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The case of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)

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ABSTRACT

Non-tariff measures (NTMs), such as sanitary and phytosanitary (SPS) measures and technical barriers to trade (TBT), are used as policy instruments to achieve objectives, such as the protection of health, safety and the environment. However, they also increase production and trade costs. An important component of such costs is the high divergence of regulations across countries. Producers have to comply with thousands of different regulations in their export markets. Policymakers increasingly aim to address this through provisions on regulatory cooperation such as mutual recognition or harmonization in regional trade agreements (RTA).

This paper develops a systematic approach that allows to encode RTA provisions on NTMs according to the International Classification of NTMs so that (a) many details, such as whether individual provisions are enabling or restricting policy space, if provisions relate to regulations or procedural aspects, and levels of enforceability, can be analysed including across RTAs, (b) provisions can be better compared to relevant WTO agreements, and (c) the provisions can be compared to national regulations. We apply the methodology to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) agreement and show that provisions in the area of conformity assessment dominate the SPS Chapter, while market authorization and labelling related provisions prevail in the TBT Chapter. The substantial degree of enforceability in both SPS and TBT chapters is likely to result in national legislative and institutional amendments.

1. INTRODUCTION

Trade policymakers increasingly focus on regulatory aspects such as regulations protecting health, safety and the environment as potential barriers to economic integration and trade. In recent decades, tariffs have been reduced enormously while the number and complexity of other policy measures that can potentially affect trade, non-tariff measures (NTMs),[1] has increased significantly. Already in the 1990s, this trend led to the negotiation of the two World Trade Organization (WTO) agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). These two Agreements are designed to address the delicate balance between attaining public policy objectives reflecting also local, cultural, religious or geographical needs, and not hindering trade more than necessary to achieve legitimate objectives. The increasing importance of NTMs is manifested in the increasing number of notifications of such measures to the WTO as well as in the estimated barrier effects.

Regulatory divergence across countries is high and imposes additional, sometimes unnecessary, trade costs. In the context of regional and global value chains as well as slow progress at the multilateral level, countries are increasingly using regional trade agreements to strengthen regulatory cooperation. The growing attention is well-illustrated by discussions or agreements on regulatory cooperation as part of the Transatlantic Trade and Investment Partnership (TTIP), the Trans-Pacific Partnership (TPP), the Regional Comprehensive Economic Partnership (RCEP) or the Comprehensive Economic and Trade Agreement (CETA).

Trade liberalization is no longer merely about the reduction and elimination of tariffs but rather about regulatory convergence, harmonization efforts, and mutual recognition. In Regional Trade Agreements (RTAs) regulations on human, animal or plant health, protection of the environment, animal welfare etc. are progressively gaining more weight. The number of RTAs has increased in the past 20 years as has the share of RTAs that include provisions on NTMs. It appears that a main motivation of forming an RTA in many cases was to achieve trade liberalization in the area of NTMs that could not be achieved at the multilateral level.

This paper aims to develop a systematic approach that allows to classify RTA provisions on NTMs according to the International Classification of NTMs[2] so that: (a) many details, such as whether individual provisions are enabling or restricting policy space, if provisions relate to regulations or procedural aspects, and levels of enforceability, can be analysed including across RTAs, (b) provisions can be better compared to relevant WTO agreements, and (c) the provisions can be compared to national regulations. Other studies and databases in this area, Piermartini and Budetta (2009) and Dür et al. (2014), rather focus on different aspects of chapter-level analysis of many RTAs and do not examine the provisions of RTAs in association with NTMs in the level of detail that this study proposes. By translating the RTA provisions into their associated detailed NTM codes, the new methodology applied in this paper will help to compare the provisions of any RTA to the pertinent national legislation and regulations of the Parties. Furthermore, the novel approach presented in this study would allow systematic and detailed cross-RTA comparative analysis as well as comparisons with relevant WTO agreements. The comparison with national legislation is left for future research. UNCTAD and its partners conduct a global effort to collect comprehensive national NTM data following the same approach that has been used here to decipher RTA provisions.[3] Data for more than 110 countries covering more than 90 per cent of world trade have been collected.

We develop this approach using the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) agreement between Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Viet Nam,

[1] The group of Eminent Persons of Non-Tariff Barriers defines NTMs 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" (UNCTAD, 2013).

[2] The International Classification of NTMs (UNCTAD, 2019) has been developed under UNCTAD's lead by the Multi-Agency Support Team consisting of Food and Agriculture Organization of the United Nations (FAO), International Monetary Fund (IMF), International Trade Centre (ITC), Organization for Economic Cooperation and Development (OECD), UNCTAD, United Nations Industrial Development Organization (UNIDO), World Bank and World Trade Organization (WTO), and endorsed by the United Nations Statistical Commission to be the International Classification for data on NTMs. (United Nations Department of Economic and Social Affairs, Statistics Division, AC.340/12).

[3] See unctad.org/ntm

which entered into force on 30 December 2018. The paper closely examines two CPTPP chapters, namely Chapter 7 on Sanitary and Phytosanitary Measures (SPS) and Chapter 8 on Technical Barriers to Trade (TBT), as well as the relevant Annexes, that have been incorporated into the CPTPP without any suspension.

The results of the study show that provisions in the area of conformity assessment dominate the CPTPP SPS chapter, while market authorization and labelling related provisions prevail in the TBT chapter, followed by the conformity assessment. The outcome shows a substantial degree of enforceability in both the SPS and TBT chapters, that is likely to result in national legislative and institutional amendments in the States Parties to the CPTPP. Accordingly, the prospect of national legislative amendments in the areas of conformity assessment, marketing authorization and labelling is rather high.

The paper is structured as follows: Section 2 discusses the trend in the increase of the number of RTAs, the augmentation of regulatory measures within RTAs and the CPTPP agreement; Section 3 develops the methodology to decode SPS and TBT provisions in RTAs and applies the approach to the CPTPP agreement; the detailed results are outlined in Annexes I and II; Section 4 shows examples of how the results can be analysed, for example, identifying if the CPTPP provisions raise or lower potential SPS/TBT trade barriers for the Parties.

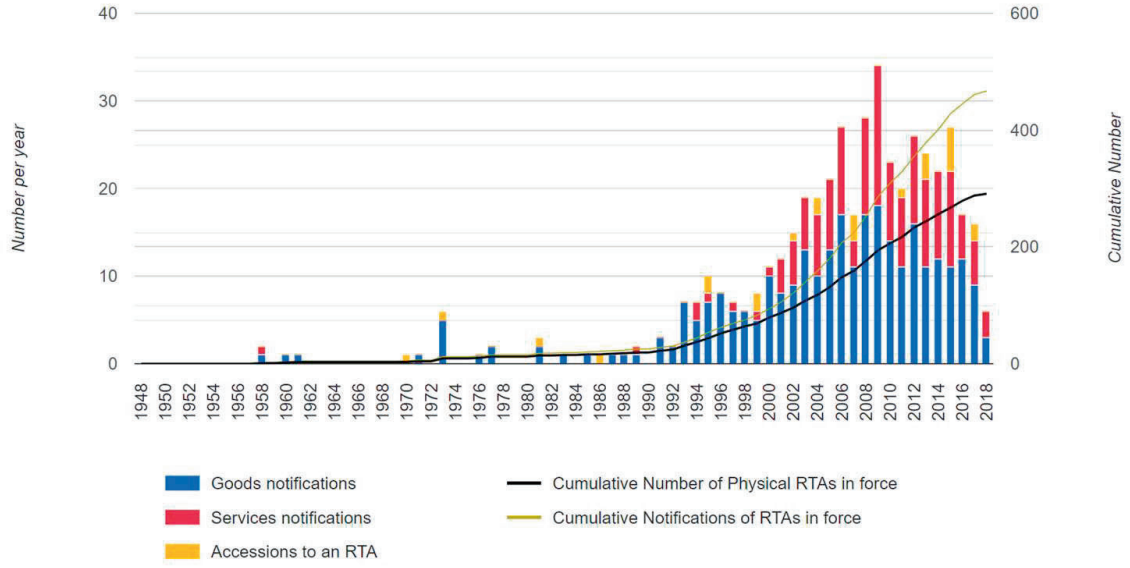
2. NTMs IN RTAs: THE CASE OF TPP/CPTPP

2.1 GROWING NUMBER OF RTAs

Since the establishment of the WTO, the number of regional trade agreements has increased significantly. One of the important factors contributing to this development appears to be the rising number, diversity and accordingly the role of regulatory measures and NTMs in general. As the number and range of trade and trade related areas rise and gain more importance, the complexity of achieving a multilateral agreement rises respectively.

These developments have contributed to an increase in the number of regional trade agreements. As of 30 December 2018, there were 309 RTAs notified under either the General Agreement on Tariffs and Trade (GATT) Article XXIV, the General Agreement on Trade

Figure 1. RTAs currently in force (by year of entry into force), 1948-2018



Note: Notifications of RTAs: goods, services and accessions to an RTA are counted separately. Physical RTAs: goods, services and accessions to an RTA are counted together. The cumulative lines show the number of notifications/physical RTAs currently in force.

Source: WTO Secretariat, 27 December 2018.

in Services (GATS) Article V or the Enabling Clause that are in force. Figure 1 illustrates the RTAs that are still in force by their entry into force year. Around 40 per cent of all RTAs in force today have been established in the last 10 years between 2008 and 2018.[4]

WTO allows Members to enter into Free Trade Agreements (FTA) which is a derogation to the Most-favoured Nation (MFN) principle, under exceptions provided by the GATT Article XXIV and Enabling Clause[5] in the goods area, and GATS Article V in the services area. The conditions to be satisfied under the GATT Article XXIV are that substantially all trade should be liberalized, and the duties and non-tariff measures should not be more restrictive than prior to the formation of the RTA.[6] A similar condition exists under the GATS, where a substantial sectoral coverage should be fulfilled, and the overall level of barriers should not be higher than before the creation of the RTA[7].

2.2 THE COMPREHENSIVE AND PROGRESSIVE AGREEMENT FOR TRANS-PACIFIC PARTNERSHIP (CPTPP)

The CPTPP entered into force on 30 December 2018. Prior to this, the comprehensive regional trade agreement Trans-Pacific Partnership agreement (TPP) was negotiated and signed by 12 countries, namely Australia, Brunei Darus

Zealand, Peru, Singapore, Viet Nam, and the United States of America. On 23 January 2017 the United States withdrew its signature from the TPP, which created ambiguity for the future prospects of the agreement. Despite the United States withdrawal however, the other 11 Parties to the agreement chose to continue negotiating an agreement without the United States and agreed on keeping almost all provisions of the TPP except a few and renamed the agreement Comprehensive and Progressive Agreement for Trans-Pacific Partnership.

Seven signatories of the CPTPP namely Mexico, Japan, Singapore, New Zealand, Canada, Australia and Viet Nam have ratified the deal, the sixth being Australia on 31 October 2018, which was necessary to meet the minimum requirement of half of the signatories to ratify the deal, for the agreement to enter into force.

Even without the United States, the CPTPP is one of the largest regional agreements in the global economy after the North American Free Trade Agreement (NAFTA) and the European Union, encompassing economies accounting for more than 13 per cent of global GDP and around 500 million people.[8]

The CPTPP incorporates TPP mutatis mutandis, with some exceptions, mainly provisions on express shipments, investment arbitration; express delivery services, patents and patent term adjustments, biologics, terms of protection for copyright, legal liability and safe harbour provisions for internet service providers, and technological protection measures.[9]

The CPTPP covers a range of trade and trade-related issues with chapters on distinct issue areas such as inter alia National Treatment and Market Access for Goods, Rules of Origin, Sanitary and Phytosanitary Measures, Intellectual Property, as well as horizontal chapters that are considered necessary for the fulfilment of obligations under vertical chapters, like inter alia dispute settlement, competitiveness, transparency and anti-corruption.

The CPTPP also covers several WTO-extra areas such as digital economy, investment, labour rights, competition policy and environmental policy.

Chapter 2 of the CPTPP is devoted to National Treatment and Market Access for goods, which covers mainly tariff liberalization issues and other hardcore

[4] Among the mentioned RTAs that are still in force about 170 of them have entered into force within the period of 40 years from 1958 to 2008. And only during the last 10 years about 140 RTAs have entered into force. Source: WTO Database on RTAs, available at, http://rtais.wto.org/UI/PublicAllRTAList.aspx

[5] Enabling Clause was agreed in 28 November 1979 by the decision (L/4903) to the Signatories to the GATT that allows for a differential and more favourable treatment in relation to developing and least developed countries and preferential arrangements among less developed countries to liberalize trade. See the link at the WTO website: https://www.wto.org/english/docs_e/legal_e/enabling1979_e.htm

[6] GATT Article XXIV available at https://www.wto.org/english/docs_e/legal_e/gatt47.pdf

[7] GATS Article V available at https://www.wto.org/english/docs_e/legal_e/26-gats.pdf

[8] Torrey (2018).

[9] Recent Developments in Regional Trade Agreements, p.3, available at https://www.wto.org/english/tratop_e/region_e/rtajun-dec17_e.pdf

traditional trade-policy measures besides tariffs such as licenses, fees and charges for imports and exports. In addition, there are entire separate chapters of the Agreement that are dedicated to different NTM groups such as SPS, TBT, Rules of Origin and Government Procurement.

This study examines the CPTPP chapters on SPS and TBT, but the same methodological approach can be applied to provisions and chapters related to other types of NTMs.

