challenges of the agri-food sector.

At the most basic level, many non-tariff issues fall within the sanitary and phytosanitary (SPS) categories of NTMs (unlike challenges in autos or many issues with medical devices). Effectively tackling these problems requires effective understanding of SPS issues and legitimate government responsibilities in safeguarding public interests as a result.

ASEAN Member States have already made numerous and significant commitments toward the harmonization of NTMs within the agri-food sector. For example, under the ATIGA, ASEAN has already pledged to identify and eliminate NTBs and apply international standards to SPS measures.

The primary responsibility for the task of removing and reducing TBTs in prepared foods lies with the Prepared Foodstuff Product Working Group (PFPWG) under the ASEAN Consultative Committee for Standards and Quality (ACCSQ). The ACCSQ is comprised of two food and safety standards task forces: a task force on harmonization and a task force on mutual recognition agreements (MRAs).

Since harmonization towards international standards is always preferable and has been a clear preference of firms in the interviews across all categories, it is a good sign that ASEAN's more recent efforts in respect of regulatory convergence and harmonization have borrowed heavily from the Codex Alimentarius Commission and Guidelines. Indeed, wholesale adoption of Codex would be quite helpful for firms and would dramatically simplify the workload of the ACCSQ. The focus could shift towards implementation, rather than the crafting of specific standards.

Such initiatives include the development of Principles and Guidelines for National Food Control Systems, General Principles of Food Hygiene, Guidelines for Import Control Systems, ASEAN Principles for Food Import and Export Inspection and Certification, ASEAN Food Safety Policy, ASEAN General Standards for the Labelling of Pre-packaged Food and ASEAN Food Safety Regulatory Framework (AFSRF).²⁰⁹ As many firms in the interviews have noted the challenges of working with inconsistent rules in

²⁰⁹ Food Industry Asia (FIA). "Removing Non-Tariff Barriers in ASEAN through Regulatory Convergence and Mutual Recognition in the Food Sector." Food Industry Asia, 2018.

many of these areas, harmonization across ASEAN would reduce uncertainty and risk for companies in the region. This would lower costs of doing business for ASEAN.

The ACCSQ, through PFPWG, is in the initial stage on the harmonization of nutrition labelling. A survey on nutrition labelling is ongoing for analysis and discussion. ASEAN members are working with industry to develop a list of priority areas.

While these are effective ways to further the harmonization of standards, there remain significant obstacles to the successful implementation of those standards and the elimination of other kinds of barriers.

The PFPWG lacks the capacity to address many of the issues raised by participating companies in this study. There are no guarantees that the development of MRAs and the harmonization of standards will result in their successful implementation. Furthermore, there is no institutional body with a mandate that allows it to identify, assess and eliminate other types of NTBs. For instance, taxation and market entry issues cannot be addressed unless an institutional body has the mandate to do so.

Therefore, ASEAN must implement the measures to ensure that it can identify, assess and actually eliminate barriers affecting the development of its agri-food sector.

ASEAN must develop its institutional capacity to ensure that the harmonization of standards and certification procedures and related commitments are actually implemented by member states for agri-food and related ASEAN sectorial bodies.

ASEAN needs to develop an institutional mechanism or body that would allow it to tackle NTMs that are not related to harmonization of standards for food safety, certification and labelling. There remain issues, such as taxation or marketing, that the ACCSQ is unable to address. Therefore, it is important that as a regional body ASEAN develops mechanisms that ensure that (i) dialogue with private sector stakeholders is consistent and (ii) that there is an institutional body capable of identifying and addressing NTBs that are not standards-based.

III. Healthcare Goods

The development of an effective and efficient healthcare sector is an important key to meeting the needs of ASEAN's growing middle income and ageing populations. To respond to these growing needs, it is expected that by 2025, total healthcare spending could rise to US\$740 billion from the current US\$420 billion.²¹⁰

The ASEAN healthcare sector has seen strong growth in recent years, fueled by an expanding middle class, a rise in personal income, and a surge in private insurance coverage.²¹¹ Such growth can be attributed to a number of factors. First, the size of the middle class within the various member states is expanding rapidly. The Asian Development Bank expects this group to grow from 24% of the total population in 2010 to 65% by 2030.²¹² Second, ASEAN Member States are affected by fast changing demographic trends such as population ageing and urbanization.²¹³ These and other market drivers are expected to fuel further demand for more and better quality healthcare, and contribute significantly to the expansion of the region's healthcare market.

While the advent of tariff-free healthcare products trade within ASEAN represents an important step in the pursuit of stronger economies of scale and access to quality healthcare products, the ASEAN healthcare goods industry is still heavily protected with a broad suite of non-tariff measures (NTMs) that currently interfere with the creative development of the diversified and innovative sector.

Health is an important regulatory area for governments of course and no citizen expects to find clearly unsafe products for sale in the marketplace. As with all goods, however, the line between legitimate measures (NTMs) and unfair barriers to trade (NTBs) can be narrow. In the healthcare sector, this division often appears extremely opaque for companies operating in the space. This project does not make judgements about whether certain concerns raised by firms during interviews fit into the former category or into the latter.

But it is fair to say that companies raised points about issues like satisfying multiple regulatory regimes within individual ASEAN Member States, battling high taxation that often means greater competition from illegitimate products in the marketplace, forced localization rules, and non-transparent procurement processes that are prevalent across many of the markets in the region. These types of concerns often appear to fit the criteria of NTBs, rather than NTMs.

The healthcare sector is also unique in many ways in combining the private and public sectors. For instance, to enter the market, many firms must get products registered in

²¹⁰ Gildea, Deborah "The cost of healthcare is rising in ASEAN. How can nations get the most for their money?", World Economic Forum, 31 Aug. 2018.

²¹¹ Jakovljevic, Mihajlo, and Thomas E. Getzen. "Growth of global health spending share in low and middle income countries." *Frontiers in pharmacology* 7 (2016): 21.

²¹² Kang, Jong, and Grendell Magoncia. "How to Fill the Working-Age Population Gap in Asia: A Population Accounting Approach." (2016).

²¹³ Tan, Derrick "Tapping on ASEAN's Healthcare Opportunities through Singapore", Asia Biotech, <https://www.asiabiotech.com/19/1909/19090017x.html>

advance on specific government lists called formularies. Items that are not on the formulary may not be sold in the market at all, or may not be sold to public facilities. Hence the procedures for placing items on the formulary are critically important to companies and a possible location for an NTB to cross over into an NTB.

It is important that ASEAN Member States and the institution begin to address these NTBs to allow the healthcare sector to continue to grow and meet the increasing needs of the healthcare services sector. A failure to effectively address unjustified, difficult, and costly NTBs will increasingly negate much of the investment, innovation and collaboration needed for the future.

The healthcare sector is complex. To begin to get a handle on the specific types of NTBs that may plague the industry, this project conducted interviews with companies across the region in two goods categories: pharmaceuticals and medical devices. Such goods range from prescription drugs to over-the-counter products to a wide range of devices used in hospitals, clinics, and in-home settings.

Given the extent and range of concerns thrown up by firms in these two sectors, future research may be warranted to investigate these issues in greater depth.

Case Study Pharmaceuticals– Importing a New Products into Indonesia

Indonesia's pharmaceutical market is one of the fastest-growing markets in the world and the largest market in ASEAN. Driven by a rising demand for medicines and the Indonesian government's Universal Health Coverage scheme, Indonesia's pharmaceuticals market is poised to expand and continue to offer opportunities for local and foreign pharmaceutical manufacturers. However, there remain market access and technical barriers that are making it increasingly difficult for foreign pharmaceutical companies to sell their products in Indonesia. This case study explores some of those barriers from the perspective of a foreign pharmaceuticals company trying to sell a new product in Indonesia. The analysis is based on issues raised by ASEAN based firms who participated in the study "Assessment of ASEAN NTBs and Net Benefits of Elimination." under the Enhanced Regional EU-ASEAN Dialogue Instrument (E-READI) cooperation program.

Forced localization requirements through Patent Restriction and Removal.

Indonesia has implemented a series of forced localization and IP laws that make it almost impossible for foreign pharmaceuticals companies to import or sell new products into the country.

Under Article 20 of the Indonesian Patent Law of 2016, patent holders must "work" their patents in order to support the "transfer of technology, investment and/job opportunities in Indonesia."²¹⁴ This requires patent owners to either manufacture their patented products or use their patented processes in Indonesia: in other words, to obtain a patent in Indonesia foreign pharmaceuticals companies must set up a manufacturing/processing facility that produces the new drug the company intends to sell.

Furthermore, Article 82 of the same law states that if the patent is not worked within thirty-six months after the patent has been granted, a third party can file an application for compulsory licensing.²¹⁵ This decision is made by the Ministry of Law on a case-by-case basis. In sum, to obtain a patent, a foreign pharmaceutical company trying to sell their new product into Indonesia must manufacture or produce the patented drug within thirty-six months after their patent is approved. Otherwise, the company runs the risk of having their patent revoked through compulsory licensing.

²¹⁴ Mueller, Lisa and Handayani, Indah. "Implementing Regulations Provide Clarity on the Working Requirement in Indonesia." Tilleke & Gibbins, 24 Sep. 2018, <https://www.tilleke.com/resources/implementing-regulations-provide-clarity-working-requirement-indonesia>

²¹⁵ Pharmaceutical Research and Manufacturers of America (PhRMA). "Special 310 Submission 2019." PhRMA, 2019, <http://phrma-docs.phrma.org/files/dmfile/PhRMA-2019-Special-301-Submission.pdf>

The forced localization laws under Indonesia's new IP law represent a significant barrier for a foreign pharmaceutical company trying to sell a new drug in Indonesia. First, the requirements are counterproductive to the development and evolution of global pharmaceutical supply chains as they involve research and development, as well as active ingredient manufacturing, packaging, and distribution that must be optimized across multiple localities. Pharmaceutical firms with the capacity to supply their product in Indonesia using their existing supply chain, have to incur significant and unnecessary costs to set up a production or processing facility in Indonesia. Second, the level of technology within existing Indonesian facilities makes them a potentially challenging fit for the development of new and innovative drugs. Pharmaceutical producers will likely incur significant costs as a result of a lack of infrastructure and technology and lower productivity at their Indonesian production or processing facilities.

Local Manufacturing and Technology Transfer Requirement:

Under the Ministry of Health (MOH) Decree 1010, implemented in 2010, there are local manufacturing and technology transfer requirements that bar pharmaceutical products companies from registering their drugs in the Indonesian market. Under the regulations, the products of foreign pharmaceutical companies cannot obtain a Market Authorization — a “form of approval of drug registration to be able to be distributed in Indonesia” — unless they have a manufacturing facility in Indonesia.²¹⁶ This means that such companies must either:

- establish a local manufacturing facility or
- transfer IP sensitive data to another pharmaceutical firm with local manufacturing facilities in Indonesia.²¹⁷

The first condition would be difficult to meet for most companies, given the fragmented and global structure of pharmaceutical companies supply chains. As previously mentioned, firms would incur significant costs setting up an entirely new production facility to supply products that their current supply can already provide. The second condition forces technology transfer of new drugs, and thus poses a threat to IP protection.

Decree 1010 also requires companies to locally manufacture imported products within five years after the first importation. There are only exceptions for products under patent protection, which under the 2016 Patent Law, must be manufactured or processed in Indonesia. The requirement increases the production costs of companies with a local manufacturing or processing facility, since these import most of their active ingredients and lack the capacity or infrastructure to produce those ingredients in Indonesia.

²¹⁶ Ministry of Health “Decree of the Minister of Health Republic of Indonesia No 1010/Menkes/Per/Xi/2008 on Drug Registration.” Minister of Health Jakarta, 3 Nov. 2008, <http://www.comercio.gob.es/es-ES/comercio-exterior/politica-comercial/obstaculos-comercio/con-terceros-paises/PDF/documentos-relacionados-portal-barreras-comercio-sec/Decreto10102008ProductosFarmaceuticos.pdf>

²¹⁷ Pharmaceutical Research and Manufacturers of America (PhRMA). “Special 310 Submission 2019.” PhRMA, 2019, 110 – 116, <http://phrma-docs.phrma.org/files/dmfile/PhRMA-2019-Special-301-Submission.pdf>

As a result, to register their drugs for sale, foreign pharmaceutical companies must incur significant costs to (i) set up a manufacturing facility and (ii) manufacture the drug in Indonesia within five years of importation.

Local Content Requirement:

Under the Presidential Instruction No. 6/2016, the Ministry of Industry is establishing a detailed local content calculation methodology for pharmaceutical products sold in Indonesia. The law defines local content as including manufacturing, raw ingredients, research and development, and packaging.²¹⁸ So far, the method lacks clarity and it may be impossible to implement or monitor. It might create a significant barrier for the development of new drugs in Indonesia.²¹⁹ The requirement adds new barriers for companies that have set up local manufacturing/processing facilities in Indonesia and lack the personal and infrastructure to produce their active ingredients locally. As a result, local content requirement is likely to lower productivity and increase production costs for firms and prices for consumers. Overall, content requirement restrictions like this add significant disruptions and costs for companies already following Indonesia's forced localization and IP requirements.

Inconsistent IP Protection System:

Indonesia's IP protection system remains inconsistent. Firms that have complied with the myriad of forced localization and IP requirements might still be subject to compulsory licensing. Between 2004 and 2012, Indonesia issued compulsory licenses on nine patented pharmaceutical products.²²⁰ This added risk creates further uncertainties and discourages the development of pharmaceutical drugs in Indonesia.

Limited Access to National Formulary:

Moreover, it has become increasingly difficult to list new medicines in Indonesia's National Formulary, which makes cost-focused listing decisions. Participating companies claimed that listing decisions appear to be primarily based on price and the overall Social Insurance Administration Organization (BPJS) budget. This is a significant barrier to trade since it is not consistent with international guidelines that state that listing decisions should reflect multiple sources of evidence, which include scientific data demonstrating drug safety and efficacy.

²¹⁸ World Trade Organization (WTO). "Indonesia – Local Content Requirements for Pharmaceutical Products and Medical Devices." WTO Committee on Trade-Related Investment Measures, 21 Sep. 2018, G/TRIMS/Q/IDN/3.

²¹⁹ Pharmaceutical Research and Manufacturers of America (PhRMA). "Special 310 Submission 2019." PhRMA, 2019, 110 – 116, <http://phrma-docs.phrma.org/files/dmfile/PhRMA-2019-Special-301-Submission.pdf>

²²⁰ Pharmaceutical Research and Manufacturers of America (PhRMA). "Special 310 Submission 2019." PhRMA, 2019, 110 – 116, <http://phrma-docs.phrma.org/files/dmfile/PhRMA-2019-Special-301-Submission.pdf>

Mandatory Halal Certification:

The 2014 Halal Products Law makes Halal Certification mandatory for all pharmaceutical products in Indonesia.²²¹ This means that all pharmaceutical producers need to obtain a halal certificate. Non-compliance means administrative penalties or reduced product competitiveness as Indonesians opt for halal-certified alternatives.²²² Pharmaceutical producers must incur additional costs to obtain a halal certificate and bear any costs of non-compliance under a set of non-transparent rules. The costs of compliance are also likely to be burdensome for smaller firms — the Employer's Association of Indonesia (Apindo) estimates that each halal certificate will cost about 15 million rupiah on average.²²³

Delays in the Product Registration Process:

Last, pharmaceutical companies are likely to face regulatory delays in the registration process of new products, which may result in new products being temporarily or permanently blocked from entering the market. Such delays can increase a firm's inventory carrying costs and create inventory stock outs that lead to sales losses.

