

**More Restriction or Facilitation on PPE amid COVID-19:
Limitations and Options of International Trade Law**

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Type of Contribution: Research Paper
Word Count: 8,637 (excluding footnotes)

Keywords: Export restriction, mutual recognition agreements (MRAs), PPE,
COVID-19, trade law

**A contribution to the Policy Hackathon on Model Provisions for Trade in Times of
Crisis and Pandemic in Regional and other Trade Agreements**

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More Restriction or Facilitation on PPE amid COVID-19: Limitations and Options of International Trade Law

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Abstract

As the COVID-19 pandemic continues to spread around the world, international trade has prompted widespread fears especially when it comes to the scramble for person protective equipment (PPE) as a result of critical shortages. This study examines trade-related measures on PPE in selected jurisdiction, including both export restriction and import facilitation in response to a crisis-within-a-crisis. These measures have brought considerable attention to the role of the multilateral trading system and have also exposed the existing limits of international trade law. The study provides analysis of the issues associated with these measures from an international trade law perspective and advances possible solution including greater is of Mutual Recognition Agreements (MRAs) on essential goods in future Regional Trade Agreements(RTAs). We also conclude with a model provision for the future negotiation of RTAs on essential supplies based on a comparison of existing MRAs.

I. Introduction

The escalation of the COVID-19 global pandemic has caused an unprecedented, far-reaching impact on human health, social well-being and economic growth around the world. Efforts to contain the virus are ongoing. Many governments have been compelled to respond with measures that affect the delivery of such critical supplies of essential goods including personal protective equipment (PPE)¹ medical products and foodstuffs. Many governments have swiftly enacted temporary trade measures to restrict exports of essential goods, as well as to liberalize and facilitate imports of such products. The information thus far suggests by May 2020, WTO Members implemented over 250 trade-related measures in the context of COVID-19.² (Figure 1)

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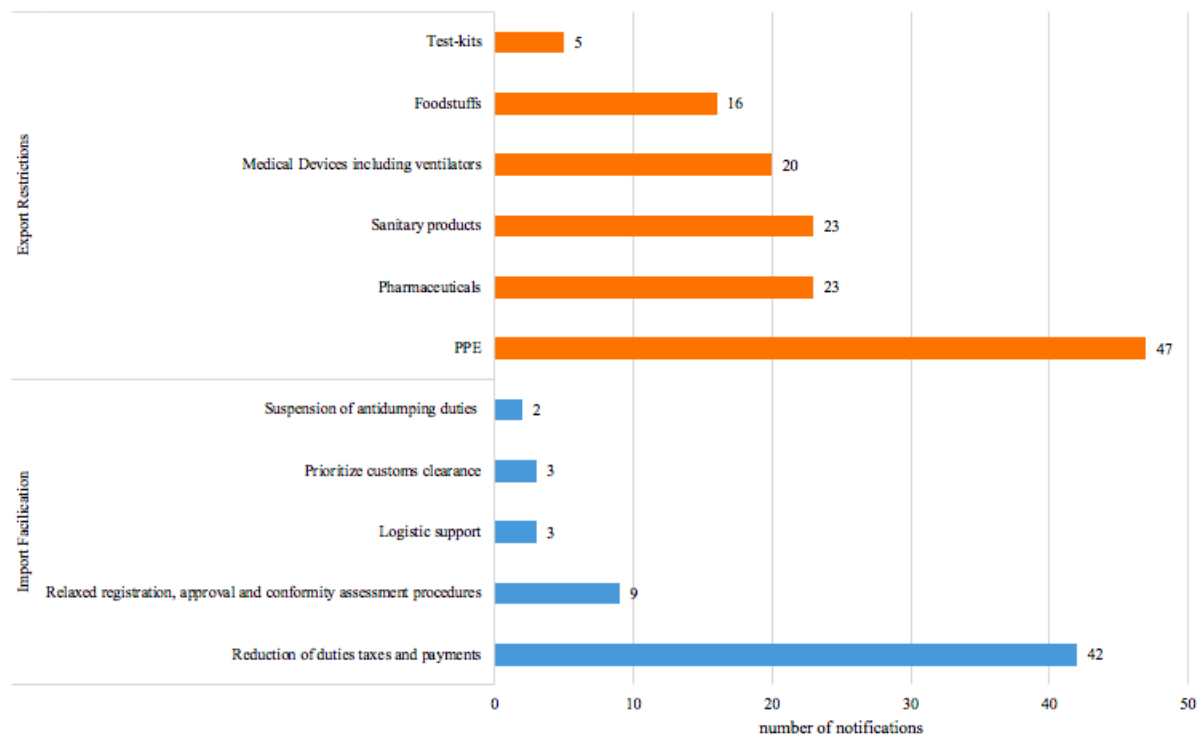
This article is based on two forthcoming publications: Fu, J and McMahon J “*Tackling Technical Barriers to PPE: Pathways to Mutual Recognition Agreements in the Post-Pandemic Future.*” *Global Trade and Customs Journal* (2020); Fu, J and McMahon J “*The Global Scramble for PPE amid COVID-19: Exposing the Limits of International Trade Law*”.

¹ COVID-related PPE in this article applies to broader sense of protective equipment unless specified, that include mainly 6 kinds of products based on the 6-digit Harmonized system (HS) codes: HS 630790 including face masks and surgical masks; HS 392690- including respirators, HS 621010 including protective gowns and surgical gowns; HS 392620 including protective suits; HS 900490 including protective googles; and HS 401511 including surgical gloves. By a strict legal interpretation, some PPE such as surgical masks, surgical gowns and gloves fall into the definition of “medical device” rather than PPE in many jurisdictions.

² WTO report shows members moving to facilitate imports even as trade restrictions remain high https://www.wto.org/english/news_e/news20_e/trdev_24jul20_e.htm. See also *WTO Report on G20 Trade Measures (Mid-October 2019 to May 2020)* (WTO, June 2020) available at https://www.wto.org/english/news_e/news20_e/report_trdev_jun20_e.pdf

Not surprisingly, export restrictions on PPE is pronounced among all trade-related measures. It was reported that more than 3000 healthcare workers have been infected as of early March in Wuhan, whilst in Italy, 20% of responding healthcare workers were infected as a result of exposure to the virus in addition to physical and mental exhaustion.³ PPE supplies have become a key concern since the outbreak of the COVID 19. As most governments were not properly prepared, many of them are now scrambling to acquire PPE supplies wherever they can with additional measures to curb PPE exports and/or to facilitate imports from other countries.

Figure 1, Trade-related Measures during the Pandemic



Source: The authors compilation based on the WTO trade-related measures information update, as of 19 June 2020.