2.3 INCREASING REGULATORY MEASURES IN RTAs

As the number of RTAs has been increasing during recent years, the amount and depth of the provisions on regulatory measures in RTAs have also been growing steadily. In this regard, it is useful to examine available statistical information on the SPS and TBT provisions in RTAs.

The Design of Trade Agreements research project (DESTA)[10] developed a database that contains systematic information on the design of 651 preferential trade agreements that have been signed since 1945. The database has seven variables on TBT and four variables on SPS issues. The variables are binary variables such as "Does the agreement contain a TBT chapter or provision, yes or no".

According to the DESTA database, more than half of these RTAs have provisions on TBT. About one sixth have provisions on TBT harmonization with 83 indicating harmonization as a general aim, 38 indicating selective TBT harmonization and three indicating a full TBT harmonization aim. Similarly, for SPS, more than half of all analysed RTAs have provisions or chapters on SPS. While 71 of them indicate harmonization as a general aim, 42 have provisions on full harmonization in the SPS area, which is much higher than in the TBT area (Dür et al., 2014). Most of the cases where we see the aim as full harmonization in the SPS field, are the agreements within Europe. This can be referred to the fact that, many of the Eastern European countries are harmonizing their legislation based on the European Union legislation, as part of the preparation for prospective membership of the European Union.

Another factor that contributes to this difference between TBT and SPS might be the different levels of clarity around international standards. The WTO SPS Agreement explicitly refers to international standards which are Codex Alimentarius, the International Plant Protection Convention (IPPC) and the World Organisation for Animal Health (OIE) standards, while the TBT Agreement does not provide any specific names of international standards or standard setting bodies.[11] Any sanitary and phytosanitary measure shall be based on international standards unless there is a scientific justification for a more stringent measure. TBT measures on the other hand, shall also use international standards unless they are ineffective or inappropriate to fulfil the legitimate objectives, the list of which is provided in the TBT agreement. However, both the SPS and TBT measures should be the least trade restrictive for achieving the legitimate objective.[12]

The fact that about half of all RTAs examined in the DESTA database contain regulatory provisions on SPS and TBT and that 87 per cent of the RTAs which entered into force after 2000 comprise TBT provisions and 85 per cent SPS provisions indicates an enormous growing importance of NTMs in RTAs.

The DESTA database provides very useful information on the existence of certain provisions in the large number of examined RTAs. It provides comprehensive information about RTAs and their provisions in accordance with variables identified for different thematic areas such as SPS, TBT, Intellectual Property etc. It does not inform on the legal enforceability of these provisions, which this study will try to shed light on, as it is a significant variable that eventually matters. Without enforceability and a functioning mechanism to enforce the provisions, they could have a best endeavour character and encouragement spirit which leaves actual implementation to the individual political will of the parties.

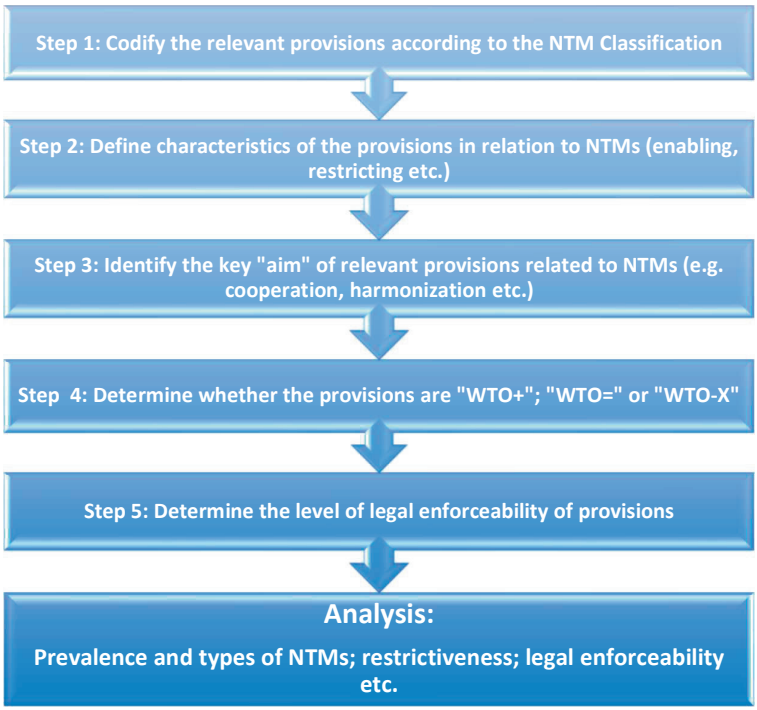
This study focuses only on SPS and TBT chapters of one RTA, namely the CPTPP, and identifies all NTM related provisions in these chapters classifying them into their respective NTM codes. We will identify those NTMs in the SPS and TBT chapters of the CPTPP

[10] In this context RTA is defined as "all agreements that have the potential to liberalize trade, including partial scope agreements if they liberalize at least some trade, excluding framework agreements (with very few exceptions), trade and cooperation agreements." Dür et al. (2014).

[11] Annex A of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

[12] WTO Agreement on Technical Barriers to Trade (TBT) and WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

Figure 2. Methodology to decipher NTM provisions in RTAs



Source: Authors.

that might potentially affect national legislation, the extent to which CPTPP SPS and TBT provisions have elements of restrictiveness or granting flexibility in regulatory fields, including whether they provide for harmonization, cooperation or other systemic issues and very importantly whether the provisions are enforceable.

3. METHODOLOGY

3.1 "CODIFYING" RTA PROVISIONS

In order to assess the regulatory impact that the CPTPP might have on its participating Parties and those considering joining this mega-regional free trade agreement, we analyse the provisions of two Chapters of the Agreement, namely the SPS and TBT chapters. The methodology of the assessment is summarized in Figure 2.

The initial step is to identify CPTPP provisions in the SPS and TBT chapters of the RTA that may either (i) explicitly or implicitly allow or encourage a Party to apply certain regulatory measures or NTM, (ii) require or recommend the elimination of certain measures, or (iii) adjust certain existing NTM(s) to new conditions. The CPTPP provisions and their associated Articles are reflected in Columns 2 and 1 respectively, of Annex I and Annex II.

We then examine which type of NTMs the identified CPTPP provisions may affect. For this purpose, the International Classification on NTMs[13] serves as a basis for assigning particular NTM codes to each identified CPTPP provision. The International Classification of NTMs has separate chapters on SPS and TBT that correspond to the WTO SPS and TBT agreement definitions. Column 3 in Annex I and II of this paper indicates a particular NTM code, while column 4

[13] In 2006, UNCTAD established the Multi Agency Support Team (MAST) group comprising eight international agencies (FAO, IMF, ITC, OECD, UNCTAD, UNIDO, World Bank and WTO) to work on the taxonomy of Non-tariff Measures (NTMs) with the objective of developing a classification system of NTMs to facilitate data collection process and analysis. As of 2018, UNCTAD and its partners have collected comprehensive and comparable NTM data in more than 100 countries in accordance with the International NTM Classification available at https://unctad.org/en/Pages/DITC/Trade-Analysis/Non-Tariff-Measures/NTMs-Classification.aspx

describes the type of measure according to the NTM classification. For example, CPTPP Article 7.3 (2) is:

> *"Nothing in this Chapter prevents a Party from adopting or maintaining halal requirements for food and food products in accordance with Islamic law."*

Potentially, this provision may affect such areas of regulation as labelling for the objectives covered by chapter B[14] of the NTM classification, which is the NTM code B31, certification which falls under the NTM code B83 and production processes which is categorized as B41. Therefore, corresponding NTM codes were assigned to the mentioned provision. It does not necessarily signify that these NTMs will be affected, or enabled. It is only to show which regulatory areas might potentially be affected, and by coding these areas with their respective NTM codes based on the International NTM classification, we have the possibility to compare different provisions and to understand which regulatory areas are potentially most affected.

This novel approach put forward by this paper, where RTA provisions are juxtaposed with the corresponding NTM codes and type of measures may help to identify the areas of RTAs' primary focus as well as provide for further quantitative analysis of the regulatory impact in the contracting Parties after joining the respective RTA.

3.2 ASSESSING THE REGULATORY PROCESSES THAT RTA PROVISIONS MIGHT PROMOTE

In step 2, each CPTPP provision is labelled with letters E, R, N, (column 5, Annex I and II) depending on the ability of the provisions to enable or restrict NTMs. The provisions that are marked with **"E"** provide for the possibility/flexibility of introducing new NTMs or enable the regulator to exercise certain flexibility related to NTMs (table 1). **"R"** indicates that certain provisions aim to restrict regulatory freedom, i.e. restrict the regulator's ability to introduce new NTMs or prohibit certain ways of regulating. Column 5 is marked with **"N"** – when the provisions are neutral towards any regulatory activity, i.e. neither enabling, nor restricting the regulatory capacity of the Party, though still relating to a certain type of NTM (e.g.

Table 1. Explanation of the Labels for the CPTPP provisions that provide flexibility or restriction on regulatory policy

Acronym	Explanation of Acronyms for column 5 in Annex I and II
E	Enabling NTMs or providing regulatory flexibility
R	Restricting regulatory policy/NTM's scope
N	Neutral

Step 3 reflected in Column 6 of Annex I and II, elaborating on the idea of column 5, explains what the particular CPTPP provision may promote or intends to achieve. The list of main outcomes the provisions are promoting is shown in table 2.

Table 2. Which Systemic processes do CPTPP provisions promote?

	Main outcome the provisions promote
Systemic issues	Cooperation
	Recognition
	Transparency
	Harmonization
	Fairness
	International standards (use of)
	Review (appeal) process
	Notification mechanism
	Non-discrimination
	Regulatory restriction
	Regulatory flexibility

In certain instances, a provision may promote flexibility in regulating. For example, Article 7.9 (3) (b) reads:

> *"Nothing in this Chapter shall be construed to prevent a Party from: …(b) establishing or maintaining an approval procedure that requires a risk analysis to be conducted before the Party grants a product access to its market".*

In this case the provision aims to ensure regulatory flexibility and provides policy space.

Column 7 indicates whether the provision in question is mainly NTM related or more focused on

[14] Chapter B of the NTM Classification covers TBT measures (UNCTAD, 2013).

the Procedural Obstacle (PO)[15] associated with the indicated NTM code. Thus, the column is labelled as either **NTM** or **PO** accordingly. Procedural obstacles relate to the administration and implementation procedures of the measures rather than the policy measures themselves. They can be issues related to discriminatory enforcement, long queues, non-transparent practices etc.

Step 4 reflects the comparison between the SPS and TBT provisions of CPTPP and those of the WTO SPS and TBT Agreements. This is shown in column 8 of the Annexes to this paper. The purpose of such comparison was to identify WTO-plus (WTO+) and WTO-extra (WTO-X) areas. This methodology was put forward by Horn et al. (2009), where WTO+ is meant to denote policy areas that are covered by the existing WTO Agreements, but which can impose further obligations in these areas, for instance, further reduction of tariffs, while WTO-X represents the policy areas that are beyond the current scope of WTO Agreements such as labour rights issues or human rights.

However, evaluation of what policy measures fall under or outside the scope of WTO agreements would inevitably involve judgement, as there is no agreed-upon classification of policy areas covered by the WTO (Horn, 2009). For example, the fact that the Preamble to the WTO Agreement speaks about environmental policies, does not qualify a particular RTA's provisions on environmental protection to be assessed as 'WTO+' because there are no provisions in the WTO specifically addressing the conduct of environmental policies with a trade impact.[16] Such provisions of a respective RTA would therefore fall under category 'WTO-extra'.

In addition to WTO+ and WTO-X, we have added a new category, which we call WTO-equal (WTO=), to mark provisions of an RTA that are identical to WTO SPS or TBT Agreement provisions.

[15] The concept of "procedural obstacles", refers to issues related to the process of application of an NTM, rather than the measure itself (UNCTAD, 2010). For example, reports on the procedural obstacles faced by the exporters revealed that "inefficiency or cases of outright obstruction" and "arbitrary or inconsistent behaviour" were the key obstacles associated with various NTM categories, such as SPS and TBT measures.

[16] Ibid.

3.3 ASSESSING THE ENFORCEABILITY OF THE CPTPP PROVISIONS

Finally, Column 9 which embraces step 5 describes each identified CPTPP provision from a different angle, by considering whether such provisions are enforceable. This is a very significant variable, as whether or not the provisions restrict or enable certain NTMs, or procedural obstacles, they could ultimately be redundant if they have no legal enforceability. Table 3 demonstrates a brief explanation of the Column 9 Acronyms.

Table 3. Explanation for the Labels for different types of Enforceability of the CPTPP Provisions

Column 8 Acronyms	Enforceability of the CPTPP Provisions, explanation of Acronyms
Er	Enforceable Right
Eo	Enforceable obligation
R	Recommendation
WE	Weak Enforceability
UE	Unenforceable

For the identification of enforceability, we have used the methodology put forward by Henrik Horn et al[17], however we went further to differentiate between different levels of enforceability. The most important distinction of the enforceability between the current and Horn et al's study is that we scrutinize the enforceability of each provision on a very detailed level, while the latter study examines enforceability of 52 policy areas from 28 FTAs largely on a chapter level. Hence the mentioned study takes quite a generalized approach denoting the whole policy area as enforceable when there is at least one enforceable provision, whereas our analysis examines each and every provision separately. Of course, this is due to the nature and scope of different studies, since we limit our study to the two chapters of one RTA, which makes our detailed approach practicable.