Indonesia's policies surrounding the importation and development of pharmaceutical products are consistent with practices found across ASEAN. Issues with the length, validity and reliability of patents, a lack of transparency and discriminatory practices within procurement process, and the limited scope of national formulary registration continue to be an impediment to the trade and development of new pharmaceutical products across ASEAN.

²²¹ Mariska, Made Ayu. And Ng, Jefferson. "Indonesia's New Halal Law" Impact on the Political Economy, RSIS No. 010, 17 Jan. 2019, <https://www.rsis.edu.sg/rsis-publication/idss/co19010-indonesias-new-halal-law-impact-on-the-political-economy/#.XH15sZMzbOQ>

²²² Mariska, Made Ayu. And Ng, Jefferson. "Indonesia's New Halal Law" Impact on the Political Economy, RSIS No. 010, 17 Jan. 2019, <https://www.rsis.edu.sg/rsis-publication/idss/co19010-indonesias-new-halal-law-impact-on-the-political-economy/#.XH15sZMzbOQ>

²²³ "Halal Update 2019: Indonesia streamlining Halal Certification through New Government Agency (BPJPH)." *Agroberichten Buitenland*, 20 Feb. 2019, <https://www.agroberichtenbuitenland.nl/actueel/nieuws/2018/04/13/halal-update-indonesia-streamlining-halal-certification-through-new-government-agency-bpjph>

A. Pharmaceuticals

ASEAN has one of the fastest growing pharmaceutical sectors in the world and is heavily involved as both producer and consumer. The pharmaceuticals sector in ASEAN is rapidly growing driven by the increasing demand caused by an ageing population, increasing medical tourism, rising middle classes and a general trend in increasing risks of illness and diseases of ageing. Rapid economic development and the need to meet health needs of rising middle classes and ageing populations have spurred high growth rates for pharma.

These same factors have made it important for the ASEAN region to foster an attractive investment climate for innovation and research collaboration within the pharmaceuticals sector. However, the development of the region's pharmaceuticals sector continues to be undermined by a lack of harmonization of standards and conformity assessment procedures, an unpredictable intellectual property (IP) rights environment, and a complex and often inaccessible public procurement tenders — all of which make it increasingly difficult to develop and sell pharmaceuticals across the region. A failure to identify and eliminate such barriers will increasingly negate much of the growth and innovation needed to meet the region's evolving healthcare needs.

Most ASEAN members are involved in the production of pharma products. Conventional pharmaceuticals can be divided into two groups, original drugs and generic drugs, of which the former have typically had high production costs with 20-year patent protection, while the latter are copies of original drugs which were previously patent-protected. Countries Indonesia have been mostly involved in the production of generics for the domestic market, while countries like Singapore have established manufacturing bases for patented products created by international pharmaceuticals companies. Thailand and Malaysia operate in a middle ground with the production of generics for global markets.

Even though the pharmaceutical market in ASEAN currently accounts for slightly more than 2% of the global pharmaceutical market, it enjoys high growth in the region — some of the highest growth rates worldwide.²²⁴ Between 2016 and 2021, the industry is expected to grow at a rate of 9.1%.²²⁵

Figure 20 shows that ASEAN's pharmaceutical trade volume with the world has been growing since 2005.²²⁶ Import and export market trends continue to show that ASEAN imports most of its pharmaceutical products. While export growth has flattened, imports continue to grow at a steady rate. This might be the result of a series of favourable policies set by regional governments to attract many of the world's leading pharmaceutical companies to set up operations in their country.

²²⁴ Zion Market Research, "Global Generic Drug Market Size & Share to Reach \$380.60 Billion by 2021." Global News Wire, 21 Mar. 2018 <https://globenewswire.com/newsrelease/2018/03/21/1443577/0/en/Global-Generic-Drug-Market-Size-Share-to-Reach-380-60-Billion-by-2021-Zion-Market-Research.html>

²²⁵ Singh, Bijay. "Top trends impacting south east asia's pharma market – a conversation with pharmaceutical commerce," DKSH, 17 Jul. 2017, <http://www.dksh.com/global-en/tl-hec-trends-impacting-south-east-asia-pharma-market>

²²⁶ "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

Figure 20: Imports and Exports of Pharmaceuticals in ASEAN (2005-2017) in USD

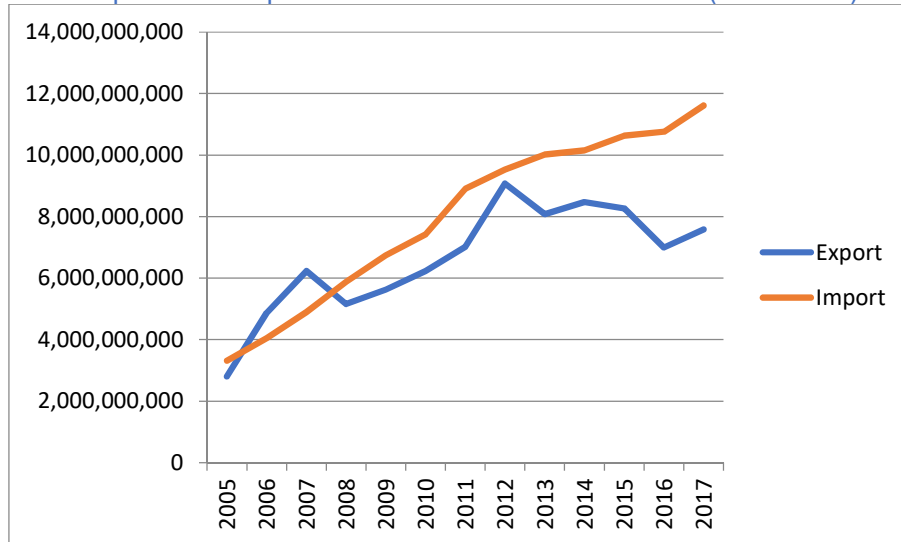
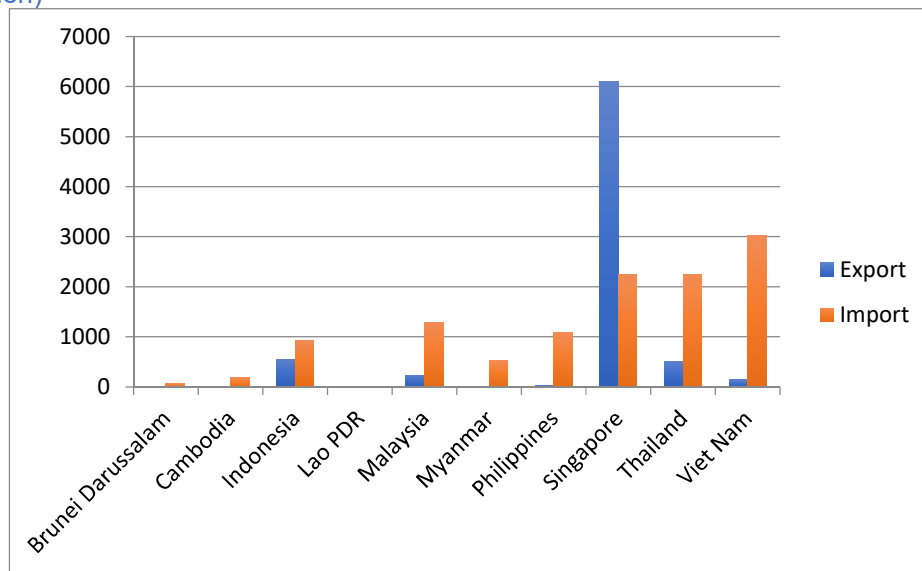


Figure 21 shows the current breakdown of pharmaceuticals trade and consumption in ASEAN.²²⁷ In particular, Singapore stands out as the biggest exporter and the only country in ASEAN exporting more than it imports. This might be a result of Singapore’s efforts to establish itself as a hub for the development of pharmaceutical products. Vietnam and Thailand are the biggest importers of pharmaceutical products. Large markets like Indonesia trade very little, since their market is heavily weighted in favour of locally produced generic drugs, particularly as the country attempts to expand access to healthcare.²²⁸

Figure 21: Pharmaceutical Imports and Exports in ASEAN by Country 2017 (in USD Million)



²²⁷ "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

²²⁸ "Indonesia A Regional Outperformer For Drugmakers", *Fintch Solution*, 9 Sep. 2018

<https://www.fitchsolutions.com/corporates/healthcare-pharma/indonesia-regional-outperformer-drugmakers-11-09-2018>

NTMs in ASEAN's Pharmaceutical Sector

ASEAN pharmaceutical NTMs encompass broad areas including product registration, non-automatic import licensing, conformity assessment procedures, taxes and patent requirements. According to UNCTAD, the ASEAN database in all member countries, registration and certification to import and distribute pharmaceutical products is the most prominent NTM in the region.

Overall, UNCTAD figures show that ASEAN imposes 493 NTMs pharmaceuticals products, which amounts to 9% of the total NTMs applied to pharmaceutical products around the world.²²⁹

Figure 22: Number of NTMs in ASEAN by Country in HS Code 30

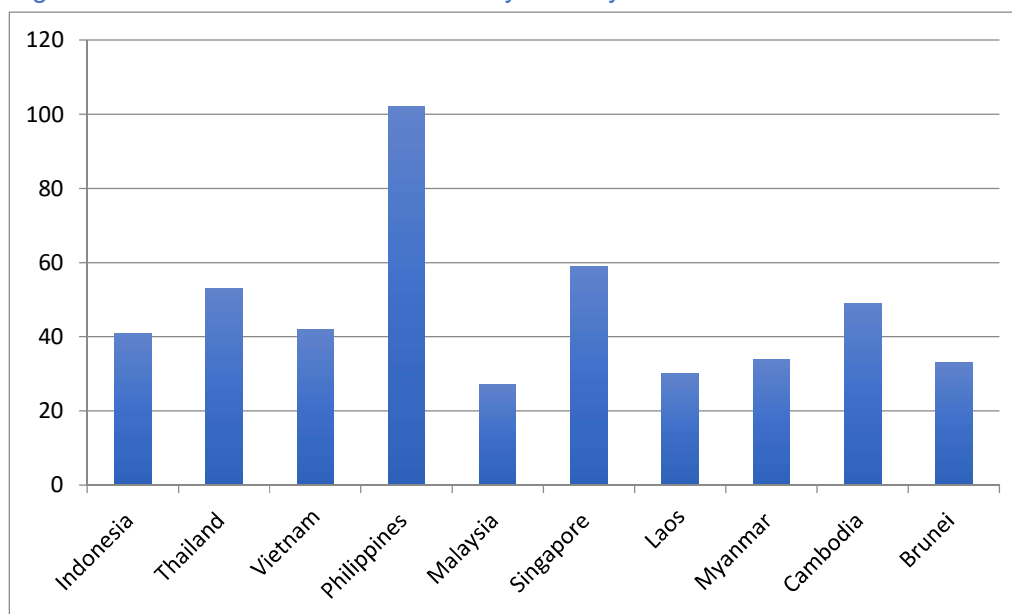


Figure 22 shows that TBTs are the most prevalent within the pharmaceuticals sector; following the global trend where 58% of NTMs affecting pharmaceutical products are TBTs.²³⁰ Most of ASEAN's TBT's NTMs fall under conformity assessment and prohibition and restrictions categories which is also similar to global trends where these two types of TBTs account for 54% of total NTMs affecting pharmaceutical products.²³¹

Most of ASEAN's conformity assessment restrictions on pharmaceutical products fall under traceability information, testing, and certification requirements.²³² Most of

²²⁹ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

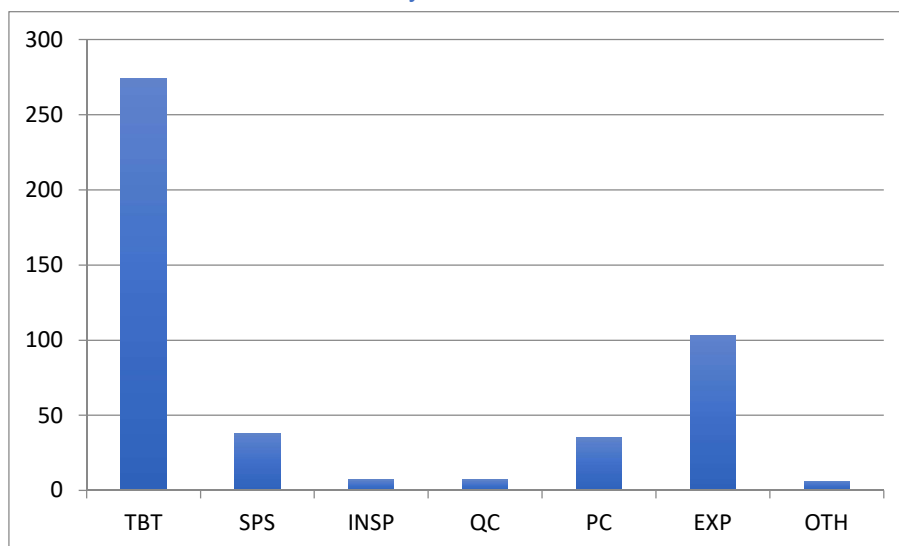
²³⁰ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

²³¹ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²³² "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

ASEAN's restrictions on pharmaceutical imports fall under authorization requirements.²³³

Figure 23: Number of ASEAN NTMs by Measure in HS Code 30



Technical Barriers to Trade (TBT); Sanitary and Phytosanitary (SPS); Pre-shipment Inspection (INSP); Quantity Control Measures (QC); Price-Control Measures (PC); Export Related Measures (EXP); Others (OTH)

Existing literature on pharmaceutical barriers has noted that MNCs face intense pressure on pricing because of local, unbranded generics, which are generally very inexpensive.²³⁴ In many cases, the disadvantages for MNCs are intensified by market access challenges, poor intellectual property protections, and regulatory and procedural barriers.

Country-specific reports and assessments have documented these types of barriers. Reports done by The Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Association for Business and Commerce, have both highlighted different types of barriers faced by pharmaceutical companies in some of the main markets in the ASEAN region.

For instance, a 2019 report PhRMA highlighted specific barriers in Malaysia, Indonesia and Thailand.²³⁵ The report outlined the following priority issues in those markets:

- Compulsory licensing — the forced removal of patents — in Malaysia and Indonesia;
- Inadequate intellectual property protection and enforcement in all three markets;
- Inequitable access to the markets as a result of strong localization requirements in Indonesia or preferential treatment of local drug manufacturers in Malaysia and Thailand; and
- Halal certification requirements in Malaysia and Indonesia.

²³³ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. Asean.I-Tip.Org. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²³⁴ Munir, Zafir. "A Pharma Playbook for Success in Southeast Asia", BCG, 13 Aug. 2016, <https://www.bcg.com/it-it/publications/2016/pharma-playbook-success-southeast-asia.aspx>

²³⁵ The Pharmaceutical Research and Manufacturers of America (PhRMA), "2019 National Trade Estimate Report on Foreign Trade Barriers." PhRMA, 2019.

Similarly, in its 2018 Position Paper, the European Association of Business and Commerce (EABC) highlighted a number of issues faced by the pharmaceutical sector in Thailand.²³⁶ The report raised concerns around:

- The mandatory disclosure of patent information and prices for innovative drugs;
- Delays in patent approvals as a result of patent backlogs;
- The use of maximum price for drugs in government procurement processes;
- Preferential treatment of state-owned pharmaceutical enterprises; and
- Preferential market access for local manufacturers.