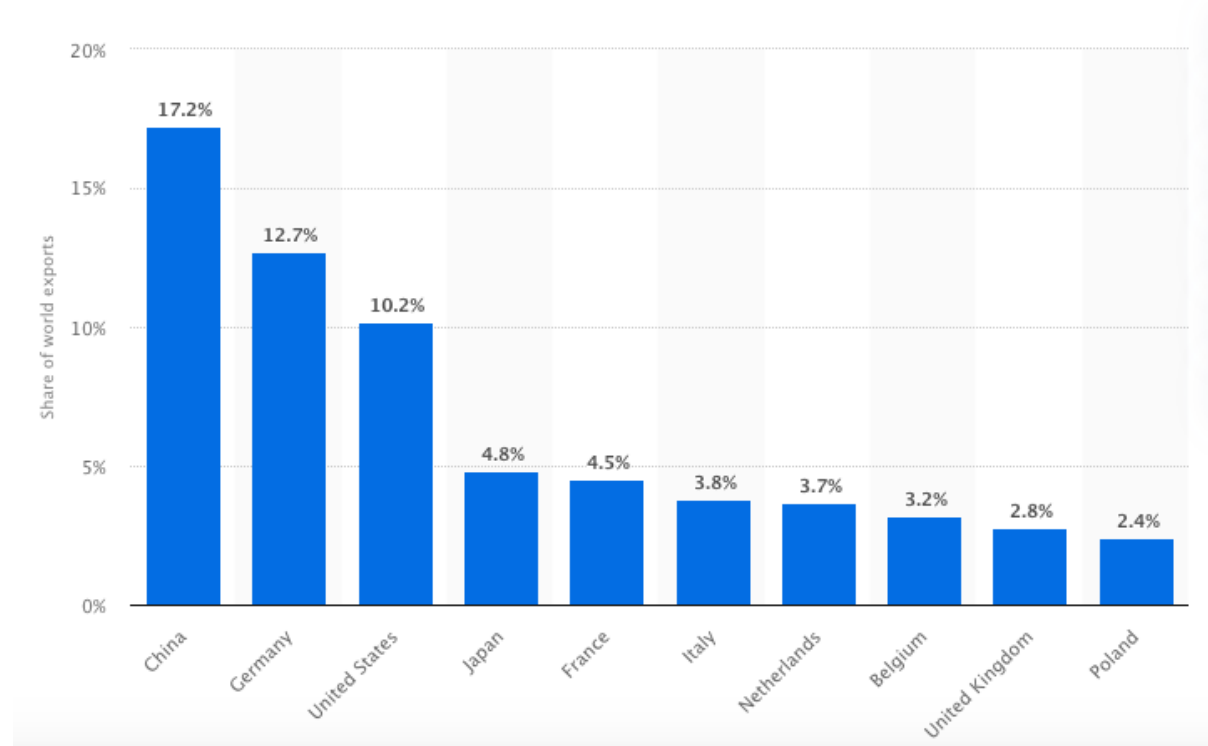
This article does not aim to provide an analysis of the full spectrum of all trade-related measures imposed by countries during the crisis, but, rather, aims to present an overview of both the export restrictions and import facilitation measures on PPE in a select number of jurisdictions in the context of COVID-19, as an example, and to analyze the issues associated with both export and import measures in the international trade law regime. Section II details export restrictions on PPE applied by the European Union (EU) and a number of other WTO Members (Australia, Thailand and China) and the potential issues associated with the measures in the context of the WTO. Section III examines the trade facilitation measures for PPE imports, with a focus on the role MRAs play in addressing technical barriers and facilitating PPE trade and the potential of a model provision on mutual recognition in the future regional trade agreements. Section IV concludes with some thoughts on global solidarity and cooperation in battling COVID-19.

II. Export Restrictions on PPE

³ Editorial, 'COVID-19: Protecting Health-Care Workers' (2020) 395 *The Lancet* 922, 19.

The initial COVID-19 outbreak saw many governments introduce trade restrictions on essential relief supplies, especially PPE. This caused abrupt and large supply chain disruptions. Bespoke global manufacturing of PPE is highly concentrated. The global PPE market is reliant on key countries China, the United States (US), Japan and some EU countries prior to the pandemic (Figure 2). Export restrictions, particularly from world major exporters, have worsened the supply chain bottleneck in the pandemic and have put developing countries, especially those reliant on foreign imports, in an extremely precarious position to tackle the unfolding health, economic and humanitarian crises.

Figure 2: Top 10 exporters of personal protective products worldwide, 2019



Source: UNCTAD, <https://unstats.un.org/unsd/ccsa/2>

This section examines the restrictions imposed by a number of WTO Members to cope with the shortage of PPE arising from the arrival of COVID-19 in their countries from the initial fragmented response to the introduction of EU export restrictions before examining the relevant WTO disciplines and concluding with an assessment of the WTO-compatibility of these measures.

a. EU Export Restrictions

Speaking to the European Parliament on March 26 2020 as those Member States who produced PPE introduced export restrictions, the President of the EU Commission, Ursula von der Leyen, opined:⁴

A crisis without borders cannot be resolved by putting barriers between us. And yet, this is exactly the first reflex that many European countries had. This simply makes no

⁴ *Speech by President von Der Leyen at the European Parliament Plenary on the European Coordinated Response to the COVID-19 Outbreak*, European Commission (26 March 2020) https://ec.europa.eu/commission/presscorner/detail/en/speech_20_532.

sense. Because there is not one single Member State that can meet its own needs when it comes to vital medical supplies and equipment. Not one.

As the virus took hold in Europe, some countries imposed limits on the export of PPE regardless of its destination (both intra-and extra-EU) in early March.⁵ In response to the intra-EU export restrictions and as a *quid pro quo* for the agreement to remove barriers to intra-EU trade, on 14 March 2020 the Commission introduced Implementing Regulation 2020/402 outlining a procedure for export authorisations for PPE equipment, defined in Annex I of the Regulation, from the EU.⁶ The Regulation was issued under Article 5(1) of Regulation 2015/479 of the European Parliament and of the Council on common rules for exports which allowed the Commission to make the export of products subject to authorisation “to prevent a critical situation from arising on account of a shortage of essential products.”⁷ It is important to note here that despite Commercial Policy being an area of EU exclusive competence, Article 10 of the Regulation allowed Member States to adopt quantitative restrictions on export on grounds of the protection of the health and life of humans. Nevertheless, in the Commission’s Communication of 13 March entitled *Coordinated economic response to the COVID-19 Outbreak* it emphasised that the Single Market lay at the EU’s heart so that “[i]n times of crisis it is the solidarity instrument to ensure that essential goods necessary to mitigate health risks outbreak can reach all those in need.”⁸

In April 2020 the Commission issued a new Implementing Regulation, Implementing Regulation 2020/568, replacing the initial Regulation, as amended.⁹ The Preamble makes it clear that:¹⁰

It is not the intention of the Union to restrict exports any more than absolutely necessary, and the Union also wishes to uphold the principle of international solidarity in this situation of a global pandemic. Union measures should therefore be proportionate and ensure that exports remain possible, subject to a prior authorisation. To this effect, Member States should grant export authorisations under specific circumstances, where the shipment in question poses no threat to the actual need for PPE within the Union and serves to satisfy a legitimate need for official or professional medical use in a third country. In contrast, Member States should not authorise exports that would create speculative distortion and serve stockpiling and hoarding of essential equipment by those with little or no objective need.

The main objective of the system put in place is to protect public health within the EU. It was emphasised again that authorisations should not pose a threat to PPE availability in the relevant Member State and, as a result of the need to contact the Clearing House established by the

⁵ Measures were taken by countries where production of PPE is concentrated, such as Germany, France, Poland, Bulgaria and the Czech Republic. See Paulette Vander Schueren and others, *EU and EU Member States Impose COVID-19-Related Export Restrictions on Medical and Protective Equipment*, Mayer Brown (17 March 2020) <https://www.mayerbrown.com/en/perspectives-events/publications/2020/03/eu-and-eu-member-states-impose-covid-19-related-export-restrictions-on-medical-and-protective-equipment>.

⁶ [2020] OJ L 77/1. The Regulation was amended by Implementing Regulation 2020/426, [2020] OJ L 84/1.

⁷ [2015] OJ L 83/34.

⁸ COM (2020) 112 final at 3. It also noted that national measures created a domino effect. See also C(2020) 1753 *Guidelines for border management measures to protect health and ensure the availability of goods and essential services*, para 6.

⁹ [2020] OJ L 129/7.

¹⁰ *Id*, Recital 11.

Commission, across the EU. The need to contact the latter is not needed in context of the provision of emergency supplies as part of humanitarian aid.¹¹

In recognition that the single market for PPE is closely integrated beyond the EU, a number of third countries are excluded for the need for export authorisation and this now extends, for example, to the member States of the European Free Trade Association (EFTA) (i.e. Iceland, Liechtenstein, Norway and Switzerland) and the Western Balkans (Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia and Serbia).¹² Third countries beyond Europe even if they had an agreement with the EU were not excluded from the scope of the Regulation. To avoid undermining the objective pursued by the Regulation, the authorities of the excluded countries and territories should make PPE exports available to the EU. Finally, the Commission under Article 5 is to “monitor the situation and, when necessary, review expeditiously the period of application of this Regulation, and its product scope, taking into account the evolution of the epidemiological crisis caused by the COVID-19 disease” and the adequacy of supply and demand in the EU. The April Implementing Regulation reduces the scope of PPE products subject to export authorisation whilst extending the countries excluded from such authorisations. The Trade Commissioner, Mr Phil Hogan, speaking on the adoption of Implementing Regulation 2020/568 noted that:¹³

The scheme reflects our continuing commitment to protect people’s health and support humanitarian actions and the needs of our neighbours or trade partners. We have concluded that a short extension of the export authorisation requirements is consistent with those commitments. This scheme is also fully in line with our commitments at the G20: it is temporary, targeted, proportionate and transparent.