Moreover, we distinguished between two kinds of enforceable provisions, Enforceable Right and Enforceable Obligation. Both of them refer to provisions that are legally enforceable, however, the former provides a right, while the latter provides an obligation. Below a few examples are provided to

[17] Ibid, pp. 9-10.

make the point clear. The CPTPP Article 7.10 (1) is an example of the Enforceable Right, and it states:

> *"To determine an exporting Party's ability to provide required assurances and meet the sanitary and phytosanitary measures of the importing Party, each importing Party shall have the right, subject to this Article, to audit the exporting Party's competent authorities and associated or designated inspection systems."*

This provision is enforceable as the legally enforceable language "shall" is used, and it does not impose an obligation but rather a right by the importing Party if they choose to.

Article 7.11 (8) of the CPTPP is an example for the Enforceable Obligation as it points out:

> *"An importing Party that prohibits or restricts the importation of a good of another Party on the basis of an adverse result of an import check shall provide an opportunity for a review of the decision and consider any relevant information submitted to assist in the review."*

As the legally enforceable language "shall" has been used in this provision, it is assessed as legally enforceable, and since it is an obligation in contrast to a right which we saw above, these kinds of provisions are labelled as Enforceable Obligations (Eo).

Recommendations are non-enforceable, and are rather in the spirit of encouragement, for example Article 7.7 (3) of the CPTPP provides:

> *"The Parties may cooperate on the recognition of pest - or disease -free areas, and areas of low pest or disease prevalence with the objective of acquiring confidence in the procedures followed by each Party for the recognition of pest-or disease-free areas, and areas of low pest or disease prevalence."*

Another example of the Recommendation is from the Annex 8 G to the TBT chapter of the CPTPP on Organic Products. Clause 4 indicates:

> *"A Party is encouraged to consider, as expeditiously as possible, a request from another Party for recognition or equivalence of a technical regulations, standards or conformity assessment procedures that relates to the production, processing, or labelling of products of another Party as organic."*

The provisions that are labelled as Recommendations have no legal enforceability, however, the Parties may choose and are implicitly encouraged to implement them if they have the political will to do so.

We have labelled those provisions with WE (Weak Enforceability), which state the legally enforceable statement for example, with "shall", and which is quite precise, but provide some exceptions for the imposition of this provision, which is not very precise. For example, Annex C to the TBT chapter of the CPTPP, clause 17 notes:

> *"… each Party shall, with respect to the inspection of a pharmaceutical product within the territory of another Party: (a) notify the other Party prior to conducting an inspection, unless there are reasonable grounds to believe that doing so could prejudice the effectiveness of the inspection;"*

The provision imposes an obligation that prior to conducting an inspection the Party shall notify the other Party, and then provides an exception (loophole) which gives the Parties the freedom not to notify if they believe that doing so prejudices the effectiveness of the inspection. There is no precise way of proving whether there are reasonable grounds to believe or not, as the term "reasonable and believe" is quite ambiguous. Therefore, this type of provision is marked with weak enforceability.

There are also other non-enforceable provisions, that are stating some rights or obligations, but cannot be legally enforced. For example, clause 17, Annex C to the TBT chapter indicates:

> *"The Parties shall seek to improve their collaboration on pharmaceutical inspection"*

Though "shall seek" denotes an obligation, it is virtually impossible to prove whether a Party has tried to improve collaboration. The whole sentence is quite general and vague. Another such type of example is in Annex 8-D, clause 25 which points out:

> *"Each Party shall endeavour to avoid re-testing or re-evaluating cosmetic products that differ only with respect to shade extensions or fragrance variants, unless conducted for human health or safety purposes."*

Again, though "shall endeavour" is an obligation, there is no effective way of verifying whether endeavour was made or not, that is why it is marked as unenforceable obligation/right.

When talking about the legal enforceability, alongside the language used in the provisions, we should also examine whether the provisions are subject to the Dispute Settlement mechanism (Chapter 28) of the TPP. In as much as, if they are not subject to the Dispute Settlement mechanism, we cannot consider them enforceable even if they have legally authoritative language. The Dispute Settlement which is reflected in Chapter 28 of the CPTPP Agreement applies to the SPS chapter except for a few provisions in Article 7.9 (2) and Article 7.8 (6). In addition, there are a few provisions where Dispute Settlement will be applied one and two years after the date of entry into force of the Agreement for that Party, namely Article 7.8 on Equivalence, Article 7.10 on Audits and Article 7.11 on Import Checks after one year, and Article 7.9 on Science and Risk Analysis after two.

The Dispute Settlement applies to the TBT chapter in its entirety except the provisions incorporated from the WTO TBT Agreement under the TBT chapter paragraph 1.

4. POTENTIAL IMPACT OF THE CPTPP SPS AND TBT PROVISIONS ON REGULATORY POLICIES OF THE PARTIES

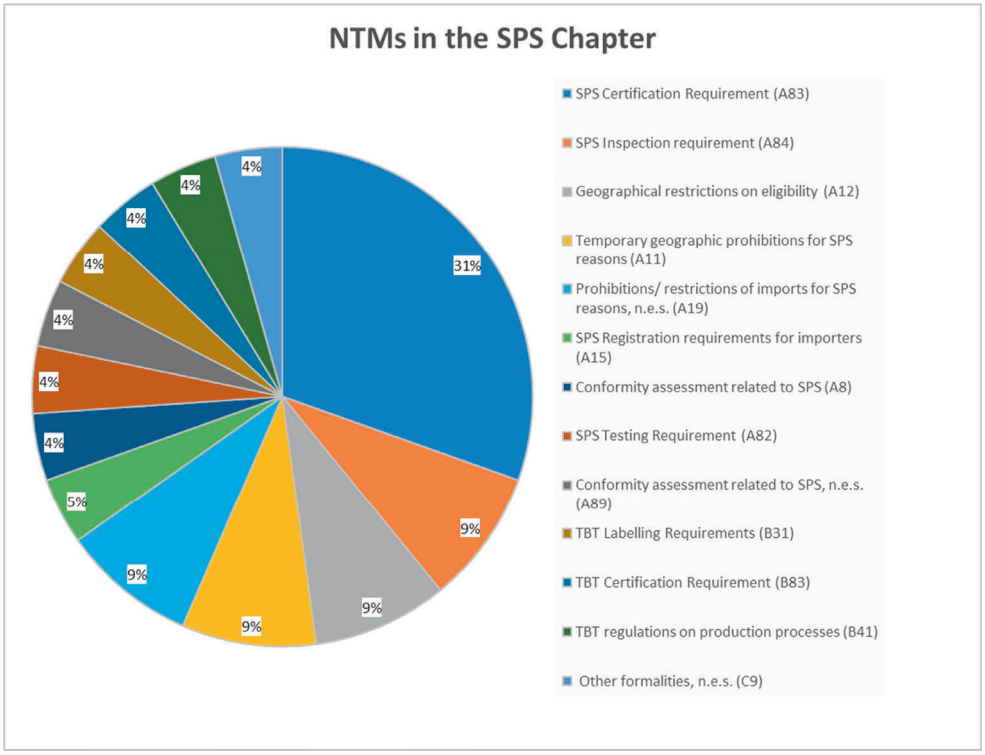
4.1 WHAT TYPES OF NTMs ARE COVERED?

Having identified the NTMs that might be affected by the application of the CPTPP SPS and TBT chapters, we can see what type of NTMs prevail in each chapter.

4.1.1 Types of NTMs in the CPTPP SPS chapter

Our analysis shows that the CPTPP SPS chapter provisions may affect national regulations (NTMs) such as geographical restrictions on eligibility, SPS registration requirements, inspection, testing, certification and some others. Figure 3 shows all the NTM codes with their descriptions that have been identified.

Figure 3. Potentially affected NTMs identified in the SPS Chapter of the CPTPP



Source: Authors' calculations based on Annex I to this paper.

The result suggests that the requirement for Certification is the potentially most affected NTM in this Chapter. It comprises 31 per cent of all the NTMs identified in the CPTPP SPS chapter. Article 7.12 of the SPS chapter is devoted to Certification, and the main purpose is to ensure that the certification is applied only to the extent necessary to protect human, animal and plant life or health. If other methods besides certification can reach the same objectives, then those less stringent methods are encouraged to be applied. One should bear in mind, that in this part, we only talk about the prevalence of provisions that may either explicitly or implicitly allow or encourage a Party to apply certain regulatory measures or NTMs, require or recommend to eliminate certain measures, or adjust certain existing NTMs to new conditions. So just by looking at this graph we cannot conclude whether certification practices are restricted, encouraged, allowed or adjusted in certain ways. This further information will be reflected in the coming subsections, since for making any judgements we also need information as to enforceability of the particular provisions.

The next most dominant measures are SPS geographical restriction and prohibition requirements, where all three measures together comprise 27 per cent of all SPS related provisions identified, each of them making 9 per cent.

It should be noted that there are also provisions in the CPTPP SPS chapter that are not related to particular NTMs, but are more systemic issues, or meta-NTM issues, like provisions on general transparency. For example, Article 7.13 of the SPS chapter on Transparency is about encouraging Parties to exchange information on SPS measures and providing the opportunity for interested parties to comment. The provisions in the section on transparency are more about the procedures to develop the sanitary and phytosanitary measures, informing about them in advance and allowing for comments rather than the measures themselves. Thus, they cannot be transformed into NTM codes and are out of the scope of this study.

The results show that most of the potentially affected NTMs in the SPS chapter belong to conformity assessment, which makes for more than 50 per cent of the NTMs identified. This is quite intuitive since countries generally try to retain their regulatory freedom in identifying the risk levels that are acceptable to them, in particular for food and agricultural products, while there is more room for cooperation and convergence in mutual recognition of conformity assessment and audit bodies of each other or developing common or mutually acceptable requirements in conformity assessment procedures.

One interesting point which seem counter-intuitive is identification of a few TBT NTM codes within the CPTPP SPS chapter. This is due to some borderline cases that can sometimes be evaluated as both SPS and TBT where there is still room for discussion and subjectivity. For example, the provisions on halal products are being identified as TBT measures, even though the objective might be safety while at the same time following the religious rituals/rules. Since WTO SPS Agreement covers only the measures with the objectives specified in Annex 1 of the SPS Agreement, not all safety issues are under the realm of the SPS Agreement.

4.1.2 Types of NTMs in the CPTPP TBT chapter

Some provisions on meta-NTM issues can also be found in the CPTPP TBT chapter. For example, Article 8.5 on International Standards, Guides and Recommendations is about the recognition of the importance of international standards by the Parties and an obligation to apply the Decisions and Recommendations adopted by the WTO Committee on Technical Barriers to Trade since 1 January 1995, in determining whether international standards exist within the meaning of Articles 2 and 5 and Annex 3 of the TBT Agreement. So, it is not about NTMs themselves, therefore these types of provisions are not reflected in Annex II to this paper.

Though the Annexes to the CPTPP TBT chapter in general reflect rather detailed requirements related to NTMs, several provisions address or touch upon the meta-NTM issues, such as the obligation to take reasonable measures to prevent unnecessary overlap or duplication in the scope of the regulatory requirements when several agencies are responsible for the regulation of the same group of products, which is mentioned in the Annexes on Pharmaceutical, Cosmetics and Medical Devices.

Overall, the majority of the NTMs in the TBT provisions of the CPTPP are found in the Annexes of the Chapter. The TBT chapter has Annexes on Wine and Distilled Spirits; Information and Communication Technology (ICT) Products that use Cryptography, Pharmaceuticals; Cosmetics; Medical Devices;

Proprietary Formulas for Pre-packaged Food and Food Additives and on Organic Products.

In the CPTPP TBT chapter and its Annexes, we have identified provisions that are related to NTMs such as authorization requirements (B14), labelling (B31), production processes (B41), product identity requirements (B6), product quality and performance requirements (B7), TBT product registration requirement (B81), conformity assessment related to TBT (B8) and conformity assessment n.e.s. (B89), testing (B82), certification (B83), inspection (B84), traceability requirement (B85), customs inspection, processing and servicing fees (F61), and even a measure related to intellectual property (N).

As we can see from Figure 4, authorization requirement and labelling are the two measures that are the most prevalent, the former being 30 per cent while the latter 28 per cent of all NTMs identified in the TBT chapter and its Annexes. Third and fourth places are shared by two conformity assessment measures, namely certification and testing requirements. Product quality and performance requirements share the same percentage as TBT testing requirements, namely 6 per cent.