Overall, even though most NTMs imposed on pharmaceutical products in ASEAN are TBTs, other types of measures are also major concerns for pharmaceutical companies operating across ASEAN. Controls on drug pricing, market access, local content, and intellectual property rights continue to be flagged by multiple industry reports. Similar issues were also highlighted in the industry interviews conducted in the course of this project.

²³⁶ European Association of Business and Commerce (EABC). "2018 European Business Position Paper." EABC, Jun. 2018, <http://www.eabc-thailand.org/business/download/167/47/2018+European+Business+Position+Paper+%28Light+version%29.pdf>

Interview Findings: Pharmaceuticals

The following section is based on the results of a large series of interviews conducted largely between December 2018 and February 2019 in key ASEAN markets with industry players in the pharmaceuticals sector. Interview candidates included ASEAN companies as well as foreign players. It does not cover all ASEAN markets, nor highlight all potential issues — only those explicitly raised by interview subjects. All NTM tables are tabulated from the UNCTAD Integrated Trade Intelligence Portal.

As with other interview sections, the “impact scoring” of red/yellow/green was not developed by the firms directly. It was derived from company interviews and by the extent to which a particular barrier was repeatedly raised by firms as well as by how much of an obstacle any specific barrier poses to doing business. The impact score should be viewed as a continuum from red to green, rather than a clear shift from one category to another. As might be expected, the charts below reflect few “green” impact scores, as firms typically did not spend time discussing issues that were not viewed as problematic. If viewed across time, however, some of the listed items could very well decline from red to yellow to green or the reverse.

Indonesia

Indonesia’s pharmaceutical market is one of the fastest-growing markets in the world and the largest market in ASEAN.²³⁷ It increased at a Compound Annual Growth Rate (CAGR) of 10.3% from IDR33.9 trillion (US\$3.13 billion) in 2009 to IDR67.2 trillion (US\$6.20 billion) in 2016, accounting for 27% of the ASEAN pharmaceutical market. The growth was driven by the government’s Universal Health Coverage scheme (*Jaminan Kesehatan Nasional* or JKN) and improved macroeconomic conditions. The market is expected to reach IDR109.6 trillion (US\$10.11 billion) in 2021.²³⁸

Currently there are 24 multinational pharmaceutical companies active in Indonesia with a combined IDR 12.7 billion market share or 28% of the total Indonesian market.²³⁹ Driven by rising demand for medicines and the Indonesian government’s ambitious program to provide health insurance to all Indonesians, the pharmaceutical market in Indonesia is expected to expand.

However, operational challenges persist. The market is heavily weighted in favour of generic drugs, principally due to the lack of adequate intellectual property protection, as well as by a limited ability to afford such high-value medicines, particularly as the country attempts to expand access to health care.²⁴⁰



²³⁷ GlobalData, “Country Focus: Healthcare, Regulatory and Reimbursement Landscape – Indonesia.” GlobalData, Sep. 2017, <https://www.globaldata.com/store/report/gdhc0058chr--countryfocus-healthcare-regulatory-and-reimbursement-landscape-indonesia/>

²³⁸ GlobalData, “Country Focus: Healthcare, Regulatory and Reimbursement Landscape – Indonesia.” GlobalData, Sep. 2017, <https://www.globaldata.com/store/report/gdhc0058chr--countryfocus-healthcare-regulatory-and-reimbursement-landscape-indonesia/>

²³⁹ “Pharmaceutical Industry Indonesia: Is 10% Growth Possible in 2017?.” Indonesia Investments, 2017, <https://www.indonesia-investments.com/news/todays-headlines/pharmaceutical-industry-indonesia-is-10-growth-possible-in-2017/item7978?>

²⁴⁰ “Indonesia A Regional Outperformer For Drugmakers.” FitchSolutions, 11 Sep. 2018, <https://www.fitchsolutions.com/corporates/healthcare-pharma/indonesia-regional-outperformer-drugmakers-11-09-2018>

Technical Barriers to Trade

Category	Description	Impact
Product Requirements based on Religious Reasons	<p><u>Mandatory Halal Law: From voluntary to mandatory</u></p> <p>The new Halal law covers a broad range of products and requires that producers label their products as “halal” or as “non-halal,” based on whether the products are halal certified. Many pharma products may not be able to be manufactured to halal standards (depending on the definitions).</p>	
Procedural Obstacles – Product Registration	<p><u>Regulatory Delays in Registration Process</u></p> <p>Interviewed companies face regulatory delays in the registration process of new products. There are a variety of causes for the unpredictable delays, which ultimately result in new products being temporarily or permanently blocked from entering the market.</p>	

Investment Related Issues

Category	Description	Impact
Local Content Measures	<p><u>Decree 1010</u></p> <p>Requirement to locally manufacture imported products within five years after the first importation with some exceptions.</p> <p>This is difficult since:</p> <ul style="list-style-type: none"> • most pharmaceutical companies operating in Indonesia need to import active ingredients to produce their products. • there is a lack of resources in Indonesia, • it is difficult to develop economies of scale, and • the global pharma supply chain cannot have factories all over the world. 	


Local Production Measures	<u>Local Facilities Requirement for Registration</u> Companies will only be allowed to register products if they have facilities in Indonesia.	Red
	<u>Limited Market Access</u> Pharmaceutical products produced outside Indonesia can only be imported within five years under the following the conditions: <ul style="list-style-type: none"> the products are not commercially viable; patents are still valid; there is public demand and public need for the products; and there are no local facilities that manufacture these products. 	Red

Intellectual Property


Category	Description	Impact
Patent Restriction	<u>Patent Law 2016 Article 20</u> To register patents in Indonesia, firms must have manufacturing plants or processing plants in Indonesia.	Red
Patent Payment	<u>IP Payments</u> Indonesian Law stipulates that companies must pay fees to register their patents. Indonesia is the only country in the world that does this.	Yellow
Compulsory Licensing	<u>Compulsory Licensing</u> Companies showed concerns around the compulsory licensing (CL) of patented pharmaceutical products. The government did not engage or work collaboratively with the affected companies.	Red

Government Procurement Restrictions

Category	Description	Impact
Procedural Obstacles – Reimbursements	Hospital payments for Pharma are delayed. Payments may take up to two to three months.	Yellow

<p>Access to National Formulary</p>	<p><u>Challenges Accessing the National Formulary</u> Challenges developing drugs that are accepted under the National Formulary. Companies said that actual listing decisions appear to be primarily based on price and the overall Social Insurance Administration Organization (BPJS) budget.</p>	 <p>Yellow</p>
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Others

Category	Description	Impact
<p>Consultation Private Sector</p>	<p>Companies highlighted the lack of consultation with the private sector in the development and implementation of regulations.</p>	 <p>Yellow</p>

Malaysia

Government initiatives such as Entry Point Projects (EPPs) and National Key Economic Areas (NKEAs) to increase investment in the pharmaceutical industry have so far been successful. The country’s pharmaceutical market was estimated at US\$2.3 billion in 2015 and is projected to reach approximately US\$3.6 billion by 2020 at a CAGR of 9.5%. The positive trend can primarily be attributed to government initiatives, an increasing elderly population, and increasing medical tourism.²⁴¹

According to Malaysia’s competition commission, the pharmaceutical sector has grown by an average annual rate of 8% over the last decade, reaching MYR8.6 billion or 16.5% of total healthcare expenditure (MYR52 billion) in 2016.²⁴² Imported medicines at MYR5.4 billion still account for the largest part (63%) of the pharmaceutical market, while exports are only MYR0.7 billion.²⁴³

Generic medicines now account for 55% of the controlled (prescription) medicines market by value. Out of 28 companies manufacturing controlled medicines in Malaysia, 23 are locally owned and five are foreign-owned, with none from high-income countries. The total sales revenue of controlled medicines was MYR1.7 billion in 2014/15.²⁴⁴ In 2017, foreign pharmaceutical exports were about 70% of Malaysia’s total

²⁴¹ GlobalData, “Country Focus: Healthcare, Regulatory and Reimbursement Landscape – Malaysia.” GlobalData, Sep. 2017, <https://www.globaldata.com/store/report/gdhc0058chr--countryfocus-healthcare-regulatory-and-reimbursement-landscape-malaysia/>
²⁴² Malaysia Competition Commission “Market Review on Priority Sector Under Competition Act 2010 Pharmaceutical Sector.” MyCC, 27 Dec. 2017, 2, <http://www.mycc.gov.my/sites/default/files/media-review/Market%20Review%20on%20Pharmaceutical%20Sector.pdf>
²⁴³ Malaysia Competition Commission “Market Review on Priority Sector Under Competition Act 2010 Pharmaceutical Sector.” MyCC, 27 Dec. 2017, 2, <http://www.mycc.gov.my/sites/default/files/media-review/Market%20Review%20on%20Pharmaceutical%20Sector.pdf>
²⁴⁴ Malaysia Competition Commission, “Market Review on Priority Sector under Competition Act 2010 Pharmaceutical Sector.” Nov 2017, <http://www.mycc.gov.my/sites/default/files/Draft%20Report%20Pharmaceutical%20Market%20Review%20MyCC.pdf>



drug market. In 2016, Malaysia's foreign pharmaceutical imports were worth \$1.3 billion, a fifth of which came from Germany and the United States.²⁴⁵

Malaysia is also working to establish itself as a pioneer in the certification, manufacturing, and distribution of the rapidly-growing international halal pharmaceutical market. Malaysia has established the *Malaysian Standard* (MS 2424:2012), the first international standard for the manufacturing and handling of halal pharmaceutical products.²⁴⁶

According to PhRMA, Malaysia's National Medicines Policy gives preferential treatment to local manufacturers through its National Essential Medicine List (NEML). The policy endorses potential price controls, generic drugs substitution, and preferences for generics and local manufacturers by promoting national self-reliance for drugs listed on the NEML.²⁴⁷

Malaysia issued a compulsory license in September 2017. This action sent shock waves through the global pharmaceutical market. Although the use of compulsory licenses is allowed under WTO rules (Paragraph 6 of the Trade Related Intellectual Property Rights or TRIPs agreement), WTO members have not implemented the provision. It was originally intended for circumstances of public health emergencies, particularly for short-term catastrophes like Ebola, where the public health sector might be unable to respond fast enough and still provide sufficient protection to IP rights holders. Malaysia's government issued a compulsory license for a Hepatitis C, effectively breaking the patent for Gilead, in favour of a generic drug called Sofosbuvir.

Technical Barriers to Trade


Category	Description	Impact
Product Registration	<p><u>Delays in Product Registration</u></p> <p>The registration process only allows for one indication procedure at a time. Each indication takes between six to twelve months. This means that it can take up to five years to get approval for products with multiple indications.</p>	
Conformity Assessment	<p><u>Traceability Information Requirements</u></p> <p>Malaysia asks for data that goes beyond the common ASEAN technical dossier commonly used across the region. This means that firms must provide higher levels of requirements, such as providing raw analytical data. These requirements are higher than those established by the PPWG group of ACCSQ in ASEAN.</p>	

²⁴⁵ Pacific Bridge Medical, Malaysia Drug Market Update 2017, <https://www.pacificbridgemedical.com/publication/malaysia-drug-market-update-2017/>





²⁴⁶ "Halal Pharmaceuticals – General Guidelines MS 2424:2012." Malaysian Standard, <https://law.resource.org/pub/my/ibr/ms.2424.2012.pdf>

²⁴⁷ Pharmaceutical Research and Manufacturers of America (PhRMA), "Special 301 Submission 2018." PhRMA, 2018, 63.

Measures Affecting Competition



Category	Description	Impact
Selective Import Channel	<u>Bumiputra Law:</u> Companies must engage a Bumiputra partner to sell to government bodies.	 Yellow

Government Procurement Restrictions


Category	Description	Impact
Procedural Obstacle: Procurement	<u>Lack of Transparency in Procurement Process</u> The government gives procurement preferences for locally manufactured products. For example, it recently announced that it will grant three-year procurement contracts to companies who move production of imported products to Malaysia (with the potential for a two-year extension if those locally produced products are exported). ²⁴⁸ Some participants claim that the process often leads to cases where even generics are often more expensive than foreign drugs.	 Red
Reimbursements	<u>Lengthy Reimbursement Process:</u> It may take up to five years to get reimbursed	 Yellow
Access to National Formulary	<u>Lack of Transparency in the process to enter the national formulary:</u> The process lacks transparency and appears to be based on ambiguous criteria. It appears to be based on pricing and not value.	 Red
	<u>Data Requirements</u> In addition, the final guidelines require one year of post-marketing surveillance data prior to listing in the national formulary.	 Red

²⁴⁸ The Pharmaceutical Research and Manufacturers of America (PhRMA), "2019 National Trade Estimate Report on Foreign Trade Barriers, October 2018.

Intellectual Property

Category	Description	Impact
Procedural Obstacle – Patent Protection	<u>Uncertainty About Patent Protection for Certain Drugs:</u> Compulsory Licencing is a problem for many firms, especially since it leads to uncertainty about the practice in the future. Participants showed concern about the government’s grant of a compulsory licence for the Hepatitis-C drug. There remains uncertainty about the protection of IP rights moving forward.	 Red
Procedural Obstacle – Patent Approval	<u>Low Patent Approval Rate for Innovative Drugs:</u> A small number of patents for “biologics” and innovative drugs are approved.	 Yellow

Others

Category	Description	Impact
Consultation Private Sector	Companies highlighted a lack of consultation with the private sector in the development and implementation of regulations.	 Yellow

The Philippines

The Philippines pharmaceutical market is the third-largest pharmaceutical market in ASEAN, after Indonesia and Thailand. It was estimated to be worth US\$3.4 billion in 2015 and expected to reach US\$4.1 billion by 2020. The market grew nominally at a Compound Annual Growth Rate (CAGR) of 3.7% over the 2008-2020 period.²⁴⁹

Paulyn Jeal Ubial, the Philippine Department of Health (DOH) secretary, confirmed that generics enjoy 65% of the total pharmaceutical market when it comes to volume sales. This is mostly due to the passing of the Cheaper Medicines Act of 2008, as well as the efforts of the current administration to promote generics use.²⁵⁰


²⁴⁹ “Philippines Drug Market Update 2017”, Pacific Bridge Medical, July 14, 2017.