The Implementing Regulation was temporary (under Article 6 it lasts for thirty days) and, in the interests of transparency, would be notified to the WTO.

b. Selected Export Measures from Other Economies

On 18 March 2020, the Australian Government made the *Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) Declaration 2020* noting that COVID-19 had entered Australian territory and that it posed “a severe and immediate threat to human health on a nationally significant scale.”¹⁴ Shortly thereafter the Government amended the Customs (Prohibited Exports) Regulations 1958 prohibiting the export of “equipment that, when worn, is capable of limiting the transmission of organisms to humans.”¹⁵ Among the six exceptions to the prohibition were items exported by a humanitarian organisation, provided the export was not by international mail. The Minister for Home Affairs, Peter Dutton, noted in

¹¹ *Id*, Recital 14 acknowledges the principle of international solidarity. See also Article 2(6) of the Regulation.

¹² *Id*, Article 2(4). The export authorisation requirement does not apply to overseas countries and territories listed in Annex II of the Treaty or to the Faeroe Islands, Andorra, San Marino, the Vatican City and Gibraltar. A number of other customs territories are also excluded, and these include the Principality of Monaco and the territories of Büsingen, Heligoland, Livigno, Ceuta and Melilla.

¹³ *Coronavirus: Commission Adjusts Export Authorisation Scheme for Personal Protective Equipment to Suit Current Needs*, European Commission (24 April 2020) <https://trade.ec.europa.eu/doclib/press/index.cfm?id=2139>.

¹⁴ Paragraph 6(d). The Declaration is available at <https://www.legislation.gov.au/Details/F2020L00266>.

¹⁵ See Customs (Prohibited Exports) Amendment (COVID-19 Human Biosecurity Emergency) Regulations 2020 available at <https://www.legislation.gov.au/Details/F2020L00343>. The items are issue were disposable face masks, disposable gloves, disposable gowns, goggles, glasses or eye visors, alcohol wipes and hand sanitizer.

the Explanatory Statement to the Regulations that they “may engage the right to enjoyment of the highest attainable standard of physical and mental health under Article 12 of *International Covenant on Economic, Social and Cultural Rights*” and “may also engage also the right to life in Article 6(1) of the *International Covenant on Civil and Political Rights*” but also that these rights were not limited to persons in Australia, hence the exceptions.¹⁶ Entering into force on 30 March, this temporary measure will expire when the Declaration is no longer in force; it is currently due to expire on 17 September 2020. The measures were notified to the WTO on 12 May 2020 under the Decision on Notification Procedures for Quantitative Restrictions alongside other restrictions and again, more specifically, on 18 June with Article XI(2)(a) of the GATT being listed as the justification for the measure.¹⁷

Just as Australia was moving to introduce measures to deal with the arrival of COVID-19 on their shores, Thailand notified measures to the WTO.¹⁸ The products covered by the notification included Surgical masks and Face-masks and were set to expire one year after their introduction on 5 February 2020. Just like the Australian notification, the Thai notification cited Article XI(2)(a) of the GATT as a justification for the measure but because it was also accompanied by a notification under Article 12 of the Agreement on Agriculture which covers export restrictions and prohibitions. This notification, which was effective for seven days, was aimed at preventing a critical shortage of chicken eggs in Thailand.¹⁹ Chicken eggs also featured in the list of export restrictions imposed by the Kyrgyz Republic which also included rice, sugar, wheat and meslin, and wheat flour; the latter two products were subject to the export restrictions applied by North Macedonia.²⁰ Further restrictions emerged as Members notified new measures adopted under the Agreement on Technical Barriers to Trade and the Agreement on Sanitary and Phytosanitary measures thus impacting on trade in agri-food products, though it must be noted that more recent measures under these two agreements have focussed on facilitating trade.²¹

Such facilitation can be seen in the measures adopted by China. On 31 March 2020 the China Ministry of Commerce, the National Medical Products Administration (NMPA), and the General Administration of Customs (GAC) issued the Notice on the Orderly Exportation of Medical Supplies, which established new export requirements for Chinese manufacturers and exporters of medical supplies.²² Among the five categories of medical supplies listed in the Notification were medical masks and medical protective clothing with a distinction being made between those manufacturers who has a medical device registration certificate issued by the NMPA and those that did not.²³ Those having the certificate were able to export the relevant medical supplied, subject to an assurance letter under the Notification, without having to be added to the approved list of medical suppliers maintained by the Chinese Chamber of

¹⁶ See <https://www.legislation.gov.au/Details/F2020L00343/Explanatory%20Statement/Text>, Attachment B.

¹⁷ See G/MA/QR/N/AUS/4 and G/MA/QR/N/AUS/4/Add.1.

¹⁸ See G/MA/QR/N/THA/2

¹⁹ Ibid. See also G/MA/QR/N/THA/2/Add.3 which extended the restriction under 30 April 2020. Also notified as G/AG/N/THA/107/Add.1.

²⁰ See G/AG/N/KGZ/8 and G/AG/N/MKD/26.

²¹ See for example, “Members underline importance of facilitating safe agri-food trade in times of crisis”, available at https://www.wto.org/english/news_e/news20_e/sps_24jun20_e.htm.

²² This Notice is referred to as Notification 5, available at <http://www.nmpa.gov.cn/WS04/CL2138/376203.html>. See also the Notice on Further Strengthening the Quality Administration of Exported Epidemic Prevention Supplies, issued on 25 April 2020 covering non-medical masks, which is known as Notification 12. It can be accessed at http://www.gov.cn/zhengce/zhengceku/2020-04/26/content_5506162.htm.

²³ Other categories included testing reagents for COVID-19, ventilators, and infrared thermometers.

Commerce for the import and export of medical supplies. For those not on the list (i.e. those that have not obtained foreign standard certification or registration), under Notification 12 exports were only possible after being added to the list and an export declaration that the products meet the quality standards of the importing country. These measures were notified by China under Articles 1.4 and 10.6.2 of the Agreement on Trade Facilitation.²⁴

c. Relevant WTO Disciplines

On 24 March the WTO Director General called on Members to submit information to the WTO Secretariat about recent trade and trade-related measures adopted in response to the COVID-19 pandemic.²⁵ As of 30 April, the EU has notified the various Implementing Regulations along with the amended guidelines for their implementation.²⁶ Their notifications are among the 46 WTO Members who have introduced export prohibitions or restrictions.²⁷ The G20 Ministerial Statement of 30 March 2020 noted: “We agree that emergency measures designed to tackle COVID-19, if deemed necessary, must be targeted, proportionate, transparent, and temporary, and that they do not create unnecessary barriers to trade or disruption to global supply chains, and are consistent with WTO rules.”²⁸ The relevant WTO rules are contained in Articles XI of the GATT on quantitative restrictions and, assuming a breach of a GATT provision, Article XX of the GATT on general exceptions.

The relevant provisions of Article XI of the GATT provide that: “No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through ... export licences or other measures, shall be instituted or maintained by any contracting party ... on the exportation or sale for export of any product destined for the territory of any other contracting party” but this prohibition in paragraph 1 according to paragraph 2 does not extend to “export ... restrictions temporarily applied to prevent or relieve critical shortages of ... other products essential to the exporting contracting party.” Examining these provisions, in the context of a complaint which included one on an export licensing requirement, the Appellate Body in *China – Raw Materials* concluded:²⁹

The term “prohibition” is defined as a ‘legal ban on the trade or importation of a specified commodity.’ The second component of the phrase ‘export prohibitions or restrictions’ is the noun ‘restriction’, which is defined as ‘a thing which restricts someone or something, a limitation on action, a limiting condition or regulation’, and thus refers generally to something that has a limiting effect.