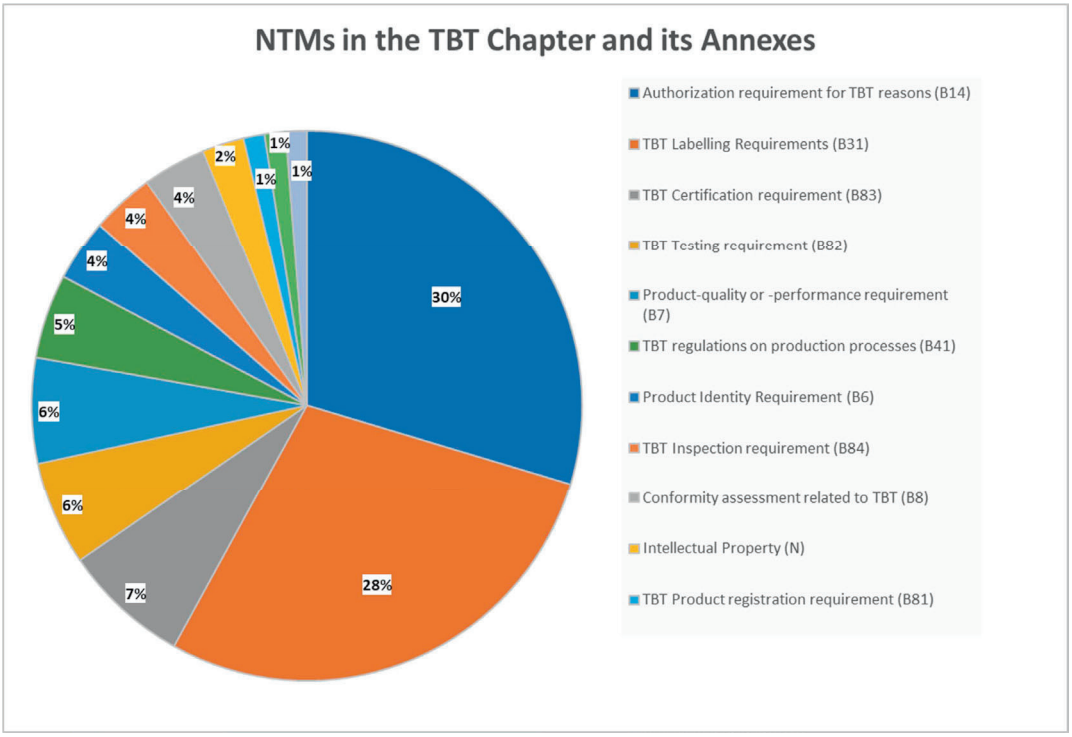
The Annexes to the TBT chapter on Pharmaceuticals, Cosmetics and Medical Devices have fairly detailed provisions on the Marketing Authorization. This is likely to be due to the fact that marketing authorization is one of the prevalent measures applied by countries for the sensitive products that the Annexes regulate.

Annexes on Wine and Distilled Spirits, Cosmetics, Medical Devices, Proprietary Formulas for Pre-packaged Food and Food Additives and on Organic Products have comprehensive and detailed provisions on labelling. In particular, the Annex on Wine and Distilled Spirits has numerous provisions on labelling, also stemming from the fact that labelling is a measure of foremost importance for this type of product.

About 20 per cent of measures belong to conformity assessment measures, including testing, certification, inspection, registration and traceability requirements.

In one instance, we see that some TBT provisions serve even as a protection of some intellectual property rights. For example, Annex 8 B on Information and Communications of the CPTPP TBT chapter, states:

Figure 4. Potentially affected NTMs identified in the TBT Chapter of the CPTPP



Source: Authors' calculations based on Annex II to this paper.

> *"With respect to a product that uses cryptography and is designed for commercial applications, no Party shall impose or maintain a technical regulation or conformity assessment procedure that requires a manufacturer or supplier of the product, as a condition of the manufacture, sale, distribution, import or use of the product, to:*
>
> *(a) transfer or provide access to a particular technology, production process or other information, for example, a private key or other secret parameter, algorithm specification or other design detail, that is proprietary to the manufacturer or supplier and relates to the cryptography in the product, to the Party or a person in the Party's territory;*
>
> *(b) partner with a person in its territory; or*
>
> *(c) use or integrate a particular cryptographic algorithm or cipher,*
>
> *other than where the manufacture, sale, distribution, import or use of the product is by or for the government of the Party."*

Very interestingly, by restricting the application of NTMs related to the disclosure of certain technological information, the Parties try to ensure that intellectual property rights are safeguarded.

4.2 WHAT DO THE SPS AND TBT PROVISIONS PRIMARILY PROMOTE?

Now that we have an overview of which NTMs might be potentially affected by looking at the CPTPP SPS and TBT chapters together, it is useful to see in which direction the provisions of the CPTPP try to impact the regulatory policy. Is it mainly trying to restrict and impose limitations on the measures governments can impose, or do some provisions also reiterate the right to regulate as deemed appropriate by the Parties?

For this we need to examine whether the provisions restrict the regulatory policy, enable them or are simply neutral as identified in column 5 of the Annexes to this paper.

Within the SPS chapter, there are eight restrictive (R), four enabling (E) and three neutral (N) provisions. It is very interesting to see that there are also enabling provisions, as the provisions do not only try to limit the regulatory policy but can also assert the right to apply a certain regulatory policy. For example, Article 7.3 (2) states:

> *"Nothing in this Chapter prevents a Party from adopting or maintaining halal requirements for food and food products in accordance with Islamic law."*

This provision gives the Parties the flexibility of introducing NTMs relevant to halal requirements, that have been identified to be B31 (TBT labelling), B41 (TBT regulations on production processes), and B83 (TBT certification requirement).

It should be noted that, sometimes the same provision can have both restrictive and enabling elements. The following paragraph from Article 7.12(1) (CPTPP Agreement) illustrates this case:

> *"The Parties recognise that assurances with respect to sanitary or phytosanitary requirements may be provided through means other than certificates and that different systems may be capable of meeting the same sanitary or phytosanitary objective."*

This provision shows a recommendation or encouragement to recognize other conformity assessment methods besides certificates if they meet the same sanitary and phytosanitary objective. In that sense while the regulatory policy on certification is implicitly recommended to be restricted, the other forms of conformity assessment systems besides certification are enabled, meaning other forms of conformity assessment may be used in lieu of the certification.

Observing both restricting and enabling provisions is very useful to understand that NTMs are not always barriers and undesirable. They are predominantly for the attainment of legitimate objectives such as protection of health, safety, environment, national security etc. The provisions in the SPS chapter of the CPTPP show that the Parties are ensured with the regulatory flexibility to achieve the legitimate objectives, while at the same time limited in certain ways to apply only measures that are least trade restrictive.

This is a delicate balance between allowing flexibility in achieving legitimate objectives and restricting unnecessary regulations, that the CPTPP SPS chapter tries to further achieve on top of the WTO SPS agreement.

Within the TBT chapter of the CPTPP, most of the provisions have a more restrictive effect on regulatory policies. The results show that while 66 provisions have restrictive elements, only nine provisions have enabling elements and four provisions are neutral.

The SPS chapter of the CPTPP does not explicitly mention harmonization but rather points out the enhancement of the transparency of each Party's sanitary and phytosanitary measures, which means that different measures can be applied and shall be respected, while encouraging adoption of international standards and guidelines. While there are no explicit provisions on harmonization, the SPS chapter provides provisions on Equivalence that the Parties shall apply to a group of measures or on a systems-wide basis, to the extent feasible and appropriate.

There are, however, few provisions that implicitly refer to harmonization. For example, paragraph 6 of Article 7.12 on Certification states that:

> *"The Parties may agree to work cooperatively to develop model certificates to accompany specific goods traded between the Parties, taking into account relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations."*

With this provision, the Parties are encouraged to develop model certificates, which means harmonization of the design of certificates they require. Consequently, though harmonization is not used in general as the main message of the SPS and TBT chapters in CPTPP, it is still found in some provisions, despite the term "harmonization" not being used.

For the effective implementation of the SPS chapter, the CPTPP Parties shall establish a Committee whose main responsibilities inter alia would be to serve as a forum for mutual understanding of each other's sanitary and phytosanitary measures, exchanging and providing relevant information and cooperation. The TBT chapter also focuses on transparency and regulatory cooperation.

Certain provisions of the WTO TBT Agreement have been incorporated as part of the TBT chapter of CPTPP, in particular, many provisions of Article 2 on preparation, adoption and application of technical regulations and Article 5 on procedures for assessment of conformity.

Similar to SPS, the Parties shall establish a committee on TBT that would encourage cooperation, exchange of information and monitor the implementation of the TBT chapter. As was noted above, a lot of measures in the TBT chapter annexes have the elements of restrictions of regulatory policy which provide certain conditions on applying NTMs and try to restrict certain procedural obstacles related to the NTMs.

Though harmonization has not been stated as a general aim in the CPTPP TBT chapter either, there are however, some provisions on encouragement of sectoral harmonization. In particular, the Annexes of the CPTPP TBT chapter on Pharmaceuticals, Medical Devices and Cosmetics promote collaboration of the Parties through international initiatives aimed at harmonization for alignment of their corresponding regulations in the three sectors mentioned above.

4.3 NTMs AND PROCEDURAL OBSTACLES RELATED TO NTMs

Though many provisions, have been identified relating to the non-tariff measures themselves, some of them are rather about how these measures should be implemented or administered, which are defined as procedural aspects. Within the CPTPP SPS chapter there are six provisions that are directly NTM-related, while four provisions are related to the administration of NTMs, which we have marked as PO in the seventh column of the Annexes to this paper. Thus, depending on whether the provision is about the NTM itself or the way it should be administered, we label column 7 of the Tables in the Annexes to this paper either with NTM or PO.

Within the CPTPP TBT chapter and its Annexes, 60 provisions have been identified as related directly to NTMs, while 17 of them are related to procedural obstacles associated with the identified NTMs that are reflected in the third and fourth columns of Annex II to this paper.

For example, Annex 8-C on Pharmaceuticals of the CPTPP TBT chapter states in clause 23:

> *"Each Party shall make its determination whether to grant marketing authorisation for a specific pharmaceutical product on the basis of:*
>
> *(a) information, including, if appropriate, pre-clinical and clinical data, on safety and efficacy;*

(b) information on the manufacturing quality of the product;

(c) labelling information related to the safety, efficacy and use of the product; and

(d) other matters that may directly affect the health or safety of the user of the product.

To this end, no Party shall require sale data or related financial data concerning the marketing of the product as part of the determination. Further, each Party shall endeavour to not require pricing data as part of the determination."

Marketing authorization is an NTM, it is coded as B14 Authorization requirement in accordance with the International Classification on NTMs. Any requirement on the substance of marketing authorization, such as on which basis marketing authorization is granted as the above provision indicates, is a measure itself. However, the way the measure should be applied, as the CPTPP TBT chapter Annex on Pharmaceuticals, clause 12 below shows, is a procedural obstacle.

"Each Party shall administer any marketing authorisation process that it maintains for pharmaceutical products in a timely, reasonable, objective, transparent and impartial manner, and identify and manage any conflicts of interest in order to mitigate any associated risks.."

Thus, if the marketing authorization is not administered in a timely, reasonable, objective, transparent and impartial manner, there is a procedural obstacle. Very interestingly, our results in Column number 5 of the Annexes to this paper, on whether the provisions have restrictive or enabling elements are identified as R (restrictive), and in some cases N (neutral) for all the procedural obstacles, which is rather logical, as procedural obstacles by nature are not desirable and should be restricted, while we cannot claim the same about NTMs, which do not per se need to be limited or eliminated, but can even be empowered and enabled as we have seen.

4.4. WTO-PLUS OR EXTRA

As was noted in the section on methodology, the provisions of RTA are assessed as WTO= when they simply incorporate certain articles of the WTO SPS or TBT Agreements, or reiterate the same obligations, without adding new commitments, while WTO+ refers to areas that add or provide more details on top of WTO SPS and TBT agreement provisions. By allowing the differentiation between WTO+ and WTO=, we can distinguish between the obligations that are WTO= which the Parties have already undertaken as Members of the WTO, from new obligations that are WTO+ which Parties undertook as part of the RTA Membership, in particular if they are legally enforceable.

Most of the provisions in SPS and TBT chapters of the CPTPP are WTO+ and only a few of them are WTO= and none of them have been identified as WTO-X. This is due to the fact that we only focus on the SPS and TBT chapters of the CPTPP, the two areas for which WTO has not only provisions, but the entire two Agreements.

Though it could have been argued that the Annexes of the CPTPP TBT chapter can be assessed as WTO-X, since WTO does not have product specific TBT provisions, as part of the TBT chapter, we consider its Annexes to be WTO+ too.

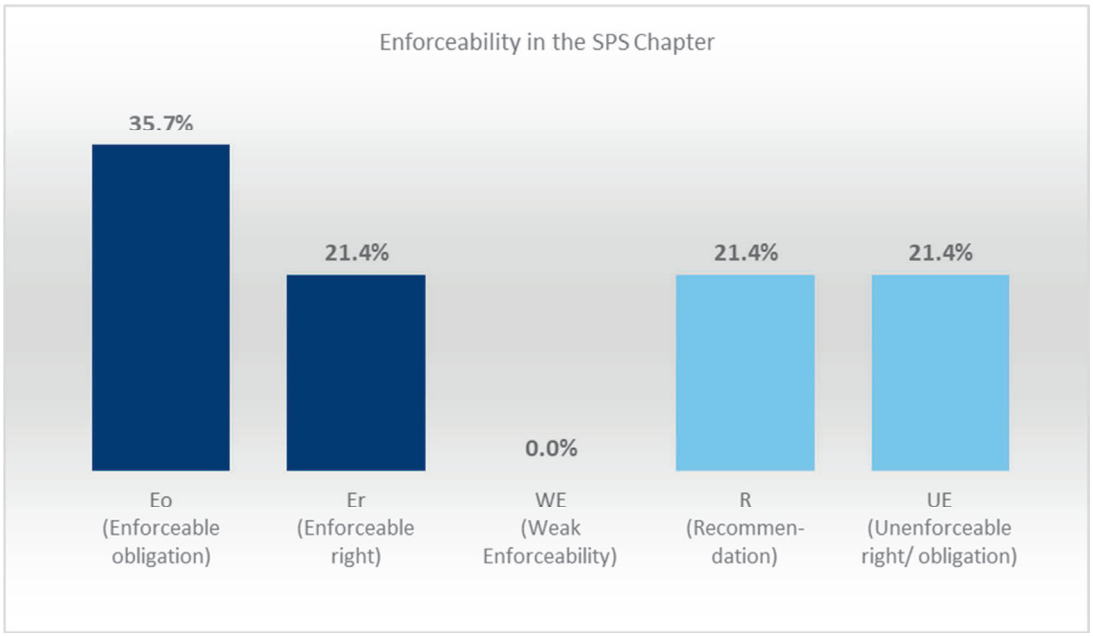
4.5 ENFORCEABILITY

In the previous subsections, we discussed the types of NTMs that were identified in the CPTPP SPS and TBT chapters, whether they have restrictive, enabling or neutral elements, what they promote, whether they are related to the requirements on substance of measures or rather their associated procedural aspects. A very important consideration on top of all that is whether particular provisions are legally enforceable, or whether they are simply recommendations.