<https://www.pacificbridgemedical.com/publication/philippines-drug-market-update-2017/>



²⁵⁰ “4 Fast Facts About the Pharmaceutical Market in the Philippines.” Regicon, 17 Apr. 2017,

<https://regiconservices.com/pharmaceutical-market/>



Technical Barriers to Trade

Category	Description	Impact
Procedural Obstacle – Product Registration	<p><u>Slow registration processes:</u></p> <p>Slow regulatory processes remain a major hurdle in providing access to innovative medicines. Current committed turnaround time for Certificate of Product Registration (CPR) is 254 calendar days. In practice, turnaround time ranges from two to four years.</p>	


Price Control Measures

Category	Description	Impact
Tax	<p><u>Taxes to Pharmaceuticals</u></p> <p>The government taxes pharmaceuticals at all points of the distribution process and has only begun to reduce taxes at the consumer level. They currently tax from 12% - 13%.</p>	
Price Ceilings	<p><u>The National Disaster Response Plan has imposed a price ceiling:</u></p> <p>It is difficult for companies to negotiate or offer their innovative products.</p>	

Intellectual Property

Category	Description	Impact
Patents	<p><u>Limited Patent Criteria</u></p> <p>The Cheaper Medicines Act amended the Philippines Intellectual Property Code to limit the patentability of new forms and uses of pharmaceutical products.</p>	
Compulsory Licensing	<p><u>Special Compulsory Licensing Provisions</u></p> <p>The IP Code of the Philippines was recently amended to include provisions allowing things like parallel importation and government use of special compulsory licensing.</p>	

Government Procurement Restrictions


Category	Description	Impact
Procedural Obstacle – Access to National Formulary	<u>Lack of Clarity regarding Philippine National Formulary</u> Timelines for the registration process are unclear and review of medicine inclusion can take up to three years.	 Red

Singapore

Singapore is consolidating its global position as a regional pharmaceutical manufacturing hub. Today the industry is a pillar of Singapore's economy that contributes over three percent to national GDP.²⁵¹ According to Fitch Solution's *Singapore Pharmaceuticals & Healthcare Report* published in 2018, Singapore's pharma market hit SG\$1.22 billion (US\$948 million) in 2017. The report also forecasts that over the five-year period to 2022, the pharmaceutical market will reach a value of SG\$1.62 billion (US\$1.2 billion), experiencing a compound annual growth rate (CAGR) of 5.8%.²⁵²

Singapore will likely remain a highly attractive manufacturing base for international pharmaceutical companies. Eight of the world's top 10 drugmakers have chosen Singapore to be their base for Asia Pacific operations and facilities, including Roche, GlaxoSmithKline, Pfizer and Sanofi. These pharmaceutical companies account for more than a 35–40% share of Singapore's regional market.²⁵³

Technical Barriers to Trade



Category	Description	Impact
Procedural Obstacle – Approval	The approval time for pharmaceutical products in Singapore is too long. It may take from 12-to 18 months.	 Yellow

²⁵¹ Leithc, Anne. "Future-proofed Pharma" *Scientific American*, 7 Dec. 2018. <https://www.scientificamerican.com/custom-media/future-proofed-pharma/#fn2>


²⁵² "Singapore Pharmaceuticals & Healthcare Report", *FitchSolution*, Jan 2018.

²⁵³ "Singapore Pharmaceuticals & Healthcare Report", *FitchSolution*, Jan 2018.

Government Procurement

Category	Description	Impact
Procedural Obstacle – Procurement Process	<p><u>Lack of Transparency in the Role of the Agency for Care Effectiveness (ACE)</u></p> <p>The ACE conducts drug evaluations to guide government subsidy decisions on treatments and produces guidance on the appropriate use of treatments for public hospitals and institutions in Singapore.</p> <p>Companies claim that the way ACE operates lacks transparency, public consultation, and close engagement with the industry.</p>	
Procurement Access	<p><u>Difficulty Accessing and Selling into Hospital Formularies</u></p> <p>In Singapore, public healthcare institutions exercise their own autonomy in maintaining independent formulary lists with undisclosed evaluation criteria and varied timelines across different hospitals and polyclinics, resulting in less treatment options for some patients.</p> <p>Participating companies raised concerns about:</p> <ul style="list-style-type: none"> • not being able to file products for listing; • the use of cost-effectiveness as the primary criteria for selection; and • not being able to file products for listings, which they can only do through doctors. 	

Intellectual Property

Category	Description	Impact
Patents	<p><u>No Patent Term Extension (PTE):</u></p> <p>Without PTE, the clinical trial period for a drug eats into the patent period, which affects the longevity of a patent. Singapore does not grant patent term extensions.</p>	

Thailand

Thailand imported over US\$2.2 billion in pharmaceuticals in 2016, a considerable increase from US\$1.8 billion just two years ago. The value of Thailand's

pharmaceutical market was estimated at \$5.91 billion in 2015, and is expected to reach \$9.47 billion in 2020, increasing at a projected CAGR of 10%.²⁵⁴


According to the Thailand Industry Outlook 2017-19 for pharmaceuticals, the pharmaceutical market in Thailand will continue to expand, driven by:

- the increasing demand caused by an ageing population,
- increasing medical tourism and
- a general trend in increasing risk of illness and
- investment promotion efforts by Thailand Board of Investment.

Overall, the market for pharmaceuticals is forecast to grow by 5.4% per year during 2017-2019.²⁵⁵

Thailand's manufacturing sector is dominated by final stage producers of finished products and generic drugs, which import around 90% of the ingredients for their products. Only around 5% of domestic output is exported; mainly comprised of low value generics.²⁵⁶

Price Control Measures

Category	Description	Impact
Administrative Measures Affecting Customs Value	<p><u>Lack of transparency and consistency in pricing</u></p> <p>Thailand sets an effective maximum price for pharmaceutical products through what it calls a "Median Price."</p> <p>This means that companies can only negotiate under this price point. There is no consideration of clinical value in the process.</p> <p>Furthermore, what criteria or reference system is used to determine those prices remains a problem. The current methodology and implementation lack both transparency and predictability.</p>	 Red

²⁵⁴ "Country Focus: Healthcare, Regulatory and Reimbursement Landscape – Thailand." GlobalData, 2016, <https://www.globaldata.com/store/report/gdhc0035chr--countryfocus-healthcare-regulatory-and-reimbursement-landscape-thailand/>

²⁵⁵ "Thailand Industry Outlook 2017-19 Pharmaceuticals." Krungsri Research, Jul. 2017, https://www.krungsri.com/bank/getmedia/d8df53cd-070b-4b82-856a-691c12c0a806/IO_Pharmaceutical_2017_EN.aspx


²⁵⁶ "Thailand Industry Outlook 2017-19 Pharmaceuticals." Krungsri Research, Jul. 2017, https://www.krungsri.com/bank/getmedia/d8df53cd-070b-4b82-856a-691c12c0a806/IO_Pharmaceutical_2017_EN.aspx

Government Procurement Restrictions


Category	Description	Impact
Procurement Criteria	<p><u>Innovation List</u></p> <p>Government hospitals must spend at least 30% of their budget to purchase the drugs listed in the innovation list.</p> <p>Only local companies can access the list, while foreign firms cannot add their products. This deprives them of a significant share of the public market. Companies also raised concerns about potential increases to the minimum hospital budget requirement allocated to the Innovation List; possibly more than the current 30% required.</p>	Red
	<p><u>Selection National List of Essential Medicines</u></p> <p>It is unclear how products are being selected. It is unclear where drug companies are in the selection process. It might take six years or more to complete the process. The final list contains a small percentage of innovative drugs.</p>	Red
Reimbursement	<p><u>Incomplete Reimbursement Process</u></p> <p>Thailand is a semi-reimbursement country and only provides benefits to part of the population. The “Civil Servant Medical Benefit Scheme” (CMBS) represents 9% of Thailand’s market.</p>	Red

Intellectual Property

Category	Description	Impact
Procedural Obstacle – Patent Approval	<p><u>Delays in Patent Approval</u></p> <p>There is a massive backlog with patents. More than 20 years of patent filings have not been processed.</p> <p>Patent registration might take up to 12.6 years of patent life (for a patent that only gets 20 years in total).</p>	Red
Patent Term Restoration	<p>The Thai government has not set up Patent Term Restoration, which could compensate for patent delays.</p>	Yellow

Compulsory Licensing	Participants raised concerns about Thailand's threats to use compulsory licensing and the lack of engagement with affected companies.	
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Measures Affecting Competition

Category	Description	Impact
State-Owned Enterprises	<u>Government Pharmaceutical Organization</u> Preferential treatment has been given to state-owned pharmaceutical enterprises. The government procurement regulation allows the state-owned enterprises, the GPO, strong preferential in price advantages. Hospitals need to purchase medicines exclusively from the GPO. Foreign companies do not have access to those benefits.	

Vietnam

The country's pharmaceutical market was estimated to have been worth US\$3.5 billion in 2015 and is expected to reach US\$6.6 billion by 2020 at a projected Compound Annual Growth Rate (CAGR) of 13.8%.²⁵⁷ The positive trends in Vietnam's healthcare market can primarily be attributed to the increasing coverage of healthcare insurance.²⁵⁸

As a result of altering demographics, such as a higher proportion of women in work and a population shift from rural to urban, plus rapid income growth, and the demand for branded therapies, new opportunities are opening for foreign providers of branded, higher quality pharmaceuticals and medical devices.²⁵⁹

The Vietnamese government is supporting the local production of generics to reduce imports and has planned to meet 80% of domestic demand by 2020 through local production.²⁶⁰ Pharma companies importing and selling drugs will need to partner with local manufacturers.


²⁵⁷ Sivabushnam, Saranraj "Low cost and market potential make Vietnam a favourable pharma hub." Beroinc, 21 Apr. 2017 <https://www.beroeinc.com/whitepaper/Vietnam-low-cost-pharma-hub/> (21 April 2017)

²⁵⁸ "Country Focus: Healthcare, Regulatory and Reimbursement Landscape – Vietnam." GlobalData, 2016, <https://www.globaldata.com/store/report/gdhc0061chr--countryfocus-healthcare-regulatory-and-reimbursement-landscape-vietnam/> Accessed on 26 December 2018.


²⁵⁹ Hall, Robert. "The Most Exciting Region In Asia For Pharma and Medical Devices." LifeScience Leader, 27 Feb. 2017, <https://www.lifescienceleader.com/doc/the-most-exciting-region-in-asia-for-pharma-and-medical-devices-0001> Accessed on 28 December 2018.

²⁶⁰ EU-Vietnam Business Network (EVBN), "Healthcare: Research Report." Flanders Investment and Trade, https://www.flandersinvestmentandtrade.com/export/sites/trade/files/news/223150528071429/223150528071429_1.pdf


Technical Barriers to Trade

Category	Description	Impact
Product Registration	<p><u>Unclear and Lengthy Product Registration</u></p> <p>Even though the registration guidelines state that it only takes three months to register a product, it actually takes six or seven months to get the registration license that is required for the importation of products.</p> <p>Timelines vary and, according to the companies interviewed, it depends on the workload. New product registration may take up to two and half years. There are no strict guidelines, which do not even mention the approval timelines.</p>	 Red

Investment Measures

Category	Description	Impact
Local Partner Requirements	<p><u>Need for Local Distributor</u></p> <p>Under Decree 54, companies are allowed to import but not to distribute drugs.</p> <p>Such an approach requires that pharmaceutical companies importing into Vietnam have a local distributor responsible and accountable for the distribution of the product in the country. Distributors must be led by local operators, which must be a local legal entity.</p>	 Red

Intellectual Property

Category	Description	Impact
Procedural Obstacle – Patent Protection	<p><u>Patent Infringement</u></p> <p>Cases of patent infringement of certain pharmaceutical products.</p>	 Red

Cambodia, Laos, and Myanmar (CLM)

The pharmaceutical markets in the remaining ASEAN countries are not substantial. However, firms are still facing a number of non-tariff issues while operating in these markets. In most cases, these barriers are the tools for governments to encourage more investment into local production and manufacturing. In some other cases, the

NTBs are the consequences of a lack of regulations or an incomplete regulatory framework.

Myanmar

Given the interview sample, companies had rather a lot to say about specific barriers in Myanmar. (With sufficient time and outreach, it may be the case that Cambodia and Laos would have seen additional country-specific issues raised as well.)


Technical Barriers to Trade

Category	Description	Impact
Product Registration	<p><u>Lengthy Registration Process and PO</u></p> <p>To get every product licensed and registered takes 14 to 18 months. The problem, in part, is the FDA workload.</p>	Yellow
Procedural Obstacle – Labelling Requirement	<p><u>Lack of Clarity around New Labelling Regulation:</u></p> <p>There is a lack of clarity as to the coverage of the labelling regulations. For instance, different ministries give different interpretations of coverage.</p>	Yellow





Procurement

Category	Description	Impact
Tender Process	<p><u>Limited Tenders</u></p> <p>Tenders are limited to cheaper products like generics and antibiotics. Therefore, innovative or high price products cannot access government tenders.</p>	Red
Procedural Obstacle – Tender Process	<p><u>Fragmented and Corrupt Tenders System</u></p> <p>The procurement mechanisms and tender system are fragmented, with corruption and extremely poor inventory management. As a result, some medicines expire, and others arrive at the wrong place at the wrong time.</p>	Red
	<p><u>Side Payments within Procurement</u></p> <p>The procurement process encourages side payments. Companies shared evidence of cases where companies pay doctors to prescribe their drugs. Generic drug companies compete based on the amount of money they can pay to doctors.</p> <p>MNCs that rely on the compliance of their products are affected by this practice, which does not only create an uneven playing field but compromises the safety and the efficacy of the products.</p>	Red

Intellectual Property

Category	Description	Impact
IP Protection	<u>Lack of IP Protection Enforcement</u> Government does not enforce exclusive distributor rights.	 Yellow

Others

Category	Description	Impact
Marketing	<u>Unable to Market Products to Doctors</u> Medical representatives are unable to see healthcare professionals to introduce their pharmaceutical products. Interviewees suggested that this might be a result of the extremely low patient/doctor ratios in Myanmar.	 Yellow
Illegal Smuggling	Participants highlighted the rampant presence of smuggled generics into the country.	 Yellow
Regulatory Environment	<u>Poor Trade Environment</u> Companies claimed that the environment is fragmented, incomplete, contradictory, unstable, and difficult to plan around. Enforcement is uncoordinated and inconsistent: it lacks direction, follows different guidelines from different government, and does not engage stakeholders.	 Red
Healthcare Policy	<u>No Reimbursement Scheme</u> There are no government reimbursement schemes in place. Estimates are that 95% of expenses are out of pocket, as a result, patients cannot afford the high-quality drugs some of the MNCs offer.	 Yellow

B. Medical Devices

ASEAN's medical device sector is expanding as domestic production emerges and international manufacturers venture in to sell. Operating a medical device company in the ASEAN currently means working in a fragmented regional market with emerging regulatory frameworks. Unlike other sectors in this project, the device industry across ASEAN is at an earlier state in addressing the appropriate types of regulation needed to ensure safety in the marketplace while also encouraging the development of an innovative, efficient, and cost-effective medical device sector for the region.

This paper uses the World Health Organization's (WHO) definition of medical devices. According to the World Health Organization, Medical Devices are any instruments or machines intended to be used for one or more of these specific medical purposes:²⁶¹

- Diagnosis, prevention, and monitoring of diseases.
- Diagnosis, monitoring, treatment, and alleviation of injuries.
- Supporting or sustaining life
- Investigation, replacement, modification or support of a physiological processes.
- Contraception
- Provide information through in vitro examination of things derived from the human body.

The global medical device market is expected to reach an estimated \$409.5 billion by 2023, and it is forecast to grow at a CAGR of 4.5% from 2018 to 2023. The major drivers for the growth of this market are healthcare expenditure, technological development, ageing population, and increasing chronic diseases.²⁶²

Emerging trends which have a direct impact on the dynamics of the medical device industry include the changing medical technology landscape, software as a differentiator in medical devices, and design and manufacturing of patient portable and smaller devices.²⁶³

By function type, the global medical device market is segmented into diagnostic and monitoring, therapeutic, surgical, and others. The surgical segment is expected to remain the largest segment in the forecast.