²⁴ G/TFA/N/CHN/2/Rev.3.

²⁵ WTO, *DG Azevêdo Requests WTO Members to Share Information on Trade Measures Related to COVID-19*, https://www.wto.org/english/news_e/news20_e/dgra_24mar20_e.htm.

For a general overview of trade in medical goods see WTO, *Trade in Medical Goods in the Context of Tackling COVID-19*, https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf. See also more generally G/L/59/Rev.1 General Council Decision on Notification Procedures for Quantitative Restrictions.

²⁶ WTO, *COVID-19: Trade and Trade-Related Measures*, *supra* note 2. See also notifications in G/MA/QR/N/EU/4/Add.1 and G/TFA/N/EU/1/Rev.2.

²⁷ WTO, *Export Prohibitions and Restrictions: Information Note*, *supra* note 2, at 6. See also WTO *Report on G20 Trade Measures (Mid-October 2019 to May 2020)* *supra* note 2 for information on the G20.

²⁸ *G20 Trade and Investment Ministerial Meeting Ministerial Statement* https://g20.org/en/media/Documents/G20SS_Statement_Trade%20&%20Investment%20Ministerial%20Meetin%20g_EN.pdf.

²⁹ WT/DS394/AB/R, WT/DS395/AB/R, and WT/DS398/AB/R, para 319. Complaints by the US, Mexico, and the EU.

In this dispute China argued that Article XI:2(a) of the GATT was applicable and in response, the Appellate Body indicated that the phrase “temporarily applied” describes a time-limited measure (“a measure taken to bridge a passing need”) and that “critical shortage” refers to “those deficiencies in quantity that are crucial, that amount to a situation of decisive importance, or that reach a vitally important or decisive stage, or a turning point.”³⁰ The Appellate Body also concluded that if the conditions of Article XI:2(a) of the GATT were met, as no obligation to eliminate quantitative restrictions exists, there is no scope for the application of Article XX of the GATT.³¹

Assuming a breach of a GATT provision, recourse may then be had to Article XX of the GATT with the jurisprudence of the GATT and the WTO suggesting that there is a two-tiered test; a measure must fall within one of the exceptions listed in paragraphs (a) to (j) before an examination of the measure under the chapeau of Article XX.³² With respect to the export restrictions, the most obvious exception to invoke is paragraph (b) – measures necessary to protect human life or health. In their examination of this paragraph in *Brazil – Retreaded Tyres*, the Appellate Body indicated:³³

In order to determine whether a measure is 'necessary' within the meaning of Article XX(b) of the GATT 1994, a panel must assess all the relevant factors, particularly the extent of the contribution to the achievement of a measure's objective and its trade restrictiveness, in the light of the importance of the interests or values at stake. If this analysis yields a preliminary conclusion that the measure is necessary, this result must be confirmed by comparing the measure with its possible alternatives, which may be less trade restrictive while providing an equivalent contribution to the achievement of the objective pursued.

The Appellate Body went on to note that in the process of weighing and balancing these factors, it must be remembered that the protection of human health is “both vital and important in the highest degree.”³⁴

Although no Member has yet cited paragraph (j) in their notification, it is possible justification for export restrictions as it allows for measures “essential to the acquisition or distribution of products in general or local short supply.” There are also two additional requirements in paragraph (j) namely that the measure must “be consistent with the principle that all Members are entitled to an equitable share of the international supply of the products concerned” and that “the measures be discontinued as soon as the conditions giving rise to them have ceased to exist.”³⁵ This paragraph was interpreted for the first time in *India – Solar Cells* in which the Appellate Body indicated that it would use the analytical framework used in the interpretation of paragraph (d), however, a more stringent analysis was dictated by the addition of the word “essential”.³⁶ As for the analysis inherent in the phrase “products in general or local short supply”, the Appellate Body concluded that such analysis:³⁷

³⁰ *Id.*, para 323 and para 326.

³¹ *Id.*, para 334.

³² See for example WT/DS2/AB/R, *US – Gasoline* at 22.

³³ WT/DS332/AB/R, para 156.

³⁴ *Id.*, 179.

³⁵ See also decision in WT/DS476/R, *EU – Energy Package*, para 7.247.

³⁶ WT/DS456/AB/R, para 5.60 and 5.62.

³⁷ *Id.*, para 5.83.

... may, in appropriate cases, take into account not only the level of domestic production of a particular product and the nature of the products that are alleged to be ‘in general or local short supply’, but also such factors as the relevant product and geographic market, potential price fluctuations in the relevant market, the purchasing power of foreign and domestic consumers, and the role that foreign and domestic producers play in a particular market, including the extent to which domestic producers sell their production abroad. Due regard should be given to the total quantity of imports that may be ‘available’ to meet demand in a particular geographical area or market.

The relevance of these various factors would depend on the facts of each case.

Having satisfied the first part of the two-tier test, the measure must also satisfy the requirements of the chapeau of Article XX of the GATT, i.e. it must be shown that the measure is not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade. The purpose of the chapeau is to ensure that measures provisionally justified under one of the paragraphs do not constitute an abuse of that provision.³⁸ It was made clear in the early dispute *US – Gasoline* that the concepts used in the chapeau were related concepts and “imparted meaning to one another” with the concept of “discrimination” having a meaning different from that in substantive rules such as Articles I (the most-favoured-nation treatment), III (national treatment) and XI of the GATT.³⁹

One further potentially applicable GATT provision is Article XXI:2(b)(iii) which provides that: “Nothing in this Agreement shall be construed ... (b) to prevent any contracting party from taking any action which it considers necessary for the protection of its essential security interests ... (iii) taken in time of war or other emergency in international relations.” This provision has been subjected to interpretation by the Panel in *Russia – Traffic in Transit* and it concluded that it had jurisdiction to evaluate measures taken under Article XXI of the GATT i.e. it was not self-judging (non-justiciable) as argued by Russia.⁴⁰ As for the interpretation of the provision at issue (Article XXI(b)(iii)), the Panel emphasised the objective nature of this provision and that “essential security interests” was to be understood “to refer to those interests relating to the quintessential functions of the state, namely, the protection of its territory and its population from external threats, and the maintenance of law and public order internally.”⁴¹ The Panel continued to note that there is an “obligation to interpret and apply Article XXI(b)(iii) of the GATT “in good faith” with “emergency in international relations” being an objective determination which includes a situation of “heightened tension or crisis, or of general instability engulfing or surrounding a state.”⁴² One question that arises here is whether the declaration in January by the WHO Director General, Dr Tedros Adhanom Ghebreyesus, that declared the COVID outbreak is a Public Health Emergency of International Concern would be sufficient to constitute an emergency in international relations sufficient for the purposes of Article XXI:2(b)(iii) of the GATT.⁴³

³⁸ See for example, WT/DS58/AB/R *US – Shrimp*, paras 157-159.

³⁹ WTO, *supra* note 17 at 25.

⁴⁰ WT/DS512/R, paras 7.57 and 7.58.

⁴¹ *Id.*, para 7.130.

⁴² *Id.*, paras 7.132 and 7.76.