Within the CPTPP SPS chapter, we have identified three provisions with enforceable rights, five provisions with enforceable obligations, three provisions with recommendations and three provisions with unenforceable obligations/rights. Figure 5 illustrates the percentage of provisions in the SPS chapter according to their enforceability degree.

For simplicity we can evaluate enforceable rights and enforceable obligations under one group **Enforceable**, and recommendations and unenforceable rights/obligations under **Unenforceable**, and keep the third variable which is the **Weak Enforceability**. We see from the chart above that 57 per cent of the provisions in the SPS chapter that are NTM related, are enforceable, while the rest are recommendations and unenforceable rights/obligations meaning they are

Figure 5. SPS provisions according to their enforceability degree



Source: Authors' calculations based on Annex I to this paper.

not enforceable. We have not detected any provisions with weak enforceability.

More than half is rather a high percentage of enforceable provisions, which is an indication that the SPS chapter of the CPTPP will have a real impact on the NTMs design and can affect the national legislation of the Parties in that field. This would of course require a more detailed and substantial analysis of the relevant national legislation of each Party, which is beyond the scope of this study. However, the number of WTO+ provisions and their enforceable nature leads us to assume that CPTPP would most likely have regulatory impact and is definitely much more than provisions of encouragement or recommendations.

When we scrutinize the distribution of identified NTMs in each of the enforceability categories which the Annexes to this paper examine, we can observe that there is no particular correlation between the type of NTM and enforceability. Enforceability is rather dependent on different matters related to the same NTMs, meaning the type of NTM is not a criterion affecting the enforceability degree.

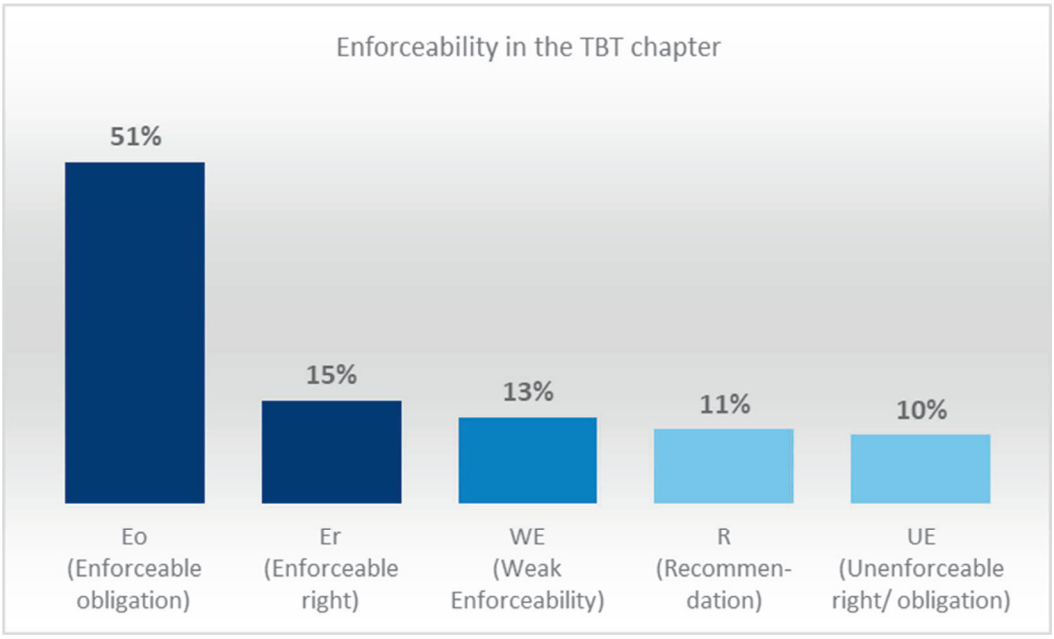
With regard to the CPTPP TBT chapter, not considering its Annexes, all the provisions which can potentially affect NTMs are enforceable. However, when examined together with its Annexes the picture is different. Figure 6 illustrates the percentage of the enforceability degree of the provisions identified in Annex II to this paper as NTM relevant.

We see that 51 per cent of all CPTPP TBT provisions are enforceable obligations, and 15 per cent are enforceable rights. Provisions with weak enforceability comprise 13 per cent of the listed provisions, while recommendations and unenforceable obligations/ rights cover 11 per cent and 10 per cent respectively of the identified provisions.

This means 66 per cent of all TBT chapter provisions listed in the Annex II to this paper have enforceable parts, while 21 per cent of the provisions are not enforceable. It is quite an impressive indication of the prospective impact of joining the CPTPP agreement on the legislation in the TBT area, in particular the sensitive product areas that the TBT chapter Annexes cover.

Hence, the level of enforceability in both CPTPP SPS and TBT chapters is quite significant, which will likely result in certain legislative and institutional amendments in the respective fields for the Parties to the CPTPP.

Figure 6. TBT provisions according to their chapter



Source: Authors' calculations based on Annex II to this paper.

5. CONCLUSION

We developed a novel systematic approach that allows for classification of RTA provisions according to the International Classification of NTMs. The approach is applied to the CPTPP agreement, in particular SPS and TBT chapters. This allows us to assess the restrictiveness or enabling nature of the provisions in terms of regulatory policies, identify the kinds of general policies the provisions promote, evaluate whether they are related to the NTMs substantially or their associated procedural aspects at the most detailed level. This approach also facilitates the comparison of the RTA provisions to relevant WTO Agreement provisions, identifying whether the provisions are WTO= or WTO+ and very importantly helps to determine which provisions are legally enforceable and to what degree.

The main findings of the paper are the following:

- Most of the provisions in the CPTPP SPS chapter are found to be in the conformity assessment area, while in the TBT chapter the prevalence is in market authorization and labelling areas, conformity assessment being in the third place.
- The results show that within the CPTPP SPS chapter, more than half of the identified provisions have restrictive elements, while some are enabling and neutral.
- As for the CPTPP TBT chapter, while 66 provisions have restrictive elements, only nine provisions have enabling elements and four provisions are neutral. It is important to note that the fact that some provisions have enabling elements, reaffirms again that NTMs are not always barriers and undesirable, but sometimes are even enabled or encouraged.
- The results of the analysis indicate a high degree of enforceability of both SPS and TBT provisions. 57 per cent of identified SPS provisions and 66 per cent of TBT provisions are legally enforceable. These results show a significant degree of enforceability in both SPS and TBT chapters, which will most likely result in certain legislative and institutional amendments in the countries Parties to the CPTPP. Consequently, the likelihood of national legislative amendments in the areas of conformity assessment, marketing authorization and labelling is rather high.

By converting the RTA provisions into the respective associated NTM measures/codes, this new methodology makes it easier to compare the provisions of an RTA to the relevant national regulations of the Parties, in particular when the NTMs data for the national regulations of the Parties have been classified and disseminated.[18] Consequently, this study will allow the comparison, without the need of going through all the national legislation of a particular Party to the RTA, but rather by simply finding the country in the database and searching for the particular NTM codes.

Moreover, the new approach presented in this study can be applied to other RTAs which would allow cross-RTA comparative analysis.

"Transposing" RTA provisions into the respective NTM codes, and analysing the effectiveness and enforceability of those NTMs, can in addition help the RTA Parties examine more profoundly the potential and unintended barriers to trade and deep integration.

[18] The NTMs data is publicly available at the Global Database on Non-tariff Measures TRAINS at the following link: https://trains.unctad.org/ (UNCTAD, 2017).

ABBREVIATIONS

CPTPP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
FAO	Food and Agriculture Organization
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GATS	General Agreement on Trade in Services
GDP	Gross Domestic Product
IMF	International Monetary Fund
IPPC	International Plant Protection Convention
ITC	International Trade Centre
MFN	Most-favoured Nation
NAFTA	North American Free Trade Association
NTM	Non-Tariff Measure
MAST	Multi-Agency Support Team
OECD	Organization for Economic Cooperation and Development
OIE	World Organization for Animal Health
PO	Procedural Obstacle
RTA	Regional Trade Agreement
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
TPP	Trans-Pacific Partnership
TPSEP	Trans-Pacific Strategic Economic Partnership Agreement
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial Development Organization
WTO	World Trade Organization

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WTO, Decision of 28 November 1979 (L/4903), Enabling Clause, available at WTO website: https://www.wto.org/english/docs_e/legal_e/enabling1979_e.htm.

WTO, General Agreement on Trade in Services (GATS), available at https://www.wto.org/english/docs_e/legal_e/26-gats.pdf.

WTO, Regional Trade Agreements Information System (RTA-IS), available at, http://rtais.wto.org/UI/PublicAllRTAList.aspx.

ANNEX I

Examining CPTPP Chapter 7: SPS

1	2	3	4
TPP provision Reference	**TPP Provision**	**NTM**	**NTM description**
Art. 7.7 (3) Pest/disease-free areas Art. 7.7 (10, 11)	The Parties may cooperate on the recognition of pest - or disease-free areas, and areas of low pest or disease prevalence with the objective of acquiring confidence in the procedures followed by each Party for the recognition of pest-or disease-free areas, and areas of low pest or disease prevalence. 10. If the evaluation of the evidence provided by the exporting Party does not result in a determination to recognise pest- or disease-free areas, or areas of low pest and disease prevalence, the importing Party shall provide the exporting Party with the rationale for its determination. 11. If there is an incident that results in the importing Party modifying or revoking the determination recognising regional conditions, on request of the exporting Party, the Parties involved shall cooperate to assess whether the determination can be reinstated.	A11 A12	Temporary geographic prohibitions for SPS reasons Geographical restrictions on eligibility
Art. 7.3 (2) Halal	Nothing in this Chapter prevents a Party from adopting or maintaining halal require-ments for food and food products in ac-cordance with Islamic law.	B31 B83 B41	Labelling requirement TBT Certification TBT TBT regulations on production processes
Art. 7.9 (3)(b),(c) Science & risk analysis	3. Recognising the Parties' rights and obligations under the relevant provisions of the SPS Agreement, nothing in this Chapter shall be construed to prevent a Party from: … (b) establishing or maintaining an approval procedure that requires a risk analysis to be conducted before the Party grants a product access to its market; or (c) adopting or maintaining a sanitary or phytosanitary measure on a provisional basis.	A14 ~A15 A19	Special authorization requirement Registration requirements for importers Prohibitions/restrictions of imports for SPS reasons, nes.
Art. 7.10 (1) Audits	To determine an exporting Party's ability to provide required assurances and meet the sanitary and phytosanitary measures of the importing Party, each importing Party shall have the right, subject to this Article, to audit the exporting Party's competent authorities and associated or designated inspection systems. That Audit may include an assessment of the competent authorities' control programmes, including: if appropriate, reviews of the inspection and audit programmes; and on-site inspections of facilities.	A89	Conformity assessment related to SPS, n.e.s.
Art. 7.11 (2),(4) Import checks	2. A Party shall make available to another Party, on request, information on its import procedures and its basis for determining the nature and frequency of import checks, including the factors it considers to deter-mine the risks associated with importations. 4. An importing Party shall provide to another Party, on request, information regarding the analytical methods, quality controls, sampling procedures and facilities that the importing Party uses to test a good. The importing Party shall ensure that any testing is conducted using appropriate and validated methods in a facility that operates under a quality assurance programme that is consistent with international laboratory standards. The importing Party shall maintain physical or electronic documentation regarding the identification, collection, sampling, transpor-tation and storage of the test sample, and the analytical methods used on the test sample.	C9 A84 ~C4 ~A82	Other import formalities, n.e.s. Inspection requirement Import-monitoring and surveillance requirements Testing requirement

5	6	7	8	9
Enabling/ Restricting/ Neutral	**Promotes what?**	**NTM or Procedural Obstacle**	**Corresponding WTO SPS/TBT Agreement provision** **WTO (=/+/x/?)**	**Enforceability (Er - Enf. Right Eo - Enf. Oblig. R - recommend, WE - weak enforceability, UE - unenforc.)**
N	Cooperation Recognition	PO	SPS 5.2, 5.5 WTO+	R
E	Regulatory Flexibility	NTM	TBT Annex 1.1 WTO+	Er
E	Regulatory Flexibility	NTM	SPS 5 5.7 WTO+ WTO=	Er
E	Cooperation Transparency	NTM	WTO+	Er
R	Transparency	PO	SPS 7, Annex B.3(b)(c),4 WTO+	Eo

ANNEX I (Continued...)