Although penetration of medical devices into ASEAN is still relatively low, the region's medical device market is expected to grow as a result of increased access. Figure 24 shows how ASEAN's medical devices trade volume with the world has been growing since 2010.²⁶⁴ Both export and import growth has been steady. Even though most of

²⁶¹ World Health Organization. "Medical Devices – Full Definition." WHO, https://www.who.int/medical_devices/full_definition/en/

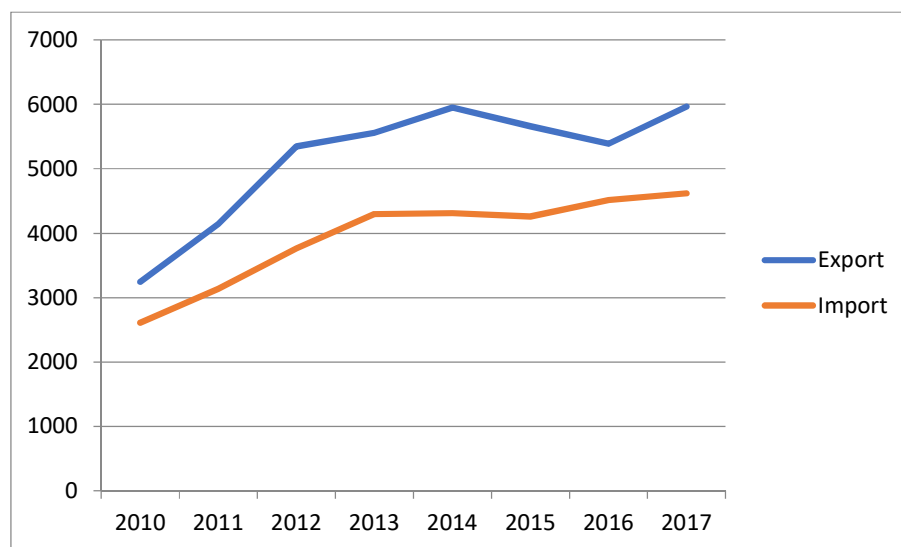
²⁶² "Global Medical Device Market 2018", *PRN News Wire*, (Dublin, April 23 2018). <https://www.prnewswire.com/news-releases/global-medical-device-market-2018-with-forecasts-to-2023---driven-by-healthcare-expenditure--technological-development--aging-population--chronic-diseases-300634442.html>.

²⁶³ Tan, Derrick "Tapping on ASEAN's Healthcare Opportunities through Singapore", Asia Biotech, <https://www.asiabiotech.com/19/1909/19090017x.html>

²⁶⁴ "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

the member states import their devices, the large number of ASEAN exports overall is driven by countries like Malaysia and Singapore, that have become major producers of certain types of devices.

Figure 24: Imports and Exports of ASEAN Medical Devices (2010-2017) in USD Millions



The region's medical device market is expected to grow strongly and access to the market will improve in the coming years due to a number of factors. The size of the middle class within the various member states is expanding rapidly and the Asian Development Bank expects this group to grow from 24% of the total population in 2010 to 65% by 2030.²⁶⁵ Demographic factors like ageing populations and rapid urbanization are likely to fuel further demand for more and better quality healthcare, and contribute significantly to the expansion of the region's medical device market.²⁶⁶ Global medical device companies are expected to continue to expand in the region and actively engage local healthcare institutions.²⁶⁷

Figure 25 breaks down device figures by ASEAN member. Singapore and Malaysia are both the top exporters of medical devices and the only two countries exporting more than they import.²⁶⁸

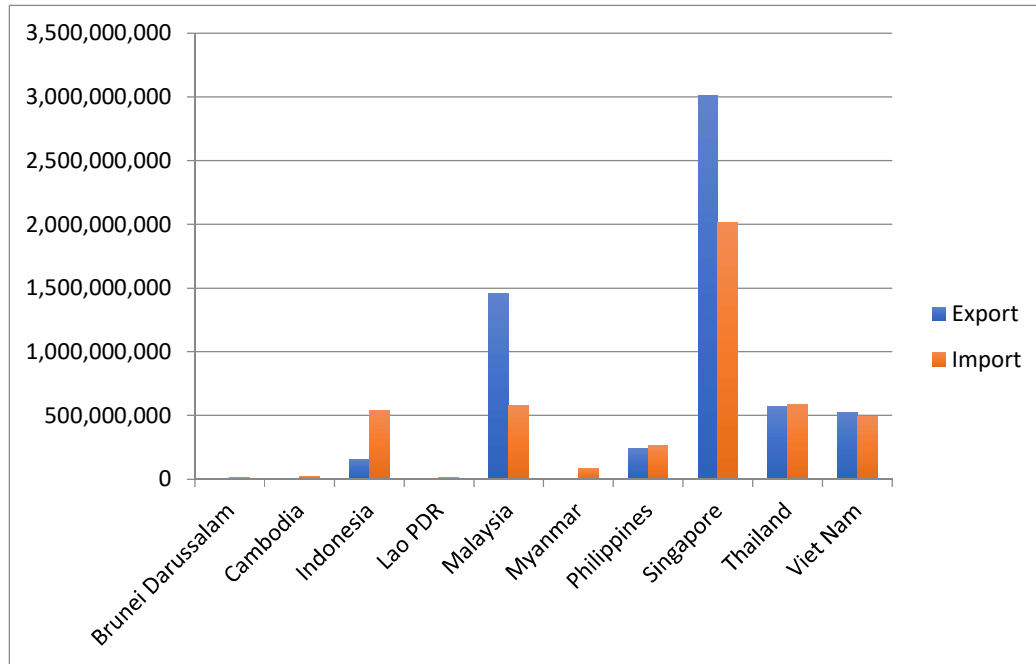
²⁶⁵ Kang, Jong, and Grendell Magoncia. "How to Fill the Working-Age Population Gap in Asia: A Population Accounting Approach." (2016).

²⁶⁶ Tan, Derrick "Tapping on ASEAN's Healthcare Opportunities through Singapore", Asia Biotech, <https://www.asiabiotech.com/19/1909/19090017x.html>

²⁶⁷ Tan, Derrick "Tapping on ASEAN's Healthcare Opportunities through Singapore", Asia Biotech, <https://www.asiabiotech.com/19/1909/19090017x.html>

²⁶⁸ "ASEAN Stats Data Portal: Trade in Goods (IMTS), Annually, HS-2-digit up to 8-digit (AHTN), in US\$" Accessed at <https://data.aseanstats.org/trade-annually>

Figure 25: Imports and Exports of Medical Devices in ASEAN by Country, 2017 (USD)



Still, one of the biggest challenges with setting up an ASEAN business division, from the perspective of a large medical device company, is coming up with an efficient setup to access and serve the fragmented regional market.²⁶⁹

Overall, the penetration and growth of medical devices will continue as a result of increasing manufacturing capacity and the continued entry of international medical devices manufacturers into the market.

²⁶⁹ Zhou, Cecilia. "ASEAN – Challenges and Opportunities for Medical Device Companies." Asia Biotech, <https://www.asiabiotech.com/19/1909/19090017x.html>

Medical Devices NTMs in ASEAN

The ASEAN medical device sector is affected by NTMs in areas like product registration, conformity assessment procedures and taxes. According to the UNCTAD NTM database, in all member countries prohibitions and restriction on imports and registration and certification requirements are the most prominent NTMs affecting medical devices in the region.²⁷⁰

Overall, ASEAN imposes 101 NTMs in the medical devices sector, only 0.7% of total NTMs applied to medical devices around the world.²⁷¹ Regionally, ASEAN NTMs only account for 18% of NTMs affecting medical devices in Asia, where China, Japan and Korea alone account for 63% of total NTMs affecting medical devices.²⁷² In ASEAN, Thailand and the Philippines impose the most NTMs, accounting for 48% of regional NTMs on medical devices as shown in Figure 26. As a whole, ASEAN's average number of NTMs on medical devices per country — 10.1 — is much lower than Asia's — 24.3 — and the world's — 15.8 — averages, and similar to Africa's — 7.7 — and Latin America's — 10.5.²⁷³ In sum, ASEAN only imposes a very small percentage of NTMs on medical devices when compared to both Asia and the world. On average, ASEAN imposes a similar amount of NTMs on medical devices than other comparable regions like Africa and Latin America.

The country with the largest amount of NTMs within the medical devices sector is Thailand, followed by the Philippines and Singapore. Thailand imposes the largest amount of TBTs on medical devices, followed by Vietnam, Indonesia and Singapore. The Philippines also impose the highest number of price control measures.²⁷⁴

²⁷⁰ UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

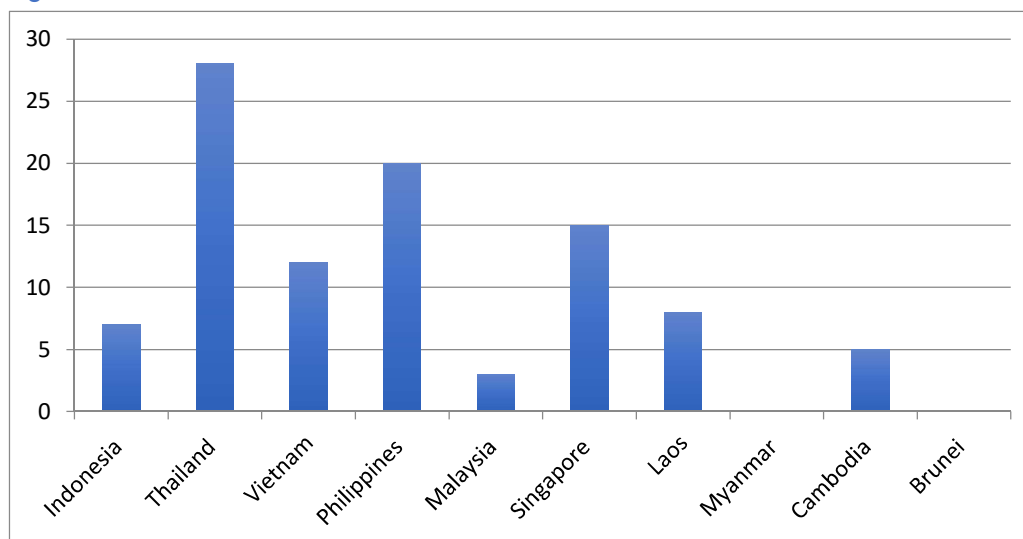
²⁷¹ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²⁷² "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²⁷³ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²⁷⁴ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

Figure 26: Number of NTMs in ASEAN Medical Devices



Most of the NTMs in ASEAN are, as would be expected, TBTs, followed by price control measures and export requirements. Such measures, shown in Figure 27, include prohibition/restrictions on the importation of medical devices, conformity assessment procedures, and service taxes.²⁷⁵

Figure 27 also shows that technical barriers to trade are the most prevalent within ASEAN's medical devices sector; following the global trend where 61% of NTMs affecting medical device products are TBTs.²⁷⁶ Most of ASEAN's TBT's fall under the conformity assessment and prohibition and restrictions categories; partially following global trends where these two types of TBTs account for 49% of total NTMs affecting medical devices.²⁷⁷ Moreover, labelling and packaging requirements, which account for 20% of global medical device NTMs, only account for a fraction of medical device TBT's in ASEAN.²⁷⁸ This means that globally medical device manufacturers are likely to face more labelling and packaging requirements than in ASEAN.²⁷⁹ Most of ASEAN's conformity assessment restrictions on medical devices fall under product, testing and certification requirements.²⁸⁰ Most of ASEAN's restrictions on pharmaceutical imports fall under authorization requirements — at least as shown in the UNCTAD data.²⁸¹

²⁷⁵ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>.

²⁷⁶ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²⁷⁷ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

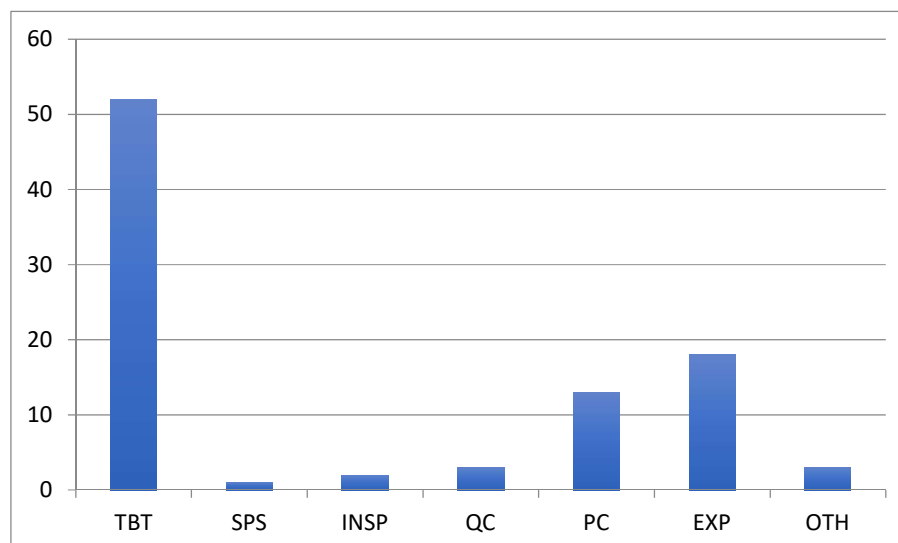
²⁷⁸ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²⁷⁹ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²⁸⁰ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

²⁸¹ "UNCTAD - Integrated Trade Intelligence Portal - Home Page". 2019. *Asean.I-Tip.Org*. <http://asean.i-tip.org/Forms/TableView.aspx?mode=modify&action=search>

Figure 27: Number of NTMs in ASEAN Medical Devices



Key: Technical Barriers to Trade (TBT); Sanitary and Phytosanitary (SPS); Pre-shipment Inspection (INSP); Quantity Control Measures (QC); Price-Control Measures (PC); Export Related Measures (EXP); Others (OTH)

Limited research has been conducted identifying NTBs within ASEAN’s medical devices sector. However, multiple reports have highlighted the regulatory and market access barriers affecting medical devices companies in the broader Asia-Pacific Region.

Reports have pointed out that fragmented regulatory and reimbursement landscapes and a shortfall in regulatory capacity are impediments for medical devices companies operating across Asia. The fragmentation of regulatory regimes across multiple countries can create additional complexities for businesses. A 2015 KPMG survey shows that 29% of medical device manufacturers saw increased regulation in the industry as their biggest challenge.²⁸² Similarly, a 2015 McKinsey report claimed that the use of different medical device classification systems across Asia was likely to cause disparate timelines in approval processes and require business to meet multiple clinical trial requirements.²⁸³ The same report also stated that a shortfall in regulatory capacity in some Asian markets, contributed to longer wait times for registration and variability in the time needed to complete similar processes across different markets.²⁸⁴

Previous reports have also pointed at the ways in which a complex range of public and private reimbursement systems can hinder the offer and availability of medical device products across the region. For instance, the implementation of full or partial reimbursement schemes can affect patient access to new technologies.²⁸⁵

²⁸² Stirling, Chris., and Shehata, Ash. “Collaboration – The future of innovation for the medical device industry.” KPMG International Cooperative, Sep. 2015, 11.

²⁸³ Angarwal, Amit., et al. “MedTech in Asia, Committing at scale to raise standards of care for patients.” McKinsey & Company, Dec. 2015, 25.

²⁸⁴ Angarwal, Amit., et al. “MedTech in Asia, Committing at scale to raise standards of care for patients.” McKinsey & Company, Dec. 2015, 25.

²⁸⁵ Angarwal, Amit., et al. “MedTech in Asia, Committing at scale to raise standards of care for patients.” McKinsey & Company, Dec. 2015, 25.

Furthermore, in some countries medical devices companies face policies designed to encourage the localization of medical device manufacturing. For instance, in its *2016 Top Markets Report on Medical Devices*, the International Trade Administration claimed that in countries like Malaysia there have been instances where government procurement favoured locally produced equipment, even when the bid price proposed by foreign companies was lower or the equipment was of equal or superior quality.²⁸⁶

Overall, regional reports have shown that a fragmented and evolving set of regulatory and reimbursement regimes and localization policies can make it difficult and costly for medical devices companies to operate across Asia.