⁴³ See WHO, *WHO Director-General’s Statement on IHR Emergency Committee on Novel Coronavirus (2019-NCoV)* (30 January 2020) [https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ih-er-emergency-committee-on-novel-coronavirus-\(2019-ncov\)](https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ih-er-emergency-committee-on-novel-coronavirus-(2019-ncov)).

d. Concluding Remarks

Speculating on the WTO-compatibility of the measure adopted by the EU, Australia and Thailand, the export restrictions on PPE may well be compatible with the GATT; questions may arise about the impact of the additional measures adopted by Thailand under the Agreement on Agriculture.⁴⁴ As for the measures introduced by the EU, it should be noted that the introduction by Members States of the EU of individual measures to deal with PPE shortages arising from the outbreak of COVID-19 represented a fracture of the integrity of the single market which was reset by the introduction of Implementing Regulation 2020/402 which was duly notified to the WTO. Examination of the relevant WTO disciplines suggest that this original measure (and those taken by Australia and Thailand) were consistent with Article XI:2(a) of the GATT rendering recourse to Articles XX(b) of the GATT (or even Article XX(j) of the GATT) unnecessary. However, with respect to the EU measures when the Regulation was amended through the introduction of Implementing Regulation 2020/426, the introduction of provisions excluding countries from export authorisations (e.g. member states of EFTA) introduced a WTO-incompatible element. The quantitative restrictions permissible under Article XI of the GATT were no longer being administered equally across all non-EU members as required by Article XIII of the GATT, which requires the application of the principle of non-discrimination to the application of quantitative restrictions, thus raising the question of whether the measures could be excepted under Articles XX or XXI of the GATT.

It is clear that they could be excepted under Article XX(b) of the GATT as a measure necessary to protect public health but it may be doubted whether the measure could satisfy the terms of the chapeau given that it introduced an element of discrimination. As for its compatibility under Article XX(j) of the GATT, there is little doubt that PPE was in short supply but whether the other conditions of that paragraph were satisfied is a much more open question. Overall, it appears that Implementing Regulation 2020/426 and its successor, Implementing Regulation 2020/568, which extended the geographical discrimination, would fail to satisfy the requirement of Article XX of the GATT. The same conclusion cannot be reached were Article XXI of the GATT to be invoked to justify the measure given, in comparison to Article XX of the GATT, the greater discretion accorded to Members under this provision.

The measures taken by China fall under a different agreement as they can be classified as measures to assure the quality of exports which is a legitimate objective of the TBT Agreement. Notifications 5 and 12 focusses on standard certification or registrations in third countries; for example, for those manufacturers not on the approved list of medical suppliers maintained by the Chinese Chamber of Commerce for the import and export of medical supplies, exports are still possible if certification or registration has been obtained in a third country.⁴⁵ This raises the question of import facilitation to which the discussion now turns.

The legality of export restrictions, in particular export bans and quantitative restrictions of PPE and other essential relief products amidst the COVID-19 has exposed limitations of the international trade law. When the crisis struck, trade literally meant saving lives. For countries, particularly developing and least developed countries without domestic technological and

⁴⁴ These are addressed in Fu, J and McMahon J “An unexpected outcome? Trade in Agri-Food Products under the Shadow of COVID-19” (forthcoming).

⁴⁵ The Notification referenced foreign standard certifications or registrations in the US (Food and Drug Administration and National Institute for Occupational Safety and Health), the EU (CE - *Conformité Européenne*), Australia (the Therapeutic Goods Administration of Australia) and Japan (the Pharmaceuticals and Medical Devices Agency).

manufacturing base, the effect of halting PPE exports by major producers is likely to be devastating. A legal analysis of international trade of PPE has demonstrated the inadequacy of the global trading system to guarantee global access to essential supplies during an emergency. The current multilateral trading system does not guarantee access to such life-saving essential supplies for countries that lack the capacity to produce them and the international trade law is inadequate as a basis for international cooperation in times of emergency. Developing countries that are reliant on imports of essential relief supplies may need to include PPE and other medical products into their strategic national stockpile and stabilise their own value chain by diversifying its imports and exports, with a focus on essential relief products.

III. PPE Import Facilitation

There are signs that trade-restrictive measures adopted in the early stages of the pandemic are starting to be rolled back, the WTO's latest report on trade measures points to significant moves to facilitate imports, including products related to COVID-19. In the context of the unprecedented levels of demand for PPE, governments have also taken dozens of measures to facilitate imports in the global scramble for PPE. Besides the most commonly applied measure of reducing of tariffs, VAT and customs fees, major jurisdictions have also applied measures to streamline registration and approval requirements to deal with relevant technical barriers to PPE trade (See Figure 1 above).

Technical barriers to trade (TBT) measures include technical regulations, standards and conformity assessment procedures.⁴⁶ TBT vary from country to country. They are necessary for a range of reasons, including to ensure the quality of exports, or for the protection of human, animal, and plant life or health, of the environment or for the prevention of deceptive practices.⁴⁷ However, they also create significant costs for producers and exporters to understand a myriad of foreign regulations and standards and to adjust production facilities to comply with these requirements. The WTO's TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade.⁴⁸ The TBT Agreement urges Members to use internationally agreed standards and give positive consideration to accepting the equivalent technical regulations of other Members, provided that the technical regulations adequately fulfill the objectives of their own regulations.⁴⁹ The TBT Agreement also explicitly implies recognition of conformity assessment procedures undertaken by designated conformity assessment bodies (CABs) in the territory of another Member in accordance with applicable technical regulations.⁵⁰ That being said, some studies have shown the general upward trend in the number of TBT notifications to the WTO over the years.⁵¹ The TBT issues are more pronounced when it comes to COVID-related PPE.

a. Technical Barriers to PPE Trade

⁴⁶ WTO, Technical Barriers to Trade, https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm.

⁴⁷ TBT Agreement, Preamble.

⁴⁸ *Id.*, Article 2.2.

⁴⁹ *Id.*, Articles 2.6 and 2.7.

⁵⁰ *Id.*, article 6.1.

⁵¹ Rajan Sudesh Ratna, 'Handling Non-Tariff Measures in RTAs: Case of ASEAN and SAARC', *Trade, Investment and Economic Development in Asia* (Routledge 2016).

1. The EU

Most PPE falls within the scope of EU Regulation 2016/425 on personal protective equipment (PPE Regulation).⁵² Some types of products that appear to be similar to PPE may actually be regulated as medical equipment if their main purpose is to protect patients from the doctor (surgical masks and medical gowns, for instance), and therefore fall into the purview of Directive 93/42 – the Medical Devices Directive (MD Directive).⁵³ Both pieces of legislation lay down very demanding requirements for the technical design, manufacture and sale of the equipment, and particularly high standards when it comes to health and safety requirements. In certain instances, depending on the type of PPE and their intended purpose, face masks and gloves may meet the definitions under both the PPE Regulation and the MD Directive. These products are considered to have a dual purpose. According to the guidelines from the European Commission, such products are covered by the MD Directive and must comply with the legal requirements of this Directive. In addition, the relevant basic health and safety requirements of the PPE regulation shall also be fulfilled.⁵⁴

PPE imported from outside the EU has to undergo a conformity assessment procedure, in order to determine whether the products comply with the relevant harmonized EU technical standards. CE (Conformité Européenne) marks can only be affixed after completion of the conformity assessment operated by non-governmental bodies (so-called “notified bodies”) accredited via the European Co-operation for Accreditation system (EA), designated by Member States, and listed by the European Commission.⁵⁵ PPE regulated by the PPE Regulation, in the context of COVID-19, falls under the “complex PPE” category (CAT III) as it is intended for use in protecting against mortal danger or risks that could seriously and irreversibly harm the wearer’s health.⁵⁶ In this case, products from third countries need to go through a review of their submitted technical documentation,⁵⁷ the “EU-type examination Module B”, for initial product approval in order to ensure the products meet all relevant essential health and safety requirements,⁵⁸ and on-going surveillance through testing (Module C2) or factory auditing (Module D) by a designated notified body to ensure that the actual versions of the item produced continue to comply with the sample that was approved by the EU-type examination.⁵⁹ All of which means that it takes months to complete the entire conformity assessment procedure.

⁵² Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC, [2016] OJ L/81.