1	2	3	4
TPP provision Reference	**TPP Provision**	**NTM**	**NTM description**
Art. 7.11 (8) Import checks. Adverse results	An importing Party that prohibits or restricts the importation of a good of another Party on the basis of an adverse result of an import check shall provide an opportunity for a review of the decision and consider any relevant information submitted to assist in the review. The review request and information should be submitted to the importing Party within a reasonable period of time.* * For greater certainty, nothing in this Article prevents an importing Party from disposing of goods which are found to have an infectious pathogen or pest that, if urgent action is not taken, can spread and cause damage to human, animal or plant life or health in the Party's territory.	A11 A12 A19	Temporary geographic prohibitions for SPS reasons Geographical restrictions on eligibility Prohibitions/restrictions of imports for SPS reasons, n.e.s.
Art. 7.12 Certification	1. The Parties recognise that assurances with respect to sanitary or phytosanitary requirements may be provided through means other than certificates and that different systems may be capable of meeting the same sanitary or phytosanitary objective.	A83 A8	Conformity assessment
	2. If an importing Party requires certification for trade in a good, the Party shall ensure that the certification requirement is applied, in meeting the Party's sanitary or phytosanitary objectives, only to the extent necessary to protect human, animal or plant life or health.	A83	Certification requirement
	3. In applying certification requirements, an importing Party shall take into account relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations.	A83	Certification requirement
	4. An importing Party shall limit attestations and information it requires on the certificates to essential information that is related to the sanitary or phytosanitary objectives of the importing Party.	A83	Certification requirement
	5. An importing Party should provide to another Party, on request, the rationale for any attestations or information that the importing Party requires to be included on a certificate.	A83	Certification requirement
	6. The Parties may agree to work cooperatively to develop model certificates to accompany specific goods traded between the Parties, taking into account relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations.	A83	Certification requirement
	7. The Parties shall promote the implemen-tation of electronic certification and other technologies to facilitate trade	A83	Certification requirement
Art. 7.13 (11) Transparency	An exporting Party shall notify the importing Party through the contact points referred to in Article 7.6 (Competent Authorities and Contact Points) in a timely and appropriate manner: (a) if it has knowledge of a significant sanitary or phytosanitary Risk related to the export of a good from its territory; (b) of urgent situations where a change in animal or plant health status in the territory of the exporting Party may affect current trade; (c) of significant changes in the status of a regionalized pest or disease; (d) of new scientific findings of importance which affect the regulatory response with respect to food safety, pests or diseases; and (e) of significant changes in food safety, pest or disease management, control or eradication policies or practices that may affect current trade.	~P69	Export technical measures, n.e.s.

5	6	7	8	9
Enabling/ Restricting/ Neutral	**Promotes what?**	**NTM or Procedural Obstacle**	**Corresponding WTO SPS/TBT Agreement provision** **WTO (=/+/x/?)**	**Enforceability (Er - Enf. Right Eo - Enf. Oblig. R - recommend, WE - weak enforceability, UE - unenforc.)**
R	Review (appeal) process	NTM	SPS, Annex C. 1 (i) WTO+	Eo
R E	New NTMs/ Flexibility	NTM	Annex C, fn 7 WTO=	R
R	Non-discrimination Fairness	NTM	SPS2.2 WTO=	Eo
R	Intl' standards	NTM	SPS3.3, 5.5 WTO=	UE
R	Regulatory restriction	NTM	SPS Annex C. 1(c) WTO=/+	Eo
R	Transparency	~SPS 5.8 NTM/PO	~SPS 5.8 WTO=	UEo
N	Cooperation Recognition Harmonization Intl' Standards	PO-	WTO+	R
N	Transparency	PO	WTO+	UEo
R	Notification mechanism		SPS Annex B WTO+	Eo

ANNEX II

Examining CPTPP Chapter 8: TBT

General Part

1	2	3	4
TPP provision Reference	**TPP Provision**	**NTM**	**NTM description**
Art. 8.6 (1) Conformity assessment	1. Further to Article 6.4 of the TBT Agree-ment, each Party shall accord to conformity assessment bodies located in the territory of another Party treatment no less favourable than that it accords to conformity assessment bodies located in its own territory or in the territory of any other Party. In order to ensure that it accords such treatment, each Party shall apply the same or equivalent procedures, criteria and other conditions to accredit, approve, license or otherwise recognize conformity assessment bodies located in the territory of another Party that it may apply to conformity assessment bodies in its own territory.	~B8	Conformity assessment
Art. 8.6 (2) Conformity assessment	2. Further to Article 6.4 of the TBT Agreement, if a Party maintains procedures, criteria or other conditions as set out in paragraph 1 and requires test results, certifications or inspections as positive assurance that a product conforms to a technical regulation or standard, the Party: (a) shall not require the conformity assess-ment body that tests or certifies the prod-uct, or the conformity assessment body conducting an inspection, to be located within its territory; (b) shall not impose requirements on con-formity assessment bodies located outside its territory that would effectively require those conformity assessment bodies to operate an office in that Party's territory; and (c) shall permit conformity assessment bodies in other Parties' territories to apply to the Party for a determination that they comply with any procedures, criteria and other conditions the Party requires to deem them competent or to otherwise approve them to test or certify the product or conduct an inspection.	B84 B83 B82	Inspection Certification Testing
Art.8.6 (3)(a), (15) Conformity assessment (inspection fees)	4. If a Party undertakes conformity as-sessment under paragraph 3, and further to Articles 5.2 and 5.4 of the TBT Agreement concerning limitation on information re-quirements, the protection of legitimate commercial interests and the adequacy of review procedures, the Party shall, on the request of another Party, explain: (a) how the information required is neces-sary to assess conformity and determine fees; 15. Further to Article 5.2.5 of the TBT Agreement any conformity assessment fees imposed by a Party shall be limited to the approximate cost of services rendered.	F61	Custom-inspection, processing and servicing fees

5	6	7	8	9
Enabling/ Restricting/ Neutral	**Promotes what?**	**NTM or Procedural Obstacle**	**Corresponding WTO SPS/TBT Agreement provision** **WTO (=/+/x/?)**	**Enforceability (Er - Enf. Right Eo - Enf. Oblig. R - recommend, WE - weak enforceability, UE - unenforc.)**
R	Recognition Harmonization Transparency Regulatory Restriction	PO	TBT 6.4 WTO=/+	Eo
	Regulatory Restriction, Recognition	NTM	TBT 6.4 WTO+	Eo
R	Transparency Regulatory Restriction	NTM	TBT5.2; 5.4 WTO+	Eo

Examining Product-specific Annexes of CPTPP TBT Chapter

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
Annex 8B - INFORMATION AND COMMUNICATIONS TECHNOLOGY PRODUCTS	Sec B, 5	Nothing in paragraph 3 shall prevent a Party from verifying a supplier's declaration of conformity.	B89
	Sec A, 3	With respect to a product that uses cryptography and is designed for commercial applications, no Party shall impose or maintain a technical regulation or conformity assessment procedure that requires a manufacturer or supplier of the product, as a condition of the manufacture, sale, distribution, import or use of the product, to: (a) transfer or provide access to a particular technology, production process or other information, for example, a private key or other secret parameter, algorithm specification or other design detail, that is proprietary to the manufacturer or supplier and relates to the cryptography in the product, to the Party or a person in the Party's territory; (b) partner with a person in its territory; or (c) use or integrate a particular cryptographic algorithm or cipher, other than where the manufacture, sale, distribution, import or use of the product is by or for the government of the Party.	B8 N
Annex 8C - PHARMACEUTICALS	17	The Parties shall seek to improve their collaboration on pharmaceutical inspection, and to this end, each Party shall, with respect to the inspection of a pharmaceutical product within the territory of another Party: (a) notify the other Party prior to conducting an inspection, unless there are reasonable grounds to believe that doing so could prejudice the effectiveness of the inspection; (b) if practicable, permit representatives of the other Party's competent authority to observe that inspection; and (c) notify the other Party of its findings as soon as possible following the inspection and, if the findings will be publicly released, no later than a reasonable time before release. The inspecting Party is not required to notify the other Party of its findings if it considers that those findings are confidential and should not be disclosed.	B84
	18	The Parties shall seek to apply relevant scientific guidance documents that are developed through international collaborative efforts with respect to inspection of pharmaceuticals.	B84
Annex 8A - WINE AND DISTILLED SPIRITS	21	No Party shall require imported wine or distilled spirits to be certified by an official certification body of the Party in whose territory the wine or distilled spirits were produced or by a certification body recognised by the Party in whose territory the wine or distilled spirits were produced regarding: (a) vintage, varietal and regional claims for wine; or (b) raw materials and production processes for distilled spirits, except that the Party may require that wine or distilled spirits be certified regarding (a) or (b) if the Party in whose territory the wine or distilled spirits were produced requires that certification, that wine be certified regarding (a) if the Party has a reasonable and legitimate concern about a vintage, varietal or regional claim for wine, or that distilled spirits be certified regarding (b) if certification is necessary to verify claims such as age, origin or standards of identity.	B83
	22	If a Party deems that certification of wine is necessary to protect human health or safety or to achieve other legitimate objectives, that Party shall consider the Codex Alimentarius Guidelines for Design, Production, Issuance and Use of Generic Official Certificates (CAC/GL 38-2001), in particular the use of the generic model official certificate, as amended from time-to-time, concerning official and officially recognised certificates.	B83

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Conformity assessment n.e.s.	R	Flexibility	NTM	WTO=	Er
Conformity assessment Intellectual property	R E	Regulatory Restriction	NTM	WTO+	Eo
Inspection	R	Cooperation Notification mechanism Transparency	PO	WTO+	UEo WEo WEo WEo
Inspection	R	Cooperation Recognition Harmonization Transparency	NTM	WTO+	UEo
Certification	R	Regulatory Restriction	NTM	WTO+	Eo
Certification	R	Harmonization Intl' Standards	NTM	WTO+	UEo

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
	23	A Party shall normally permit a wine or distilled spirits supplier to submit any required certification, test result or sample only with the initial shipment of a particular brand, producer and lot. If a Party requires a supplier to submit a sample of the product for the Party's procedure to assess conformity with its technical regulation or standard, it shall not require a sample quantity larger than the minimum quantity necessary to complete the relevant conformity assessment procedure. Nothing in this provision precludes a Party from undertaking verification of test results or certification, for example, where the Party has information that a particular product may be non-compliant.	B83
Annex 8D - COSMETICS	19	No Party shall require that a cosmetic product be accompanied by a certificate of free sale as a condition of marketing, distribution or sale in the Party's territory.	B83
Annex 8G - ORGANIC PRODUCTS	2	2. Each Party is encouraged to take steps to: (a) exchange information on matters that relate to organic production, certification of organic products, and related control systems; and (b) cooperate with other Parties to develop, improve and strengthen international guidelines, standards and recommendations that relate to trade in organic products.	B83
Annex 8A - WINE AND DISTILLED SPIRITS	23	A Party shall normally permit a wine or distilled spirits supplier to submit any required certification, test result or sample only with the initial shipment of a particular brand, producer and lot. If a Party requires a supplier to submit a sample of the product for the Party's procedure to assess conformity with its technical regulation or standard, it shall not require a sample quantity larger than the minimum quantity necessary to complete the relevant conformity assessment procedure. Nothing in this provision precludes a Party from undertaking verification of test results or certification, for example, where the Party has information that a particular product may be non-compliant.	B82
Annex 8B - INFORMATION AND COMMUNICATIONS TECHNOLOGY PRODUCTS	Sec B, 4	The Parties recognise that a Party may require testing, for example, by an independent accredited laboratory, in support of a supplier's declaration of conformity, registration of the supplier's declaration of conformity, or submission of evidence necessary to support the supplier's declaration of conformity.	B82
Annex 8D - COSMETICS	21	No Party shall require that a cosmetic product be tested on animals to determine the safety of that cosmetic product, unless there is no validated alternative method available to assess safety. A Party may, however, consider the results of animal testing to determine the safety of a cosmetic product.	B82
	25	Each Party shall endeavour to avoid re-testing or re-evaluating cosmetic products that differ only with respect to shade extensions or fragrance variants, unless conducted for human health or safety purposes.	B82
Annex 8C - PHARMACEUTICALS	12	Each Party shall administer any marketing authorisation process that it maintains for pharmaceutical products in a timely, reasonable, objective, transparent and impartial manner, and identify and manage any conflicts of interest in order to mitigate any associated risks. (a) Each Party shall provide an applicant that requests marketing authorisation for a pharmaceutical product with its determination within a reasonable period of time. The Parties recognise that the reasonable period of time required to make a marketing authorisation determination may be affected by factors such as the novelty of a product or regulatory implications that may arise. (b) If a Party determines that a marketing authorisation application for a pharmaceutical product under review in its jurisdiction has deficiencies that have led or will lead to a decision not to authorize its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient.	B81

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Certification	R	Regulatory Restriction	NTM	WTO+	WEo Eo Er
Certification	R	Regulatory Restriction	NTM	WTO+	Eo
Certification	N	Notification mechanism Harmonization Intl' Standards	PO	WTO+	R
Testing	R	Regulatory Restriction	PO	WTO+	WEo Eo Er
Testing	E	Regulatory flexibility	NTM	WTO+	Er
Testing	R	Regulatory Restriction	NTM	WTO+	Eo
Testing	R	Regulatory Restriction	NTM	WTO+	UEo
Product registration requirement	R E	Transparency Review (appeal) process Flexibility	PO	WTO+	Eo WEo Eo Eo Eo