²⁸⁶ International Trade Administration. "2016 ITA Medical Devices Top Markets Report." ITA, 2016, 41, https://www.trade.gov/topmarkets/pdf/Medical_Devices_Malaysia.pdf

Medical Devices: Interview Findings

The following section is based on the results of a lengthy series of interviews largely conducted between October 2018 and January 2019 in key ASEAN markets with industry players in the medical devices sector. Interview candidates included ASEAN companies as well as foreign players. It does not cover all ASEAN markets, nor highlight all potential issues — only those explicitly raised by interview subjects. All NTM tables are tabulated from the UNCTAD Integrated Trade Intelligence Portal.

As with other interview sections, the “impact scoring” of red/yellow/green was not developed by the firms directly. It was derived from company interviews and by the extent to which a particular barrier was repeatedly raised by firms as well as by how much of an obstacle any specific barrier poses to doing business. The impact score should be viewed as a continuum from red to green, rather than a clear shift from one category to another. As might be expected, the charts below reflect few “green” impact scores, as firms typically did not spend time discussing issues that were not viewed as problematic. If viewed across time, however, some of the listed items could very well decline from red to yellow to green or the reverse.

Indonesia

With a total population of 262 million people and an ageing population of 15.4 million, demand in Indonesia’s medical devices sector is poised to grow to US\$1.5 billion by 2022.²⁸⁷ Furthermore, with the launch of a nationwide universal health care plan in 2014 called Jaminan Kesehatan Nasional (JKN), Indonesia will be expanding its healthcare services and therefore increasing its need for medical equipment.

Indonesia’s medical device market amounted to nearly US\$1 billion in 2014 of which 95% was made up of imports.²⁸⁸ Foreign manufacturers accounted for 90% of device registrations in 2013.²⁸⁹ However, restrictions on foreign firms, like the need for a local office or distributor, can hinder medical device companies from registering their products.²⁹⁰




²⁸⁷ "Indonesia - Medical Equipment | Export.Gov." *Export.gov*. N.p., 2019. Web. 27 Feb. 2019.

²⁸⁸ Wasserbauer, Michal. "A Growing Market For Medical Devices In Indonesia." - *Your Business Partner in Indonesia and Vietnam*, N.p., 2014, <https://www.cekindo.com/blog/a-growing-market-for-medical-devices-in-indonesia-2>


²⁸⁹ Wasserbauer, Michal. "A Growing Market For Medical Devices In Indonesia." - *Your Business Partner in Indonesia and Vietnam*, N.p., 2014, <https://www.cekindo.com/blog/a-growing-market-for-medical-devices-in-indonesia-2>

²⁹⁰ Wasserbauer, Michal. "A Growing Market For Medical Devices In Indonesia." - *Your Business Partner in Indonesia and Vietnam*, N.p., 2014, <https://www.cekindo.com/blog/a-growing-market-for-medical-devices-in-indonesia-2>

Technical Barriers to Trade

Category	Description	Impact
Procedural Obstacles – Registration Process	<u>Bottlenecks in the Product Registration Process</u> Companies raised concerns about bottlenecks within the registration process. For instance, some companies mentioned that it might take 3 to 5 years after product registration to get the product license.	 Yellow
Procedural Obstacles – Registration Process	<u>Bottlenecks in the Product Registration Process</u> Companies raised concerns about bottlenecks within the registration process.	 Yellow
Product Requirements for Religious Reasons	<u>Potential Halal Regulation</u> Participants are unsure about how “voluntary” this legislation will be and where in the scope of the law medical devices will fall. It is often impossible to create halal medical devices—as an example, items that filter blood need to use blood, which could be found to be non-halal.	 Red

Price Control Measures

Category	Description	Impact
Price Negotiation	<u>Inconsistent Application of Value Based Guidelines</u> The Ministry of Finance has established value-based guidelines, which allow medical devices companies to negotiate the price of their products based on their potential value to customers. However, some companies have claimed that in certain price negotiations, such criteria do not apply.	 Red

Trade Related Investment

Category	Description	Impact
Local Partner Requirements	<u>Need for a local partner:</u> Companies must produce products locally or have a majority joint venture in order to import medical equipment in Indonesia.	 Red

Government Procurement Restrictions

Category	Description	Impact
Access	<p><u>Limited Number of Categories in the E-Catalogue</u></p> <p>There is a limited number of categories under which certain products can be listed under the E-Catalogue. Thus, some new products might not fit those categories.</p> <p>The E-Catalogue list also limits the amount of brands that can be listed per product. Thus, only a limited number of brands can sell in the e-catalogue per product category.</p>	Yellow
Price Negotiation	<p><u>Limited times for Price Negotiations</u></p> <p>Long wait times for price negotiations with Indonesia's National Public Procurement Agency (LKP). These are worsened by the fact that companies only have such opportunity once a year.</p>	Yellow
Procedural Obstacles – Access	<p><u>Unclear Selection Process that Favours Local Manufacturers in Manufacturing Process</u></p> <p>Participants pointed to a tendency to choose local manufacturers (if there is one available) to provide a given product. However, the mechanisms and criteria by which they are chosen and the product categories that underlie the preferences remain unclear.</p>	Red
Price Negotiation	<p><u>Kick-Back Model in the Public Procurement Process</u></p> <p>Ability for hospitals to negotiate procurement decisions with medical devices providers creates incentives for irregularities in the tender decision process. For instance, a public hospital can ask for a portion of the reimbursed sum, or a kickback, in exchange for awarding a tender to a particular medical device provider. This creates incentives for corruption that counteract with the well-established compliance practices of foreign companies.</p>	Red

Quantity Control Measures

Category	Description	Impact
Prohibition	<p>Restriction in the importation of refurbished medical equipment is prohibited, even though this is a sub-business model used by medical device companies. Interviewed companies claim that refurbished medical equipment is a high quality and low price alternative used in multiple markets.</p>	Yellow


Malaysia

Malaysia is projected to be one of ASEAN's largest medical device markets. It is a major producer of rubber-based medical devices, and produces a significant portion of the world's surgical gloves and catheters.

Malaysia's medical device sector is currently valued at US\$1.4 billion with a projected growth rate of 16.1%.²⁹¹ Medical device exports were forecast in 2017 to hit 17.7 ringgit billion in exports. With strong supporting industries and over 200 manufacturers, Malaysia has been posturing itself to become a medical devices research and development (R&D) hub. The Malaysia Investment Authority reported that over 30 MNCs have made Malaysia their offshore manufacture location.²⁹² Malaysia exports over 90% of locally manufactured medical devices.²⁹³

Medical device sales to certain priority sectors or Government Linked Corporations (GLCs) will require local agents or partners classified as Bumiputra—business owned by Malaysian of Malay or indigenous racial origin.²⁹⁴ In addition, exporters of medical devices need to obtain approval from the Malaysian Medical Device Authority prior to market entry.²⁹⁵

Licensing

Category	Description	Impact
Establishment License	<p><u>New Certification of Good Distribution Practices</u></p> <p>All businesses need a certification of Good Distribution Practices in order to get an establishment license, and thus sell medical devices in Malaysia. They also need to ensure that they are prepared for yearly surveillance to monitor whether companies are complying with those practices. Smaller companies might find it difficult to comply with those requirements.</p>	 Yellow

²⁹¹ "Malaysia Medical Device & Pharmaceutical Markets - Growth Rate, GDP." *Pacific Bridge Medical*. Web. 27 Feb. 2019.




²⁹² "Malaysian Investment Development Authority: Medical Devices." *Mida.gov.my*. Web. 27 Feb. 2019.

²⁹³ "Malaysia's Medical Device Industry Continues to Grow Despite Emerging Challenges." *Healthcare Asia Daily News | Asia's Leading News and Information Source on Healthcare and Medical Industry, Medical Technology, Healthcare Business and R&D, Healthcare Events*. Online since 2010. N.p., 2017. Web. 27 Feb. 2019.


²⁹⁴ Teoh, Shannon. "Pro-bumiputera policy tough to scrap." *The Straits Times*, 4 Aug. 2017, <https://www.straitstimes.com/asia/se-asia/pro-bumiputera-policy-tough-to-scrap>

²⁹⁵ "Healthcare Resource Guide : Malaysia." 2016.export.gov, 2018, https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_108601.asp


Technical Barriers to Trade

Category	Description	Impact
Product Requirements for Religious Reasons	<p><u>Potential Halal Regulation</u></p> <p>The government's proposed halal regulations are currently meant to be voluntary but that can easily become compulsory. Participants are worried about the way it will shape the perceptions of consumers within Malaysia. They claim that sales will likely go down for companies making non-halal products.</p> <p>Potential ways in which devices can be non-Halal include; using alcohol to clean the device, and bones for filtration or the use of blood in many different ways.</p>	
Product Registration Requirement	<p><u>Reference Country Requirement</u></p> <p>Malaysian authorities require a reference country that has approved the products in Canada, Australia, Japan and US. If the products have not been manufactured in those four countries, companies cannot launch those products in Malaysia.</p>	
Conformity Assessment	<p><u>Increasing Information Requirements</u></p> <p>The Malaysian government is demanding increasing information from firms. This is concerning for companies that do not want to disclose information about their products to protect their IP from potential manufacturing copycats.</p>	

Measures Affecting Competition

Category	Description	Impact
Local Partner Requirement	<p><u>Bumiputra Law</u></p> <p>Companies must engage a Bumiputra partner to trade with the government.</p>	

Procurement



Category	Description	Impact
Procedural Obstacles – Procurement Process	<p><u>Irregularities in the procurement process</u></p> <p>Participants repeatedly brought up examples of private negotiations within the procurement process, corruption, and price-based comparisons.</p>	

The Philippines

The Philippines has a population of a 100 million with a rapidly growing middle class and a steady economic growth rate of 6.7%.²⁹⁶ Growing incidences of hypertension, cardiovascular diseases, diabetes, and other non-communicable diseases have led the current administration to focus on expanding and upgrading its hospitals with a target of “full coverage to quality health.”²⁹⁷ The Philippines’ medical device sector is valued at US\$227 million with a projected growth rate of 10.7%.²⁹⁸ Imports account for almost 100% of Philippines’s medical devices sector.²⁹⁹

Medical devices are regulated by the Center for Device Regulation, Radiation Health, and Research (CDRRHR) under the Philippine Food and Drug Administration (FDA). An Administrative Order issued in January 2018, coming into effect in March 2019, will align registration requirements to the Common Submission Dossier Template (CSDT), which is based on the provisions of the ASEAN Medical Device Directive.³⁰⁰

Technical Barriers to Trade

Category	Description	Impact
Establishment License	It takes a long time to get a device approved or licensed. Even a small machine might take up to one and a half years to get approved.	 Yellow
Product Approval	<u>Lack of capacity to manage product approvals:</u> Companies often brought up issues citing large backlogs in the product approval process.	 Yellow

Singapore

Singapore is the regional hub for health. Although the market size for medical devices itself is small — valued at an estimated US\$2.5 billion — Singapore is a net exporter of medical devices with exports amounting to US\$17 billion.³⁰¹ Home to more than 60 multinational MedTech companies, Singapore produced an estimated US\$9 billion and imported another US\$9 billion worth of medical devices in 2017.³⁰²

Medical devices in Singapore are regulated under the Health Products (Medical Devices) Regulations of the Health Products Act (HPA). With the exception of certain

²⁹⁶ “Philippines Economic Update: Investing in the Future.” The World Bank, 16 Apr. 2018, <https://www.worldbank.org/en/country/philippines/publication/philippines-economic-update-investing-in-the-future>

²⁹⁷ “Healthcare Resource Guide: Philippines.” Export, 2016, https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_092021.asp

²⁹⁸ “Philippines Medical Market.” Pacific Bridge Medical, <https://www.pacificbridgemedical.com/target-asian-markets/philippines-medical-market/>

²⁹⁹ Philippines Medical Device & Pharmaceutical Markets - Growth Rate, GDP.” Pacific Bridge Medical. Web. 27 Feb. 2019.


³⁰⁰ “Healthcare Resource Guide: Philippines.” Export, 2016, https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_092021.asp

³⁰¹ “Singapore - Medical Devices | Export.Gov.” Export.gov, 2018, <https://www.export.gov/article?id=Singapore-Medical-Devices>

³⁰² “Medical Technology.” Edb.gov.sg, <https://www.edb.gov.sg/en/our-industries/medical-technology.html>

low risk medical devices, all medical devices must be registered on the Singapore Medical Device Register (SMDR).³⁰³

Technical Barriers to Trade

Category	Description	Impact
Conformity Assessment	Participants expressed concern about efforts to enact a health technology assessment (HTA) requirement for Medical Devices. The HTA is often used for pharma and relies on proof of efficacy of the products. Companies claimed that this could keep innovative medical device products off the market.	 Yellow


Thailand

Thailand's medical device market was estimated at US\$1.2 billion in 2017 with imports accounting for US\$931 million.³⁰⁴ The sector is expected to grow 8.5% to 10% per year.³⁰⁵ Expected growth is the result of an ageing population, a rise in chronic illnesses, increasing numbers of foreign patients, and the development of new private hospitals.³⁰⁶

Thailand's medical device sector primarily manufactures basic medical products, so it is heavily dependent on imports for more complex and high-end medical devices.³⁰⁷

Medical devices in Thailand are regulated and must be registered under the Medical Device Control Division of the Thai Food and Drug Administration (TFDA).³⁰⁸

Technical Barriers to Trade

Category	Description	Impact
Labelling Requirements	<u>Thai Labels</u> Requirement to have medical devices labelled in Thai.	 Yellow

³⁰³ "Medical Devices Advisories | HSA | Health Sciences Authority." Hsa.gov.sg,

https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview.html


³⁰⁴ "Thailand - Medical Equipment." Export.gov. Jul. 2018, <https://www.export.gov/article?id=Thailand-medical-equipment>

³⁰⁵ "Thailand - Medical Equipment" Export.gov. Jul. 2018, <https://www.export.gov/article?id=Thailand-medical-equipment>


³⁰⁶ "Thailand - Medical Equipment" Export.gov. Jul. 2018, <https://www.export.gov/article?id=Thailand-medical-equipment>

³⁰⁷ "Healthcare Resource Guide: Thailand" Export.gov. Jun. 2016, https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_092301.asp



³⁰⁸ "Medical Device Registration in Thailand." Pacific Bridge Medical, <https://www.pacificbridgemedical.com/regulatory-services/medical-device/product-registration/thailand/>

Registration	<p><u>No Clear Standard for Product Registration Procedures</u></p> <p>Evidence of inconsistency in product registration procedures under the Thai FDA. Sometimes the FDA requests additional documents, such as requiring documents about product testing as part of registration process.</p>	
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Price Control Measures

Category	Description	Impact
Customs Duty Rate	<p><u>Inconsistency in use of harmonization codes:</u></p> <p>Even though there is a clear Harmonization System (HS) for the raw materials, the classification code used by Thai customs often changes at the border. In those cases, customs charge the higher of the two customs duty rates. Thus, customers may have to pay based on the raw material classification of the product.</p>	

Others

Category	Description	Impact
Maritime Department Law	<p>Products arriving into the country for government bids have to get there via a Thai-flagged vessel. Thai-flagged vessels are limited in number and can entail a significant cost for importers. Companies mentioned that such a law does not seem to be evenly implemented.</p>	
Cybersecurity Law	<p>Data localization requirements might affect the use of equipment that requires the transfer of data to function.</p>	

Vietnam

Vietnam's medical devices market is expected to register an annual growth rate of 9.6% between 2017 and 2022.³⁰⁹ Such growth is the result of growing public and private healthcare expenses, higher demand for more sophisticated treatments, and rising healthcare needs.³¹⁰


³⁰⁹ "Vietnam Healthcare Market by Industry Type (Hospitals & Clinics, Diagnostic Labs, Pharmaceutical and medical Devices) – Outlook to 2022." Ken Research, Feb. 2018, <https://www.kenresearch.com/healthcare/general-healthcare/vietnam-healthcare-market-report/142714-91.html>

³¹⁰ "Healthcare Resource Guide: Vietnam" Export.gov. Oct. 2018, https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_108629.asp


Local production of medical devices has not been able to meet local demand, so Vietnam imports 90% of its medical equipment.³¹¹ Nevertheless, as the government increases investments and puts in place tax incentives to boost domestic production, Vietnam may become a medical devices manufacturing hub capable of supplying the domestic and regional markets.³¹²

To export into Vietnam, medical device companies have to be registered and granted a market authorization license by the Department of Medical Equipment and Health Works under the Ministry of Health.³¹³ Moreover, only Vietnam registered business entities with an import license are eligible to distribute medical devices in Vietnam.³¹⁴

Technical Barriers to Trade

Category	Description	Impact
Procedural Obstacle – Conformity Assessment	<u>Customs Clearance Approval</u> Goods arrive in port and are randomly assigned to customs clearance lanes through a traffic light system. This makes it tough to predict how long customs clearance process is going to take and there is no way to complete the due diligence in advance.	 Yellow

Procurement

Category	Description	Impact
Procedural Obstacle – Preference	<u>Unclear and non-transparent procurement process</u> Preference for state tenders.	 Red

Cambodia, Laos and Myanmar (CLM)

The pharmaceutical markets in the remaining ASEAN countries are not large. However, firms are still facing a number of NTMs while operating in these markets. In most cases, these NTMs seem to be tools for governments to encourage more investment into local production and manufacturing. In some other cases, the barriers are the consequences of a lack of regulations or an incomplete regulatory framework.