⁵³ Council Directive 93/42/EEC concerning medical devices, [1993] OJ L/193/1. Given the current pressure on national health authorities and manufacturers of medical devices, there is a fear that there could be shortages or delays in getting the medical devices needed to fight COVID-19. The European Parliament adopted the Commission proposal but decided to postpone the application of the Medical Devices Regulation 2017/745 by one year until 26 May 2021. See European Parliament, *Parliament Decides to Postpone New Requirements for Medical Devices* (Apr.17, 2020).

⁵⁴ European Commission, *PPE Regulation Guidelines: Guide to Application of Regulation EU 2016/425 of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment and Repealing Council Directive 89/686/EEC* (Apr. 2018).

⁵⁵ Anabela Correia de Brito, Céline Kauffmann and Jacques Pelkmans, ‘The Contribution of Mutual Recognition to International Regulatory Co-Operation’ (2016) No.2 OECD Regulatory Policy Working Papers.

⁵⁶ PPE Regulation, *supra* note 52 at Annex I.

⁵⁷ *Id.*, Annex III

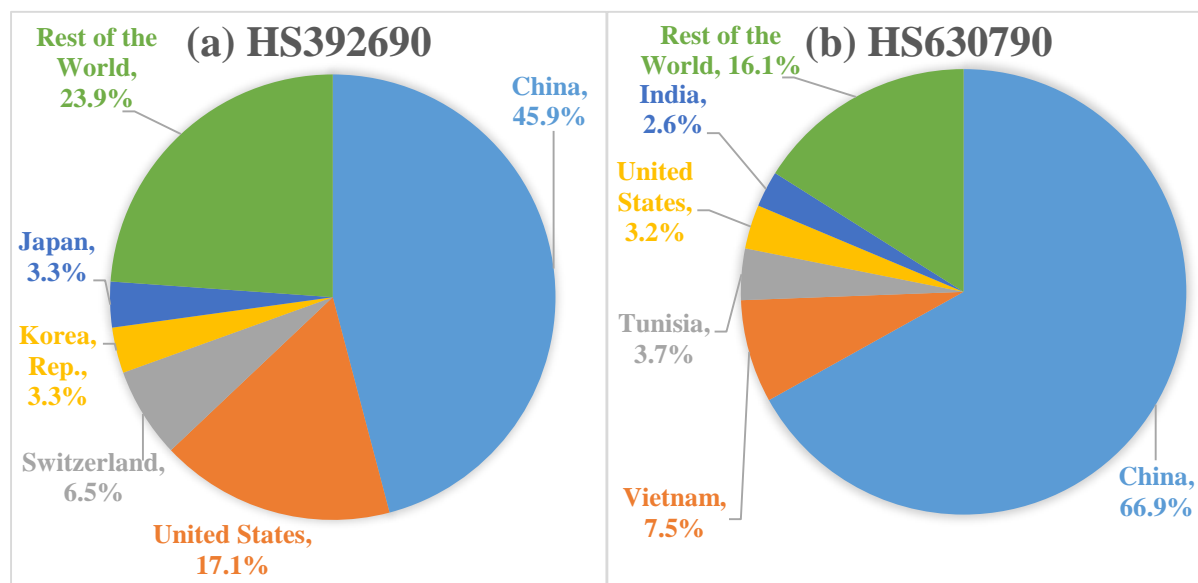
⁵⁸ *Id.*, Annex II

⁵⁹ *Id.* Article 19.

Some PPE such as surgical face masks and surgical gloves that are intended to protect patients and to be used in a medical or surgical setting are classified as Class I medical devices and should be CE marked in accordance with the essential requirements of the MD Directive. These devices require an accredited notified body in the area of medical devices to oversee whether they are sterile devices. It also takes months to complete the entire conformity assessment procedures.

Before the pandemic, the intra-EU imports of HS 392690 and HS 630790 take up approximately 70% and 40% of the EU’s total imports, while imports from third countries account for 30% and 60% of the total import volume (See Figures 3(a)-3(f)).⁶⁰ As of 13 March 2020, the WHO considered Europe the active center of the COVID-19 pandemic and the reported number of confirmed cases in Europe has exceeded over 1.3 million by early May,⁶¹ the EU is in critical shortage of PPE. The escalation of the pandemic in addition to the supply chain bottlenecks including transport constraints caused by roadblocks and the lower availability of transportation, as well as reduced workforce capacity due to illness and social distancing further contribute to the shortage.

Figure 3(a) &3(b): EU Imports of HS 392690 (including respirators) and HS630790 (including face masks and surgical masks) in 2019



⁶⁰ The authors’ calculation based on the EUROSTAT trade data.

⁶¹ ECDC, *COVID-19 Situation Update Worldwide, as of 4 May 2020*, European Centre for Disease Prevention and Control, <https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases>.

Figure 3(c) & 3(d): EU Imports of HS900490 (including protective goggles) and EU Imports of HS621010 (including protective gowns and surgical gowns) in 2019

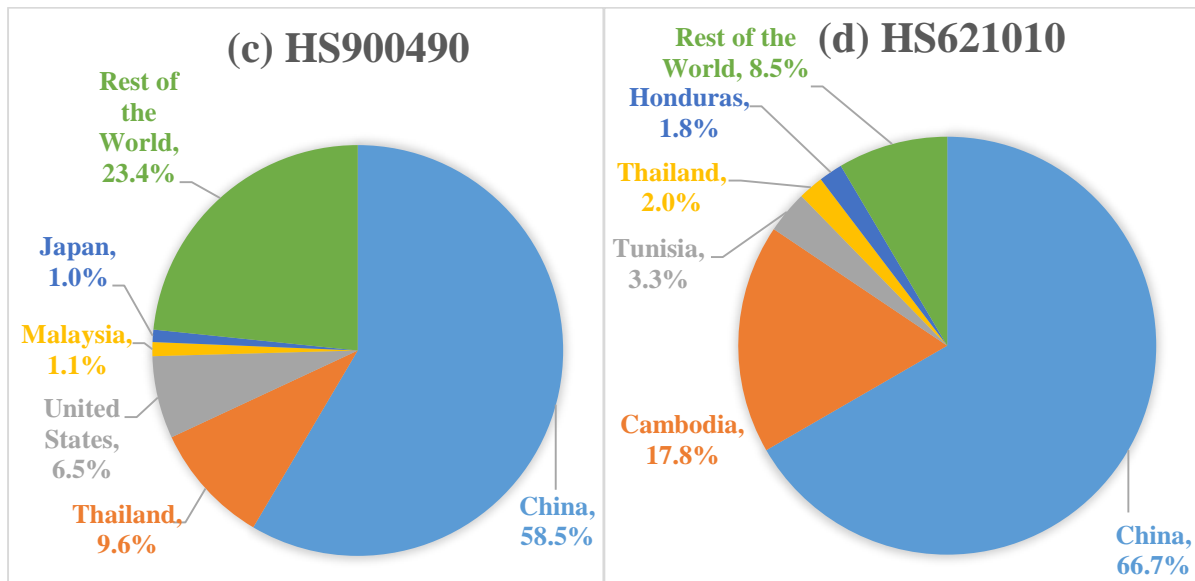
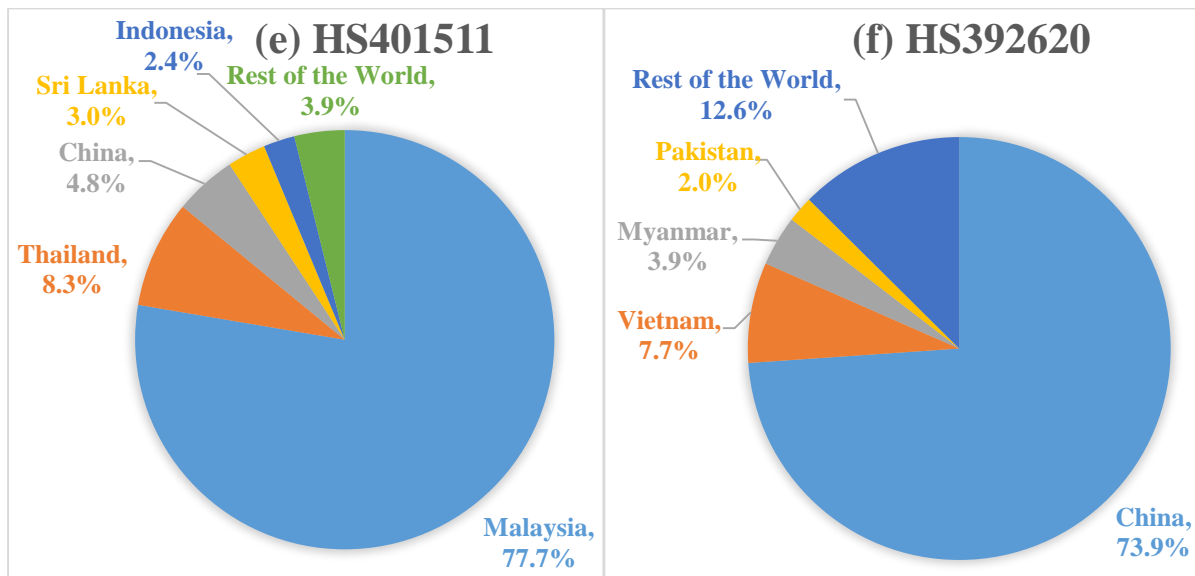