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
		(c) If a Party requires a marketing authorisation for a pharmaceutical product, the Party shall ensure that any marketing authorization determination is subject to an appeal or review process that may be invoked at the request of the applicant. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body. (d) If a Party requires periodic re-authorisation for a pharmaceutical product that has previously received marketing authorisation from the Party, the Party shall allow the pharmaceutical product to remain on its market under the conditions of the previous marketing authorisation pending a decision on the periodic reauthorisation, unless the Party identifies a significant health or safety concern.	
Annex 8B - INFORMATION AND COMMUNICATIONS TECHNOLOGY PRODUCTS	Sec A, 3	With respect to a product that uses cryptography and is designed for commercial applications, no Party shall impose or maintain a technical regulation or conformity assessment procedure that requires a manufacturer or supplier of the product, as a condition of the manufacture, sale, distribution, import or use of the product, to: (a) transfer or provide access to a particular technology, production process or other information, for example, a private key or other secret parameter, algorithm specification or other design detail, that is proprietary to the manufacturer or supplier and relates to the cryptography in the product, to the Party or a person in the Party's territory; (b) partner with a person in its territory; or (c) use or integrate a particular cryptographic algorithm or cipher, other than where the manufacture, sale, distribution, import or use of the product is by or for the government of the Party.	B8 N
Annex 8C - PHARMACEUTICALS	8	When developing or implementing regulations for marketing authorisation of pharmaceutical products, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.	B14
	9	Each Party shall observe the obligations set out in Articles 2.1 and 5.1.1 of the TBT Agreement with respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for pharmaceutical products and that do not fall within the definition of a technical regulation or conformity assessment procedure.	B14
	11	Each Party shall make its determination whether to grant marketing authorisation for a specific pharmaceutical product on the basis of: (a) information, including, if appropriate, pre-clinical and clinical data, on safety and efficacy; (b) information on the manufacturing quality of the product; (c) labelling information related to the safety, efficacy and use of the product; and (d) other matters that may directly affect the health or safety of the user of the product. To this end, no Party shall require sale data or related financial data concerning the marketing of the product as part of the determination. Further, each Party shall endeavour to not require pricing data as part of the determination.	B14

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Conformity assessment Intellectual property	R	Regulatory Restriction	NTM	WTO+	Eo
Authorization	R	Cooperation Harmonization Intl' Standards	NTM	WTO=/+	R
Authorization	R	Regulatory Restriction Notification mechanism	NTM	WTO=/+	Eo
Authorization	R	Regulatory Restriction	NTM	WTO+	Eo Eo UEo

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
	12	Each Party shall administer any marketing authorisation process that it maintains for pharmaceutical products in a timely, reasonable, objective, transparent and impartial manner, and identify and manage any conflicts of interest in order to mitigate any associated risks. (a) Each Party shall provide an applicant that requests marketing authorisation for a pharmaceutical product with its determination within a reasonable period of time. The Parties recognise that the reasonable period of time required to make a marketing authorisation determination may be affected by factors such as the novelty of a product or regulatory implications that may arise. (b) If a Party determines that a marketing authorisation application for a pharmaceutical product under review in its jurisdiction has deficiencies that have led or will lead to a decision not to authorize its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient. (c) If a Party requires a marketing authorisation for a pharmaceutical product, the Party shall ensure that any marketing authorization determination is subject to an appeal or review process that may be invoked at the request of the applicant. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body. (d) If a Party requires periodic re-authorisation for a pharmaceutical product that has previously received marketing authorisation from the Party, the Party shall allow the pharmaceutical product to remain on its market under the conditions of the previous marketing authorisation pending a decision on the periodic reauthorisation, unless the Party identifies a significant health or safety concern	B14
	14	No Party shall require that a pharmaceutical product receive marketing authorisation from a regulatory authority in the country of manufacture as a condition for the product to receive marketing authorisation from that Party.	B14
	15	For greater certainty, a Party may accept a prior marketing authorization that is issued by another regulatory authority as evidence that a product may meet its own requirements. If there are regulatory resource limitations, a Party may require a marketing authorisation from one of a number of reference countries to be established and made public by that Party as a condition for the product's marketing authorisation from that Party.	B14
	16	For a marketing authorisation application for a pharmaceutical product, each Party shall review the safety, efficacy and manufacturing quality information submitted by the applicant requesting marketing authorisation in a format that is consistent with the principles found in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Common Technical Document (CTD), as may be amended, recognising that the CTD may not address all aspects relevant to a Party's determination to approve marketing authorisation for a particular product.	B14
Annex 8D - COSMETICS	2	A Party's obligations under this Annex shall apply to any product that the Party defines as a cosmetic product pursuant to paragraph 3. For the purposes of this Annex, preparation of a technical regulation, standard, conformity assessment procedure or marketing authorisation includes, as appropriate, the evaluation of the risks involved, the need to adopt a measure to address those risks, the review of relevant scientific or technical information, and the consideration of the characteristics or design of alternative approaches.	B14
	9	Each Party shall observe the obligations set out in Articles 2.1 and 5.1.1 of the TBT Agreement with respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for cosmetic products and that do not fall within the definition of a technical regulation or conformity assessment procedure.	B14

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Authorization	R	Transparency Regulatory Restriction Review (appeal) process	PO	WTO+	WEo WEo Eo Eo Eo
Authorization	R	Regulatory Restriction	NTM	WTO+	Eo
Authorization	N	Regulatory Flexibility	NTM	WTO+	R Er
Authorization	R	Regulatory Restriction Harmonization Intl' Standards	NTM	WTO+	Eo
Authorization	N	Regulatory Restriction	NTM	WTO+	R
Authorization	R	Regulatory Restriction	NTM	WTO+	Eo

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
	12	No Party shall conduct separate marketing authorisation processes or subprocesses for cosmetic products that differ only with respect to shade extensions or fragrance variants, unless a Party identifies a significant human health or safety concern.	B14
	13	Each Party shall administer any marketing authorisation process that it maintains for cosmetics products in a timely, reasonable, objective, transparent and impartial manner, and identify and manage any conflicts of interest in order to mitigate any associated risks. (a) If a Party requires marketing authorisation for a cosmetic product, that Party shall provide an applicant with its determination within a reasonable period of time. (b) If a Party requires marketing authorisation for a cosmetic product and it determines that a marketing authorisation application for a cosmetic product under review in its jurisdiction has deficiencies that have led or will lead to a decision not to authorise its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient. (c) If a Party requires a marketing authorisation for a cosmetic product, the Party shall ensure that any marketing authorization determination is subject to an appeal or review process that may be invoked at the request of the applicant. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body. (d) If a Party has granted marketing authorisation for a cosmetic product in its territory, the Party shall not subject the product to periodic re-assessment procedures as a condition of retaining its marketing authorisation.	B14
	14	If a Party maintains a marketing authorisation process for cosmetic products, that Party shall consider replacing this process with other mechanisms such as voluntary or mandatory notification and post-market surveillance.	B14
	15	When developing regulatory requirements for cosmetic products, a Party shall consider its available resources and technical capacity in order to minimize the implementation of requirements that could: (a) inhibit the effectiveness of procedures for ensuring the safety or manufacturing quality of cosmetic products; or (b) lead to substantial delays in marketing authorisation regarding cosmetic products for sale on that Party's market.	B14
	16	No Party shall require the submission of marketing information, including with respect to prices or cost, as a condition for the product receiving marketing authorisation.	B14
	17	No Party shall require a cosmetic product to be labelled with a marketing authorisation or notification number.	B14
	18	No Party shall require that a cosmetic product receive marketing authorisation from a regulatory authority in the country of manufacture, as a condition for the product receiving marketing authorisation from the Party. For greater certainty, this provision does not prohibit a Party from accepting a prior marketing authorisation issued by another regulatory authority as evidence that a product may meet its own requirements.	B14

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Authorization	R	Regulatory Restriction	NTM	WTO+	Eo
Authorization	R	Transparency Flexibility Regulatory Restriction	PO	WTO+	WEo WEo Eo Eo Eo
Authorization	R	Transparency Regulatory Restriction Flexibility	NTM	WTO+	UEo
Authorization	R	Regulatory Restriction	PO	WTO+	UEo
Authorization	R	Regulatory Restriction	NTM	WTO+	Eo
Authorization	R	Regulatory Restriction	NTM	WTO+	Eo
Authorization	R	Regulatory Restriction Cooperation Harmonization	NTM	WTO+	Eo Er

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
Annex 8E - MEDICAL DEVICES	2	A Party's obligations under this Annex shall apply to any product that the Party defines as a medical device pursuant to paragraph 3. For the purposes of this Annex, preparation of a technical regulation, standard, conformity assessment procedure or marketing authorisation includes, as appropriate the evaluation of the risks involved, the need to adopt a measure to address those risks, the review of relevant scientific or technical information, and the consideration of the characteristics or design of alternative approaches.	B14
	8	When developing or implementing regulations for marketing authorization of medical devices, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.	B14
	9	Each Party shall observe the obligations set out in Articles 2.1 and 5.1.1 of the TBT Agreement with respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for medical devices and that do not fall within the definition of a technical regulation or conformity assessment procedure.	B14
	12	Each Party shall make a determination whether to grant marketing authorisation for a specific medical device on the basis of: (a) information, including, if appropriate, clinical data, on safety and efficacy; (b) information on performance, design and manufacturing quality of the device; (c) labelling information related to safety, efficacy and use of the device; and (d) other matters that may directly affect the health or safety of the user of the device. To this end, no Party shall require sale data, pricing or related financial data concerning the marketing of the medical device.	B14
	13	Each Party shall administer any marketing authorisation process that it maintains for medical devices in a timely, reasonable, objective, transparent and impartial manner, and identify and manage any conflicts of interest in order to mitigate any associated risks. (a) Each Party shall provide an applicant that requests marketing authorisation for a medical device with its determination within a reasonable period of time. The Parties recognise that the reasonable period of time required to make a marketing authorisation determination may be affected by factors such as the novelty of a device or regulatory implications that may arise. (b) If a Party determines that a marketing authorisation application for a medical device under review in its jurisdiction has deficiencies that have led or will lead to a decision not to authorise its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient. (c) If a Party requires marketing authorisation for a medical device, the Party shall ensure that any marketing authorization determination is subject to an appeal or review process that may be invoked at the request of the applicant. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body. (d) If a Party requires periodic re-authorisation for a medical device that has previously received marketing authorisation from the Party, the Party shall allow the medical device to remain on its market under the conditions of the previous marketing authorisation pending a decision on the periodic re-authorisation, unless a Party identifies a significant health or safety concern.	B14

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Authorization	R	Transparency Regulatory Restriction	NTM	WTO+	R
Authorization	R	Cooperation Harmonization Intl' Standards	NTM	WTO+	UEr R
Authorization	R	Regulatory Restriction	NTM	WTO=/+	Eo
Authorization	R	Regulatory Restriction	NTM	WTO+	Eo Eo
Authorization	R	Transparency Flexibility Regulatory Restriction	PO	WTO+	WEo WEo Eo Eo Eo

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
	14	When developing regulatory requirements for medical devices, a Party shall consider its available resources and technical capacity in order to minimize the implementation of requirements that could: (a) inhibit the effectiveness of procedures for ensuring the safety, efficacy or manufacturing quality of medical devices; or (b) lead to substantial delays in marketing authorisation regarding medical devices for sale on that Party's market.	B14
	15	No Party shall require that a medical device receive a marketing authorisation from a regulatory authority in the country of manufacture as a condition for the medical device to receive marketing authorisation from that Party.	B14
	16	For greater certainty, a Party may accept a prior marketing authorization that is issued by another regulatory authority as evidence that a medical device may meet its own requirements. If there are regulatory resource limitations, a Party may require a marketing authorisation from one of a number of reference countries established and made public by that Party as a condition for the medical device's marketing authorisation from that Party.	B14
Annex 8A - WINE AND DISTILLED SPIRITS	4	A Party may require a supplier to ensure that any statement required by that Party to be placed on a wine or distilled spirits label is: (a) clear, specific, truthful, accurate and not misleading to the consumer; and (b) legible to the consumer; and that such labels be firmly affixed.	B31
	5	If a Party requires a supplier to indicate information on a distilled spirits label, the Party shall permit the supplier to indicate that information on a supplementary label that is affixed to the distilled spirits container. Each Party shall permit a supplier to affix the supplementary label on the container of the imported distilled spirits after importation but prior to offering the product for sale in the Party's territory, and may require that the supplier affix the supplementary label prior to release from customs. For greater certainty, a Party may require that the information indicated on a supplementary label meet the requirements in paragraph 4.	B31
	6	Each Party shall permit the alcoholic content by volume indicated on a wine or distilled spirits label to be expressed by alcohol by volume (alc/vol), for example 12% alc/vol or alc12%vol, and to be indicated in percentage terms to a maximum of one decimal point, for example 12.1%.	B31
	7	Each Party shall permit suppliers to use the term "wine" as a product name. A Party may require a supplier to indicate additional information on a wine label concerning the type, category, class or classification of the wine.	B31
	8 9	With respect to wine labels, each Party shall permit the information set out in subparagraphs 10(a) through (d) to be presented in a single field of vision for a container of wine. If this information is presented in a single field of vision, then the Party's requirements with respect to placement of this information are satisfied. A Party shall accept any of the information that appears outside a single field of vision if that information satisfies that Party's laws, regulations and requirements. Notwithstanding paragraph 8, a Party may require net contents to be displayed on the principal display panel for a subset of less commonly used container sizes if specifically required by that Party's laws or regulations.	B31