³¹¹ "Healthcare Resource Guide: Vietnam" Export.gov. Oct. 2018, https://2016.export.gov/industry/health/healthcareresourceguide/eq_main_108629.asp

³¹² "Vietnam Medical Devices Market Outlook to 2022." Vietnam Insider, Oct. 2018, <https://vietnaminsider.vn/vietnam-medical-devices-market-outlook-to-2022/>

³¹³ "Vietnam Medical Device Industry: Facts, Figures and Opportunities." BDG Vietnam, Oct. 2017, <http://bdg-vietnam.com/de/about/news/details/items/vietnam-medical-device-industry-facts-figures-and-opportunities/>

³¹⁴ "Vietnam Medical Device Industry: Facts, Figures and Opportunities." BDG Vietnam, Oct. 2017, <http://bdg-vietnam.com/de/about/news/details/items/vietnam-medical-device-industry-facts-figures-and-opportunities/>

Myanmar


Technical Barriers to Trade

Category	Description	Impact
Import Licenses	<p><u>Complex Customs Procedures</u></p> <p>Import licenses are required for every shipment. Maximum validity of an import licenses is six months (including two extensions of the license). The procedures to get import licenses are complicated, troublesome, costly, and time-consuming.</p>	Yellow
Labelling Requirements	<p><u>Unclear labelling requirements when importing devices.</u></p>	Yellow
Conformity Assessment	<p>Implementation of certification requirements that do not comply with international standards.</p>	Yellow

Price Control Measures

Category	Description	Impact
Decreed Customs Valuation	<p><u>Customs Valuation</u></p> <p>Customs officers — when in doubt — can request the imported products to go through a customs valuation process which can take up to 15 days. A reference point for customs officers is prices listed on e-commerce platforms and online in general — there is no transparency around this. Participants claimed that up to 40% of products need to go through customs valuation.</p>	Yellow
Customs Procedures	<p><u>Procedural Obstacles</u></p> <p>Low-quality port facilities, low-skilled customs officers, low productivity, and efficiency affect device firms. No clear and transparent guidelines on the standard format and how to fill in form D, E, and the like. Importers will get fined for wrongly-completed forms even if the forms were given by exporters and aligned with regional and international standards.</p>	Yellow

Procurement

Category	Description	Impact
Procurement	<u>Lack of Transparency in Procurement Process</u> Tenders lack transparency. It is unclear what are the weighing factors when choosing a specific vendor.	 Yellow

ASEAN Recommendations: Healthcare Goods

This project is generally aimed at tackling barriers to trade in all goods areas, rather than in specific sectors. However, given the range of issues identified by companies in healthcare goods and a number of specific steps already taken by ASEAN in these sectors, there is scope for considering certain recommendations just for improving business conditions in healthcare goods at the ASEAN level.

ASEAN's efforts to address barriers in pharmaceutical products started back in 1992 under the ASEAN Consultative Committee for Standards and Quality (ACCSQ). In 1999, the group established a Product Working Group on Pharmaceuticals (PPWG). The PPWG was tasked with the objective to develop harmonization schemes for pharmaceuticals' regulations of the ASEAN member countries to complement the objective of ASEAN Free Trade Area (AFTA) in order to eliminate technical barriers to trade posed by these regulations, without compromising on drug quality, safety, and efficacy.³¹⁵ The group made progress in harmonization of medical device standards, developed Common Technical Documents and arrived at Mutual Recognition Arrangement (MRAs). The scope of pharmaceutical products covered by the PPWG included New Chemical Entities (NCEs), biotechnological products, major and minor variation products, and generics.³¹⁶

The PPWG has developed the ASEAN Common Technical Dossiers (ACTD) and ASEAN Common Technical Requirements (ACTR), which cover quality, safety, and efficacy and administrative procedures. The ACTD provides a guideline to a common format for the preparation of well-structured Common Technical Dossier (ACTD) applications to be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals for human use. But while countries have adopted the ACTR, not all drug registration and testing procedures are actually standardized across ASEAN.³¹⁷

Within the medical devices sector, ASEAN signed an agreement, formally called the ASEAN Medical Device Directive (AMDD) on 21 November 2014, that aimed to harmonize medical device regulations.³¹⁸ The AMDD was intended to provide a shorter path to the market for medical device manufacturers.³¹⁹

Within the AMDD, the ASEAN Common Submission Dossier Template (CSDT) provides a collection of information and requirements that is supposed to allow a device manufacturer to provide the same product registration documentation to the different health and drug regulatory authorities of the ASEAN Member States. Some of the ASEAN Member States are in the process of ratifying the agreement.³²⁰

³¹⁵ "ACCSQ Pharmaceutical Product Working Group." ASEAN. Oct. 2012, https://asean.org/?static_post=accsq-pharmaceutical-product-working-group

³¹⁶ "Association of Southeast Asian Nations Pharmaceutical Product Working Group." ICH, <http://www.ich.org/about/organisation-of-ich/assembly/asean.html>

³¹⁷ "Harmonization of Standards and Technical Requirements in ASEAN." ASEAN, Oct. 2012, https://asean.org/?static_post=harmonization-of-standards-and-technical-requirements-in-asean

³¹⁸ Entry into force on 1st January 2015 for members who have ratified the agreement.

³¹⁹ Association of South East Asian Nations (ASEAN). "ASEAN Medical Device Directive." ASEAN, 2015, <https://asean.org/storage/2016/06/22.-September-2015-ASEAN-Medical-Device-Directive.pdf>

³²⁰ "ASEAN Medical Device Directive (AMDD) – Progress and Updates by AMDC." Andaman Medical, 2 Jan. 2019, <https://www.andamanmed.com/asean-medical-device/>

ASEAN Member States have also signed a number of MRAs to facilitate the movement of medical products across the region. First, the ASEAN Sectorial MRA on Bio-Equivalence (BE), signed in 2017, provides recommendation for BE studies³²¹ and sets the relevant criteria under which bio-availability studies need not be required.³²² This MRA allows for mutual acceptance of BE study reports from Listed BE Centres located in ASEAN Member States, avoiding the need to produce multiple BE studies for obtaining authorization for new generic drugs in different markets. Second, the ASEAN MRA on Good Manufacturing Practice (GMP) Inspection, signed in 2009, aimed to facilitate the movement of medicinal products in ASEAN through the mutual exchange and recognition of GMP inspection reports and certificates from the ASEAN Member States.³²³ Under this MRA, all ASEAN Member States shall accept and recognize the GMP Certificates and/or inspection reports of a Listed Inspection Service, facilitating access of medicinal products across the ten ASEAN Member States.

It is clear that ASEAN has been working on specific challenges in the health care industry for a considerable length of time. The various bodies and agreements are a testament to the desire of member governments to reduce the complexity in the marketplace for both pharma and devices.

However, the field interviews also show that companies face significant barriers to doing business in the region. Some of these obstacles are domestic-level challenges unique to specific member states. Some, however, could be more usefully addressed at the ASEAN level.

In particular, ASEAN needs to do two things to improve the health care sector:

- implement and enforce existing commitments; and
- address significant barriers to trade unrelated to the harmonization of standards and mutual recognition of conformity assessment procedures.

First, it is important that ASEAN develops the institutional capacity to ensure that the harmonization of standards and certification procedures and related commitments are actually implemented. Interview findings showed irregularities in the implementation of some of those standards. It is important that commitments under the PPWG, AMDD, and the relevant technical dossiers can be tracked to monitor both their implementation and effectiveness.

Second, it is important that ASEAN develops an institutional mechanism or body that tackles NTBs that are not related to technical and conformity assessment standards. Currently, none of ASEAN's commitments or bodies covering the health sector has the capacity to assess or report on many of the barriers affecting healthcare goods companies operating within the region. At the moment ASEAN has no specialized mechanism to address concerning issues around government procurement, IP

³²¹ "Bioequivalence Study" or "BE Study" means a comparative bioavailability study designed to establish equivalence between a generic medicinal product and a comparator product.

³²² This MRA is only applicable to pharmaceutical companies of generic drugs that develops new drug formula to generics or reformulate their existing products but could also positively impact pharmaceutical businesses and consumers.

³²³ The scope of the MRA was restricted only to medicinal products in finished dosage forms and includes both prescription and non-prescription medicinal products for human use, but excludes biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products intended for clinical trials.

protection and market access — the issues at the top of the list for health companies operating within the region.

Therefore, it is important that as a regional body ASEAN develops mechanisms that ensure that: (i) dialogue with private sector stakeholders is continuously maintained and (ii) that there is an institutional body capable of both acknowledging and effectively addressing priority issues raised by stakeholders.

Health Care: Specific Recommendations

Based on the study's findings across the two selected healthcare products and best practices within the literature, the following are recommendations or principles that address the main issues found to be affecting pharmaceuticals and medical devices firms within the region.

I. Strengthen Regional Intellectual Property Regime to ensure stronger enforcement of patents and improved consistency

ASEAN should ensure that it institutionalizes the revision and assessment of IP practices within its member countries. It may do so within the implementation of its "Intellectual Property Rights Action Plan 2016 – 2025."³²⁴

Given the lack of consistency, transparency and reliability of some regional IP regimes, ASEAN must ensure that: (i) IP laws are aligned with international standards and practice, (ii) patent registration systems operate efficiently, and (iii) the IP environment enhances innovation and development. Such an environment would provide pharmaceutical manufacturers with the confidence that they are able to compete fairly with local manufacturers and accelerate the launch of new medicines across the ASEAN markets.

At a minimum the plan should incorporate: (i) capacity building efforts that alleviate long patent grant delays and (ii) a work plan for the assessment of patent criteria, patent restoration, and compulsory licensing policies across the region.

II. Continue efforts towards the harmonization of regulatory requirements

ASEAN must continue its efforts towards the mutual recognition and eventual harmonization of technical standards, product registration, and conformity assessment regulations between countries. It is important that ASEAN: (i) ensures that there are institutional mechanisms that can track and assess implementation and (ii) supports any capacity development needed to ensure that customs bodies and regulators have the capacity and knowledge to effectively and efficiently implement these types of measures.

³²⁴ "The ASEAN Intellectual Property Rights Action Plan 2016 – 2015: Meeting the Challenges of "One Vision, One Identity, One Community" through Intellectual Property." ASEAN IP, Dec. 2017, [https://www.aseanip.org/Portals/0/ASEAN%20IPR%20ACTION%20PLAN%202016-2025%20\(for%20public%20use\).pdf?ver=2017-12-05-095916-273](https://www.aseanip.org/Portals/0/ASEAN%20IPR%20ACTION%20PLAN%202016-2025%20(for%20public%20use).pdf?ver=2017-12-05-095916-273)

III. Introduction of common global best practices processes across ASEAN for government procurement practices within the healthcare sector

It is important that ASEAN encourages open, transparent, and non-discriminatory public procurement processes. ASEAN should create an institutional mechanism, like the PPWG, with a mandate to develop a work plan ensuring the assessment and review of current procurement legislation and regulatory frameworks.

This would ensure that governments:

- instil transparent procedures for healthcare and pharmaceutical product pricing and reimbursement;
- guarantee a level playing field in the development and provision of healthcare products; and
- implement best practices with due consideration for therapeutic outcomes and clinical needs rather than focus only or entirely on cost.

General Recommendations ASEAN Level

ASEAN has made significant steps towards creating an integrated region. Blueprint 2025 reinforces ASEAN's commitment to creating a highly integrated and cohesive economy with enhanced connectivity and sectorial cooperation. During the early years of the ASEAN integration process, the focus was on the removal of intra-ASEAN tariffs to create a single market and production base.

While the goal of tariff elimination has been largely accomplished, member states have been less successful at crafting a seamless economy. As tariffs have fallen, a wide variety of non-tariff issues have cropped up in various sectors. Some of these non-tariff issues are legitimate responses of governments looking to ensure, for example, the health and safety of citizens. Other non-tariff challenges are more problematic — less about legitimate public health exceptions, perhaps, than about protecting domestic markets from competition.

ASEAN's internal mechanisms to find and root out the latter obstacles to trade remain underdeveloped. However, unless the members find ways to properly address non-tariff barriers that are impeding trade in the region, the overall objectives in the Blueprint 2025 will not be met. ASEAN will not create a highly integrated and cohesive economy and it will face increasing challenges in attracting and retaining investment from abroad.

The job of tackling NTBs is not automatically difficult or impossible. The first order of business is to get beyond creating more surveys to confirm that NTBs “really do exist” in the region. This study — as all others that have come before — have clearly demonstrated that NTBs are rife across the region. They drive up costs and limit the competitiveness of ASEAN as a region. While this project has only looked at three sectors, replication of the study in other sectors would likely turn up similar results.

It is surely time, therefore, for ASEAN to actually do something to tackle NTBs. This requires three things:

- identify existing NTMs;
- identify and assess NTBs; and
- eliminate NTBs.

The project's recommendations take into consideration:

- existing ASEAN institutional frameworks and bodies;
- specific deliverables; and
- highlight suggestions and best practices raised by relevant literature.

ASEAN has had a long history of attempting to tackle the challenges of NTMs and NTBs. To really make “this time different,” the institution must do things differently. The recommendations of this report need not be followed sequentially, but should be done in parallel. It is not necessary to have a complete list of every single NTM or NTB in every ASEAN member state before any additional action can take place. ASEAN must be able to “walk and chew gum” at the same time. It can catalogue existing issues while also tackling the reduction and elimination of measures and barriers. It can ensure that no new obstacles are thrown up while reducing existing challenges.

To increase its capacity and enforcement mechanisms for the reduction of NTBs within existing bodies and commitments, ASEAN should follow five core principles:

1. Create Improved Systems to Effectively Identify and Collect Information on Both NTMs and NTBs

All relevant stakeholders need a location to identify and track all non-tariff measures that are in place in individual ASEAN Member States. Because these are NTMs, each should have a legitimate purpose that can be justified. Many of the firms interviewed in the study may have been complaining about NTMs and not, strictly speaking, about NTBs. However, if the enforcement of an NTM is unclear or non-transparent, a legitimate NTM can become an NTB. Hence, the enforcement or implementation of NTMs also must be recorded for stakeholders to access.