Figure 3(e) & 3(f): EU Imports of HS401511 (including surgical gloves) and EU Imports of HS392620 (including protective suits) in 2019



Source: Authors' calculation and depictions using data from World Integrated Trade Solution (WITS)

According to the European Safety Federation, in addition to fake documents presented as proof of compliance, issues tend to arise with regard to invalid conformity assessment when it comes to imports of PPE from third countries (See EU's major importing country-of-origins in figures 3(a)-3(f). Firstly, some CE markings are invalid because the notified body performing the conformity assessment does not cover PPE, but other products, or the notified body is accredited for some types of PPE but not for others. For instance, it may not be accredited for

respiratory protection (masks).⁶² Secondly, certificates issued by a non-EU conformity assessment body (such as by a Chinese or Indian institute) regarding an EU technical regulation is not a legally valid type examination certificate. For economies that do not have a Mutual Recognition Agreement (MRA) with the EU on PPE, certificates can only be issued by a Commission-listed EU notified body accredited for the relevant type of PPE. The “certificates” issued by such organizations cannot provide a legal basis for a CE marking nor for placing the PPE on the EU market.

2. The US

In the US, most COVID-related PPE is regulated by the US Food and Drug Administration (FDA) as “medical devices” including medical gloves, N95 respirators, surgical gowns and surgical masks. The 1976 Medical Device Amendments to the Federal Food and Drug and Cosmetic Act (FD&C) established a system under which medical devices are brought to market. In order to market a medical device in the US, manufacturers are required to go through the pre-market notification requirement (often referred to as 510(K)) described in Code of Federal Regulations (CFR) Title 21.⁶³ Specifically, foreign manufacturers and initial importers must comply with two primary requirements in order to lawfully export PPE to the US: registration of the establishment and listing of products as well as the activities that are performed on those devices. The FDA analyzes the product applications of the manufacturer, to ensure that similar devices already exist on the market. After the 510(k) clearance, the manufacturer should be prepared for an FDA quality system (21 CFR 820) inspection at any time.⁶⁴ Devices are subject to various degrees of assessments, depending on their risk classification. Surgical masks and respirators come under Class II product under the FD&C, which requires general controls as well as special controls.⁶⁵

Another government agency that deals with PPE used for non-medical purposes is NIOSH. As part of the Centers for Disease Control and Prevention (CDC), NIOSH runs several programs on PPE conformity assessment before products enter the market. Some programmes also conduct post-market activities including investigation and auditing of certified product.⁶⁶ When it comes to N95s filtering facepiece respirators (intended for use in healthcare settings), NIOSH and the FDA have joined forces to help reduce duplicative premarket processes. Since 2018, NIOSH has been responsible for approving the use of N95s in accordance with relevant federal regulations.⁶⁷ Manufacturers can submit a single application to NIOSH, rather than applications to both the FDA and NIOSH prior to marketing their product.⁶⁸

There have been very few exporters of PPE during the pandemic, and importers are extraordinarily dependent on the small number of exporters who already have existing sales channels. The complication of divergent technical regulations (these also include

⁶² *COVID-19: Suspicious Certificates for PPE*, European Safety Federation (29 April 2020) <https://www.esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe>.

⁶³ See 21 CFR part 807 *Establishment, Registration and Device Listing for Manufacturers and Initial Importers of Devices*.

⁶⁴ See *Surgical Masks - Premarket Notification [510(k)] Submissions Guidance for Industry and FDA Staff*, FDA-2003-D-0305 (2004).

⁶⁵ See 21 CFR 878.4040.

⁶⁶ See *NIOSH Program Portfolio* <https://www.cdc.gov/niosh/programs/ppt/>

⁶⁷ 42 CFR Part 84 *Respiratory Protective Devices*.

⁶⁸ See CDC, *NIOSH and FDA Collaboration Streamlines Regulatory Oversight for N95 Filtering Facepiece Respirators* (May 17, 2018) <https://www.cdc.gov/niosh/updates/upd-05-17-18.html>

documentation, packaging and labelling requirements in different exporting destination) and conformity assessment requirement, as well as their adaptation costs make it difficult for manufactures to fulfill within the limited timeframe.

According to the WITS data, the US relies heavily on the global supply chain of PPE (see Figures 4(a)-4(f) below). Without MRAs on conformity assessment, PPE manufacturers in the US's top importing countries of origin can only go through the registration and assessment procedures with NIOSH or FDA. This also explains a couple of failed or incomplete deals for PPE between the US and a number of foreign manufactures, including the delayed US \$1 billion deal with BYD, a Chinese energy vehicle company – which turned its facility into the world's largest face masks plant during the outbreak – due to failure to obtain certification within a short period of time.⁶⁹

Figures 4(a) &4(b): US Imports of HS392690 (including respirators) and US Imports of HS630790 (including face masks and surgical masks) in 2019

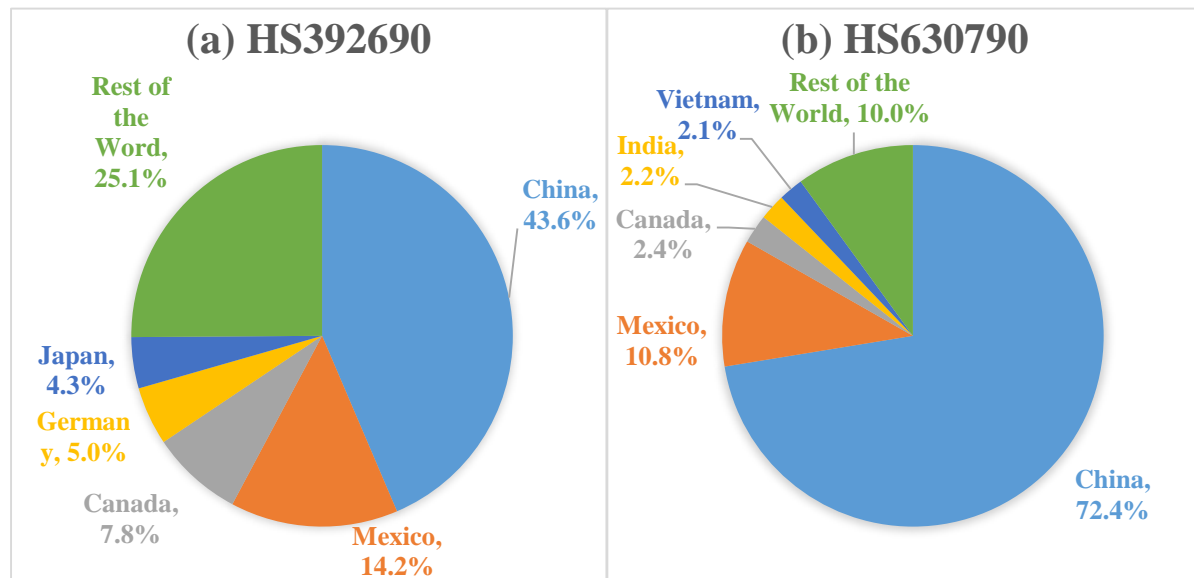


Figure 4(c) &4(d): US Imports of HS401511 (including surgical gloves) and US Imports of HS392620 (including protective suits) in 2019

⁶⁹ Liza Lin and Eva Xiao, *China's BYD Gets Extension on \$1 Billion California Mask Deal*, WALL STREET JOURNAL (Jun. 3, 2020).