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Authorization	R	Regulatory Restriction	PO	WTO+	UEo
Authorization	R	Regulatory Restriction	NTM	WTO+	Eo
Authorization	N	Regulatory Flexibility	NTM	WTO+	R Er
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Er
Labelling requirement	R	Regulatory Restriction)	NTM	WTO+	Eo Eo Er Er
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Eo
Labelling requirement	R	Regulatory flexibility	NTM	WTO+	Eo Er
Labelling requirement	R E	Regulatory Restriction Regulatory flexibility	NTM	WTO+	Eo WEo Er

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
	10	If a Party requires a wine label to indicate information other than: (a) product name; (b) country of origin; (c) net contents; or (d) alcohol content, it shall permit the supplier to indicate the information on a supplementary label affixed to the wine container. A Party shall permit the supplier to affix the supplementary label on the container of the imported wine after importation but prior to offering the product for sale in the Party's territory, and may require that the supplier affix the supplementary label prior to release from customs. For greater certainty, a Party may require that information on a supplementary label meet the requirements set out in paragraph 4.	B31
	11	For the purposes of paragraphs 4, 5 and 10, if there is more than one label on a container of imported wine or distilled spirits, a Party may require that each label be visible and not obscure mandatory information on another label.	B31
	12	If a Party has more than one official language, it may require that information on a wine or distilled spirits label appear in equal prominence in each official language.	B31
	13	Each Party shall permit a supplier to place a lot identification code on a wine or distilled spirits container, if the code is clear, specific, truthful, accurate and not misleading, and shall permit the supplier to determine: (a) where to place the lot identification code on the container, provided that the code does not cover up essential information printed on the label; and (b) the specific font size, readable phrasing and formatting for the code provided that the lot identification code is legible by physical or electronic means. … A Party may impose penalties for the removal or deliberate defacement of any lot identification code provided by the supplier and placed on the container.	B31
	14	No Party shall require a supplier to indicate any of the following information on a wine or distilled spirits container, labels or packaging: (a) date of production or manufacture; (b) date of expiration; (c) date of minimum durability; or (d) sell by date, except that a Party may require a supplier to indicate a date of minimum durability or expiration on products7 that could have a shorter date of minimum durability or expiration than would normally be expected by the consumer because of: their packaging or container, for example bag-in-box wines or individual serving size wines; or the addition of perishable ingredients.	B31
	16	No Party shall require a supplier to place a translation of a trademark or trade name on a wine or distilled spirits container, label or packaging.	B31
	17	No Party shall prevent imports of wine from other Parties solely on the basis that the wine label includes the following descriptors or adjectives describing the wine or relating to wine-making: chateau, classic, clos, cream, crusted/crusting, fine, late bottled vintage, noble, reserve, ruby, special reserve, solera, superior, sur lie, tawny, vintage or vintage character. This paragraph shall not apply to a Party that has entered into an agreement with another country or group of countries no later than February 2003 that requires the Party to restrict the use of such terms on labels of wine sold in its territory.	B31
	18	No Party shall require a supplier to disclose an oenological practice on a wine label or container except to meet a legitimate human health or safety objective with respect to that oenological practice.	B31
	19	Each Party shall permit wine to be labelled as Icewine, ice wine, ice-wine or a similar variation of those terms, only if the wine is made exclusively from grapes naturally frozen on the vine.	B31

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Labelling requirement	R	Regulatory flexibility Regulatory Restriction	NTM	WTO+	Eo Er
Labelling requirement	E	Regulatory flexibility	NTM	WTO+	Er
Labelling requirement	E	Regulatory flexibility	NTM	WTO+	Er
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Eo
Labelling requirement	R E	Regulatory Restriction Regulatory flexibility	NTM	WTO+	Eo Er
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Eo
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Er
Labelling requirement	R		NTM	WTO+	Eo Er
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Eo

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
Annex 8C - PHARMACEUTICALS	11	Each Party shall make its determination whether to grant marketing authorisation for a specific pharmaceutical product on the basis of: (a) information, including, if appropriate, pre-clinical and clinical data, on safety and efficacy; (b) information on the manufacturing quality of the product; (c) labelling information related to the safety, efficacy and use of the product; and (d) other matters that may directly affect the health or safety of the user of the product.	B31
Annex 8D - COSMETICS	17	No Party shall require a cosmetic product to be labelled with a marketing authorisation or notification number. (fn 17. This paragraph does not apply to Chile and Peru. Within a period of no more than five years from the date of the entry into force of this Agreement, Chile and Peru shall each review their respective labelling requirements in order to examine whether other regulatory mechanisms can be implemented, in a manner consistent with their obligations under this Chapter and the TBT Agreement. Chile and Peru shall separately report to the Committee about their review upon request of another Party.)	B31
	20	If a Party requires a manufacturer or supplier of a cosmetic product to indicate information on the product's label, the Party shall permit the manufacturer or supplier to indicate the required information by relabelling the product or by using supplementary labelling of the product in accordance with the Party's domestic requirements after importation but prior to offering the product for sale or supply in the Party's territory.	B31
Annex 8E - MEDICAL DEVICES	12	Each Party shall make a determination whether to grant marketing authorisation for a specific medical device on the basis of: (a) information, including, if appropriate, clinical data, on safety and efficacy; (b) information on performance, design and manufacturing quality of the device; (c) labelling information related to safety, efficacy and use of the device; and (d) other matters that may directly affect the health or safety of the user of the device. To this end, no Party shall require sale data, pricing or related financial data concerning the marketing of the medical device.	B31
	17	If a Party requires a manufacturer or supplier of a medical device to indicate information on the product's label, the Party shall permit the manufacturer or supplier to indicate the required information by relabelling the product or by using supplementary labelling of the device in accordance with the Party's domestic requirements after importation but prior to offering the device for sale or supply in the Party's territory.	B31
Annex 8F - PROPRIETARY FORMULAS FOR PREPACKAGED FOODS AND FOOD ADDITIVES	4	Nothing in paragraph 3 shall prevent a Party from requiring ingredients to be listed on labels consistent with CODEX STAN 1-1985 and CODEX STAN 107-1981, as may be amended, except when those standards would be an ineffective or inappropriate means for the fulfilment of a legitimate objective.	B31
Annex 8G - ORGANIC PRODUCTS	3	If a Party maintains a requirement that relates to the production, processing or labelling of products as organic, it shall enforce that requirement.	B31

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Eo
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Eo
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Eo
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Eo Eo
Labelling requirement	R	Regulatory Restriction	NTM	WTO+	Eo
Labelling requirement	E R	Regulatory flexibility	NTM	WTO+	Er Eo
Labelling requirement	R	Transparency	PO	WTO+	Eo

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
	4	A Party is encouraged to consider, as expeditiously as possible, a request from another Party for recognition or equivalence of a technical regulations, standards or conformity assessment procedures that relates to the production, processing, or labelling of products of another Party as organic. Each Party is encouraged to accept as equivalent or recognise the technical regulations, standards or conformity assessment procedures that relate to the production, processing or labelling of products of that other Party as organic, if the Party is satisfied that the technical regulations, standards or conformity assessment procedures of that other Party adequately fulfils the objectives of the Party's technical regulations, standards or conformity assessment procedures. If a Party does not accept as equivalent or recognise the technical regulations, standards or conformity assessment procedures that relate to the production, processing, or labelling of products of that other Party as organic, it shall, on request of that other Party, explain its reasons.	B31
	5	Each Party is encouraged to participate in technical exchanges to support improvement and greater alignment of technical regulations, standards or conformity assessment procedures that relate to the production, processing or labelling of products as organic.	B31
Annex 8A - WINE AND DISTILLED SPIRITS	21	Each Party shall endeavour to base its quality and identity requirements for any specific type, category, class or classification of distilled spirits solely on minimum ethyl alcohol content and the raw materials, added ingredients and production procedures used to produce that specific type, category, class or classification of distilled spirits.	B41
Annex 8G - ORGANIC PRODUCTS	3	If a Party maintains a requirement that relates to the production, processing or labelling of products as organic, it shall enforce that requirement.	B41
	4	A Party is encouraged to consider, as expeditiously as possible, a request from another Party for recognition or equivalence of a technical regulations, standards or conformity assessment procedures that relates to the production, processing, or labelling of products of another Party as organic. Each Party is encouraged to accept as equivalent or recognise the technical regulations, standards or conformity assessment procedures that relate to the production, processing or labelling of products of that other Party as organic, if the Party is satisfied that the technical regulations, standards or conformity assessment procedures of that other Party adequately fulfils the objectives of the Party's technical regulations, standards or conformity assessment procedures. If a Party does not accept as equivalent or recognise the technical regulations, standards or conformity assessment procedures that relate to the production, processing, or labelling of products of that other Party as organic, it shall, on request of that other Party, explain its reasons.	B41
	5	Each Party is encouraged to participate in technical exchanges to support improvement and greater alignment of technical regulations, standards or conformity assessment procedures that relate to the production, processing or labelling of products as organic.	B41
Annex 8A - WINE AND DISTILLED SPIRITS	2	2. For the purposes of this Annex: **distilled spirits** means a potable alcoholic distillate, including spirits of wine, whiskey, rum, brandy, gin, tequila, mezcal and all dilutions or mixtures of those spirits for consumption; **wine** means a beverage that is produced by the complete or partial alcoholic fermentation exclusively of fresh grapes, grape must, or products derived from fresh grapes in accordance with oenological practices that the country in which the wine is produced authorises under its laws and regulations (fn 6 For the United States, the alcohol content of wine must be not less than seven per cent and not more than 24 per cent)	B6

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Labelling requirement	R	Cooperation Harmonization Intl' Standards	PO	WTO+	R R Eo (but a weak obligation)
Labelling requirement	R	Cooperation Harmonization Intl' Standards	PO	WTO+	R
TBT regulations on production processes	R	Regulatory Restriction	NTM	WTO+	WEo
TBT regulations on production processes	E R	Regulatory Restriction	NTM PO	WTO	Eo
TBT regulations on production processes	R	Cooperation Harmonization Intl' Standards	PO	WTO+	R R Eo (but a weak obligation)
TBT regulations on production processes	R	Cooperation Harmonization Intl' Standards	PO	WTO+	R
Product identity requirements	R	Regulatory restriction	NTM	WTO+	Eo

Examining Product-specific Annexes of CPTPP TBT Chapter *(continued)*

1		2	3
TPP Annex	**TPP Reference, para**	**TPP Provision**	**NTM**
	7	Each Party shall permit suppliers to use the term "wine" as a product name. A Party may require a supplier to indicate additional information on a wine label concerning the type, category, class or classification of the wine.	B6
	20	Each Party shall endeavour to base its quality and identity requirements for any specific type, category, class or classification of distilled spirits solely on minimum ethyl alcohol content and the raw materials, added ingredients and production procedures used to produce that specific type, category, class or classification of distilled spirits.	B6
Annex 8A - WINE AND DISTILLED SPIRITS	20	Each Party shall endeavour to base its quality and identity requirements for any specific type, category, class or classification of distilled spirits solely on minimum ethyl alcohol content and the raw materials, added ingredients and production procedures used to produce that specific type, category, class or classification of distilled spirits.	B7
Annex 8C - PHARMACEUTICALS	13	When developing regulatory requirements for pharmaceutical products, a Party shall consider its available resources and technical capacity in order to minimise the implementation of requirements that could: (a) inhibit the effectiveness of procedures for ensuring the safety, efficacy or manufacturing quality of pharmaceutical products; or (b) lead to substantial delays in marketing authorisation regarding pharmaceutical products for sale on that Party's market.	B7
Annex 8D - COSMETICS	11	In applying a risk-based approach in regulating cosmetic products, each Party shall take into account that cosmetic products are generally expected to pose less potential risk to human health or safety than medical devices or pharmaceutical products.	B7
	~15	When developing regulatory requirements for cosmetic products, a Party shall consider its available resources and technical capacity in order to minimize the implementation of requirements that could: (a) inhibit the effectiveness of procedures for ensuring the safety or manufacturing quality of cosmetic products; or (b) lead to substantial delays in marketing authorisation regarding cosmetic products for sale on that Party's market.	B7
Annex 8E - MEDICAL DEVICES	14	When developing regulatory requirements for medical devices, a Party shall consider its available resources and technical capacity in order to minimize the implementation of requirements that could: (a) inhibit the effectiveness of procedures for ensuring the safety, efficacy or manufacturing quality of medical devices; or (b) lead to substantial delays in marketing authorisation regarding medical devices for sale on that Party's market.	B7

4	5	6	7	8	9
NTM description	**Enabling / Restricting/ Neutral / Establishing an obligation**	**Promotes what?**	**NTM or PO**	**WTO (=/+/x/?)**	**Enforceability (Er/Eo/R/UE)**
Product identity requirements	R	Regulatory restriction	NTM	WTO+	Eo Er
Product identity requirements	R	Regulatory restriction	NTM	WTO+	WEo
Product-quality or -performance requirements	R	Regulatory restriction	NTM	WTO+	WEo
Product-quality or -performance requirements	R	Regulatory restriction	NTM	WTO+	UEo
Product-quality or -performance requirements	R	Regulatory restriction	NTM	WTO+	WEo
Product-quality or -performance requirements	R	Regulatory restriction	PO	WTO+	UEo
Product-quality or -performance requirements	R	Regulatory restriction	PO	WTO+	UEo

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