1.1: Promote transparency in NTMs through the use of a comprehensive and ongoing database of NTMs in the region that is open to the public and easy to access

Past efforts to post information at the ASEAN level have frequently foundered over challenges from some member states to keep information current. Hence, the data needs to be created and maintained by a wide group of stakeholders, including individual member states, the ASEAN Secretariat and the private sector.

ASEAN has already begun developing a similar initiative. The ASEAN Trade Repository (ATR), a comprehensive database consolidating the national trade repositories (NTRs) from all ASEAN Member States, could be used or modified to track NTMs.³²⁵

Thus far, progress on creating the ATR has been slow. Many ASEAN Member States have not completed their domestic NTRs, even with often substantial help and assistance from the donor community (from, as an example, the ARISE+ project). Using the ATR for tracking NTMs, therefore, is not ideal unless and until ASEAN Member States dramatically improve their commitment to the process in the first place. ASEAN should clearly define, and stick to, a timeline for completion of the ATR project.

Moreover, other assessments of NTMs within ASEAN have made the following suggestions that ASEAN could also incorporate to improve the efficacy of its NTM tracking initiatives:

- a) Establishing a requirement that any notifications to the WTO of any changes in regulatory measures that have a trade effect should also be copied and notified to ASEAN Secretariat.³²⁶ This requirement is now included in the 2018 ASEAN NTM Guidelines, but a commitment on paper does not automatically mean that all ASEAN members will adhere to the promise in the future.

³²⁵ "ASEAN Trade Repository – About." ASEAN, <https://atr.asean.org/read/about-us/22>.

³²⁶ Pasadilla, Gloria O. "Addressing Non-tariff Measures in ASEAN." Asia-Pacific Research and Training Network on Trade No. 130, Sep. 2013.

- b) Partner with third-party data sources of new measures to record NTMs and alert the ASEAN Secretariat and the Coordinating Committee for ATIGA (CCA) of new measures.³²⁷ This second point will help better ensure that the NTM Guidelines are followed, whether or not individual member states maintain effective reporting.

Overall, it is important that ASEAN ensures that the ATR remains updated and, when necessary, engage third party partners to ensure it can effectively collect and keep track of NTMs.

1.2: Quickly follow, and effectively implement, the ASEAN 2018 NTM Guidelines

ASEAN produced a set of NTM Guidelines in 2018.³²⁸ The guidelines provide useful principles that should be followed when setting out new NTMs. The document can also serve a helpful purpose once it has been implemented. ASEAN Member States are now conducting surveys of existing procedures.

One key recommendation that would help improve the situation in ASEAN for companies is the effective — and timely — implementation of the Guidelines that have already been approved by all ASEAN Member States.

1.3: Allow for ASEAN Member States responses to NTMs

Since NTMs are allowed, it is important for ASEAN Member States to be given the opportunity to explain the justification for existing NTMs that have been flagged in the ATR system (or whatever tracking system ASEAN members opt to use to gather information about NTMs going forward).

The system should also allow governments to clearly define and explain the implementation and enforcement procedures attached to the identified NTMs or to redirect interested parties to domestic level sources for this information. These are, it should be noted, requirements as well in the newly approved NTM Guidelines.

To improve the business climate overall, the repository system may also want to include broader descriptions of existing regulations, including policy objectives and rationale, and provide technical background information that supports the rationale for specific regulations.

1.4: Streamline NTMs

While NTMs are allowed, not every NTM should be maintained. The stocktaking exercise should begin to highlight NTMs that could be eliminated. Many existing rules or regulations are actually duplicates, requiring firms to meet the same objectives in multiple ways. Such wasted efforts should be adjusted to reduce the burden on

³²⁷ Pasadilla, Gloria O. "Addressing Non-tariff Measures in ASEAN." Asia-Pacific Research and Training Network on Trade No. 130, Sep. 2013.

³²⁸ Found at

https://asean.org/storage/2018/12/Guidelines_for_the_Implementation_of_ASEAN_Commitments_on_NTMs-July_2018-AEM-AFTAC_32.pdf

companies. This is especially critical for smaller firms that already struggle to compete effectively in the region.

1.5: Ensure appropriate and effective mechanisms to allow businesses to notify ASEAN about probable NTBs

Not every obstacle is justifiable under existing trade rules. Some clearly cross over into NTB categories. It is critically important that these barriers to trade be identified and steps taken to remove them.

Firms doing business in the region are the most likely sources of information on such barriers. They need an easily accessible mechanism to call attention to NTBs. The mechanism must allow comments to be made anonymously or through industry associations, law firms or other collective organizations because companies may not feel confident enough on their own in the process to provide candid feedback on trade challenges.

Fortunately, ASEAN has an initiative already in place, ASSIST, which should suit the purpose. ASEAN and ASEAN Member States must do a better job of promoting the ASSIST project to ensure that it is widely used by companies in the region. The more information it collects, the better it will be at identifying actual barriers to trade faced by multiple firms. The ASSIST framework, like the ATR, needs to allow individual firms, industry bodies, law firms and trade associations to place items in the database.

Thus, ASEAN must actively promote the use of both ASSIST and the ATR at the domestic level within their business communities. ASEAN Member States must respond quickly and effectively to issues raised in both platforms, since non-responses will not encourage future comments.

2. Effectively Manage Identified NTMs and Reduce and Eliminate NTBs

Getting a firmer grip on the scale and scope of NTMs and NTBs in the region is important, but a nice database of issues will not deliver the economic integration results ASEAN members need.

Currently there are few common definitions or approaches to identifying NTBs from NTMs. As a result, NTBs cannot be identified, and much less assessed, if ASEAN does not adopt a common approach to NTM reviews. Therefore, it is important that ASEAN establishes an institutionalized and sustainable compliance review process.

2.1 Ensure that ASEAN has an institutional body in place to address NTM and NTB issues—an independent body, CCA or ATF-JCC

The existing literature on NTMs has shown that a condition for a successful review of NTMs is the selection of a body that can conduct one. International experience with regulatory organizations has shown that review bodies work if they are independent

and have the authority to conduct the review apart from the agencies responsible for issuing the regulations.³²⁹

However, unlike the WTO, ASEAN has no built-in system for trade policy review.³³⁰ Since NTMs and NTBs cut across all sectors and include more than just standards, the most appropriate institutional body to address these issues is one at the highest levels with a coordinating role over the largest set of working groups. Given the often-political nature of some NTMs and NTBs, it is also important that the institutional body with responsibility for monitoring NTMs and reducing NTBs report directly to Ministers and Leaders on progress on a regular basis.

If ASEAN does not wish to create a new body, either the Coordinating Committee on ATIGA (CCA) or the ASEAN Trade Facilitation Joint Consultative Committee (ATF-JCC) should be placed in charge of NTM/NTB review.

If existing CCA or ATF-JCC are given additional responsibilities for NTM/NTB review, monitoring and elimination instead of the creation of an independent regional body to do so, CCA or ATF-JCC will need to be properly empowered to carry out these new tasks. This will include delivering a clear mandate to do so, along with sufficient resources and institutional strengthening to deliver results.

Improved institutional arrangements should include the designation of a full-time focal point for each ASEAN member state within CCA or ATFJCC as part of a permanent secretariat for the committee working within the ASEAN Secretariat tasked with addressing the NTM/NTB agenda.

2.2: Craft targeted, time-bound NTB reduction commitments

Since the removal of NTBs can be a lengthy and complex process, ASEAN members should reach an agreement to start by removing measures that have a clear negative impact on intra-regional trade.

The selected institutional body should ensure that ASEAN Member States agree on specific targeted reductions, but not require consensus for all members to move ahead with recommendations on which NTBs should be removed.

2.3: Set principles for regulatory reform based on international best practices

Regulatory assessment and reform should follow a set of principles that ASEAN Member States can agree on to ensure that there are not divergent views regarding the appropriate procedure(s) to assess and eliminate NTBs.

³²⁹ Cadot, Oliver., Malouche, Mariem., and Saez, Sebastian. "Streamlining Non-Tariff Measures: A Toolkit for Policy Makers." The World Bank, 2012.

³³⁰ Creating a Trade Policy Review Mechanism (TPRM) for ASEAN is something that the organization may want to consider in the future. It would help ensure that member states are mindful of existing ASEAN commitments and benchmark domestic laws and regulations against ASEAN promises.

The World Bank Group's Toolkit for streamlining NTMs offers a model for the development of those principles. It suggests that regulatory assessment should include:³³¹

- a) A dedicated review process done by an independent committee that involves a wide consultation process that includes the regulatory agency, the businesses affected, and civil society.
- b) A mandate that ensures the review is undertaken in a reasonable amount of time and gathers information from multiple stakeholders.
- c) An output document that states whether a measure should be kept, changed or eliminated.

Under "The Master Plan on ASEAN Connectivity 2025" ASEAN has already proposed such procedure.³³² The master plan includes a commitment to "Increase Transparency and Strengthen Evaluation to Reduce Trade-Distorting Non-Tariff Measures." This work plan for the commitment includes the elements of an effective regulatory assessment.³³³ These procedures should be built in to the institutional body tasked with addressing NTMs and NTBs.

3. Develop Clear Procedures and Institutional Frameworks for Tracking the Elimination of NTBs

The proper identification and assessment of NTBs does not guarantee that barriers will be eliminated. While ASEAN has the Enhanced Disputes Settlement Mechanism (AEDSM), it has never been used. It is, therefore, unrealistic to assume that this untested approach would be applied to NTB elimination in the near term.

Instead of working on the assumption that ASEAN member will use a dispute settlement system, it is critically important to ensure that ASEAN develop transparent monitoring mechanisms to ensure that identified barriers to trade are eliminated.

3.1: Ensure that the review body has the capacity to track the elimination of identified NTBs

ASEAN needs to ensure that the review process includes a follow-up procedure to tracks whether countries have met their commitments to eliminate NTBs. This will help ensure that governments are upholding their promises to encourage intra-ASEAN trade and create a vibrant economic region for the future.

³³¹ Cadot, Oliver., Malouche, Mariem., and Saez, Sebastian. "Streamlining Non-Tariff Measures: A Toolkit for Policy Makers." The World Bank, 2012.

³³² The ASEAN Secretariat, "Master Plan on ASEAN Connectivity 2015." ASEAN, Aug. 2016. ISBN 978-602-6392-02-2

³³³ The work plan includes (i) A procedure to define the scope of NTMs to evaluate (ii) Conduct a study to define appropriate quantification and benchmarking approach, used to prioritize NTMs and share the quantification and benchmarking methodology with relevant stakeholders (iii) Establishment of a "high level panel" that evaluates NTMs and defines which of the measures are trade distorting based on methodology (iv) Develop and establish GRP into the process of NTMs and communicated them with ASEAN member states (V) Monitor the progress on-trade distorting NTMs.

3.2: Ensure that the review body has a mandate and sufficient resources to develop work plans and support the elimination of identified NTBs

ASEAN needs to ensure that the review body can enact actionable work plans and procedures for the elimination of identified NTBs.

4. Continue to Ensure the Harmonization of Standards and Build the Capacity of ASEAN Member States and Companies to Meet Those Standards

4.1: Continue to effectively implement programs that tackle the harmonization of national standards with international standards; mutual recognition agreements particularly for conformity assessment; and accreditation of testing laboratories

ASEAN needs to ensure the continued support of member states for the work of the ACCSQ and the Working Group on SPS measures in the harmonization of standards and conformity assessment procedures across the region.

4.2: Include clear follow-up mechanisms to ensure compliance

ASEAN needs to ensure that the ACCSQ and the Working Group on SPS have the capacity to track whether commitments on standards and procedures are being properly implemented across member states.

4.3: Ensure that there is a process to engage and hold accountable non-compliant members

ASEAN needs to ensure that the proposed NTM review body has the capacity to enact procedures and work plans that ensure all relevant stakeholders work together to tackle instances of non-compliance.

5. Strengthen Work with the Private Sector to Identify, Eliminate, and Conduct Compliance Reviews of NTBs

Private sector engagement is critically important. The private sector that knows about challenges in the market — often long before government officials and regulators do. The private sector often can identify collateral implications of legislation and regulation that are unintended and would otherwise pass unnoticed by government.

5.1: Invite the private sector to participate in ASEAN working committees, with a focus on discussing and addressing NTMs and NTBs

ASEAN need not necessarily create new institutional arrangements to better incorporate feedback from the business sector. In addition to the online portals and frameworks discussed above, it is important for ASEAN officials to engage directly with companies on issues of specific concern. ASEAN's sectorial committees often address topics of relevance that are likely to have been flagged in the ATR or ASSIST, as an example. Bringing together an agenda that includes business sector engagement with

working level officials can help ASEAN effectively and more efficiently sort through solutions to problems in the region.

5.2: Work with the private sector to identify NTMs and NTBs with the highest associated costs for business to more effectively prioritize efforts

As noted earlier, it is not possible to quantify every NTM or NTB in terms of cost to businesses. But companies can identify obstacles to trade that are more burdensome than others. ASEAN should prioritize the removal of NTBs that are most impactful on companies over those that are minor irritants and should seek to minimize NTMs that impose unnecessary strains on business operations.

Without a robust and ongoing commitment to engagement with the private sector at all points in the process from identification to removal, ASEAN's efforts to tackle NTMs and NTBs in the region will fail.

Such failure comes at high cost: ASEAN will not be able to complete the journey outlined in the Blueprint 2025. It will not build the highly integrated and cohesive economy with enhanced connectivity and sectorial cooperation.

The Ultimate Role Lies with Member States

While ASEAN can dramatically improve the mechanisms and practices to streamline NTMs and eliminate NTBs, such changes do not directly tackle the main problem with the assessment and elimination of NTBs in ASEAN: a possible lack of political will and commitment from member states. The creation of an ASEAN review body at the ASEAN level does not guarantee that states will eliminate identified barriers.

Strong political support is essential to achieve results and effectiveness — more than any formal basis such as law, decree, directive, or resolutions — to provide the institutional setup to lead the NTM review process and elimination. However, ASEAN's commitment to national sovereignty and non-interference has left the elimination of NTBs to national governments and not the ASEAN supranational body. Therefore, the elimination of NTBs in ASEAN is a process that can only take place through national level legislations.

In an extensive assessment of NTMs, both ERIA and The World Bank argue that it is necessary to set up national review bodies with dispute settlement powers to effectively address NTBs. The development of those bodies across member states will guarantee that the identification of NTBs is an enforceable process.³³⁴

The institutionalization of national review bodies with enforcing power will be difficult across all ASEAN Member States; especially when taking into account some of the vested political interests in some of the reforms. Nevertheless, it remains the only way to guarantee that the elimination of NTBs can be properly enforced.

³³⁴ Cadot, Olivier, Ernawati Munadi, and Lili Yan Ing. "Streamlining non-tariff measures in ASEAN: The way forward." *Asian Economic Papers* 14.1 (2015): 35-70.

But given the importance placed on this issue over the years at both the ASEAN level and by leaders in different settings, it is perhaps time that ASEAN and its member states prepare to effectively tackle the scrooge of non-tariff obstacles to doing better trade in the region.



ASEAN Business Advisory Council

70 A, Jl. Sisingamangaraja
Jakarta 12110, Indonesia
aseanbac@asean.org
+62 (21) 722 0539



EU-ASEAN Business Council

19/F Singapore Land Tower
50 Raffles Place, Singapore 048623
info@eu-asean.eu
+65 6631 2751