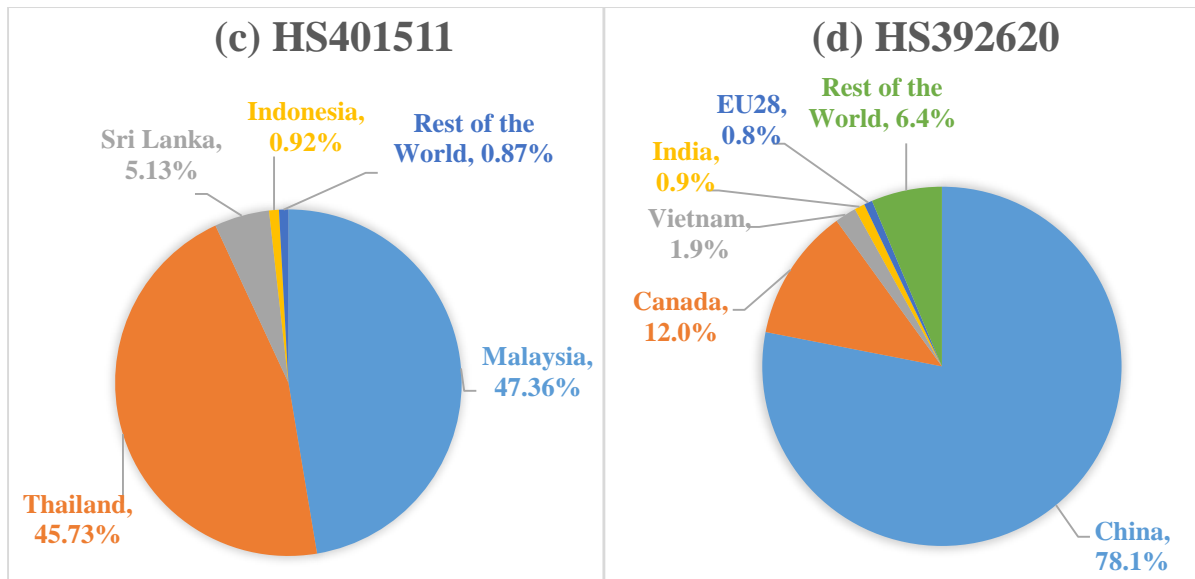
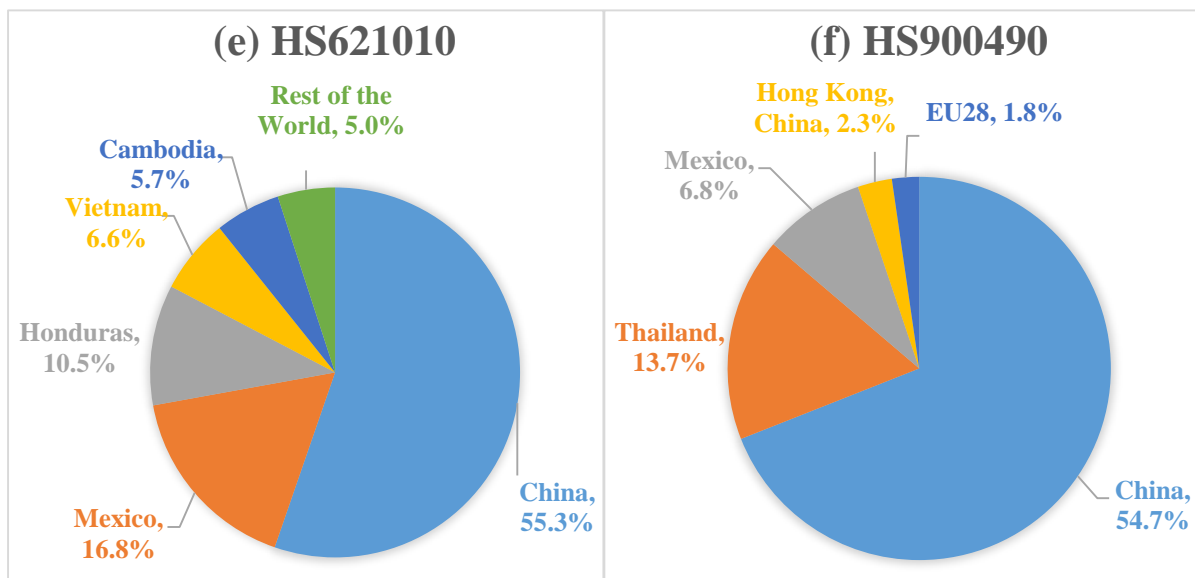


Figure 4(e) & 4(f): US Imports of HS621010 (including protective gowns and surgical gowns) and US Imports of HS900490 (including protective goggles) in 2019



Source: Authors' calculation and depictions using data from World Integrated Trade Solution (WITS)

Faced with the challenges of diverging technical regulations and conformity assessment procedures of PPE in different jurisdictions, China, in the early stage of the outbreak, issued guidelines on emergency imports of PPE in the context of COVID-19. It allowed relevant products from the US, the EU, Korea and Japan which are not yet registered with China Medical Products Administration against relevant Chinese standards, provided that manufacturers could provide test results according to their relevant domestic technical regulations, and a Declaration of Conformity as a written assurance of conformity to their individual applicable technical regulations.⁷⁰ The US explicitly listed countries, their relevant technical standards and the acceptable product classification to be used in lieu of relevant

⁷⁰ See Green Lane: Emergency Imports of Medical Devices Unregistered with CFDA (originally published in Chinese) MedtechChina (Feb. 11, 2020)

National Institute for Occupational Safety and Health (NIOSH)-certified products.⁷¹ The European Commission has also published a recommendation on conformity assessment and market surveillance procedures and now accepts PPE that has been manufactured according to technical solutions, other than harmonized EU standards and has also implemented a quicker conformity assessment procedure in order to facilitate the faster cross-border movement of PPE.⁷² These temporary trade facilitation measures of recognition are, in essence, techniques to address technical barriers to trade from the point of view of diverging technical regulations and facilitates market access without affecting domestic risk regulations.

b. Mutual Recognition under International Trade Law to Facilitate PPE Imports

Mutual recognition in many areas and on different levels requires different forms of engagement.⁷³ Above all, there are two types of mutual recognition: mutual recognition of rules and mutual recognition of conformity assessments.

1. Recognition of Rules

The economic advantages and the strategic gains associated with the mutual recognition of rules have been widely discussed, in particular among scholars in the EU. The advantage is often referred to as “favor”, “privilege” or “immunity” in the literature.⁷⁴ Even if the detailed specification of the relevant regulation differ between the importing country and the exporting country, as long as the regulatory objectives are equivalent, products are automatically exempted from the application of national technical regulations of the importing country, and exporters do not need to face the adaptation cost of having to comply with different national standards.⁷⁵ In other words, the regulation falls exclusively under the responsibility of the home country and market access can be far more easily and quickly obtained compared to the traditional approaches of approximation. The MR of rules also forces Members to rethink their national regulatory solutions and to focus on what is essential,⁷⁶ and it plays an important role in the harmonization of standards. For instance, outside the EU, Members of the Association of Southeast Asian Nations (ASEAN) have harmonized their standards for over twenty priority products including medical gloves.⁷⁷ However, MR of rules usually requires sufficient knowledge and close integration between different regulatory systems, which inevitably imposes significant negotiation costs on governments and the progress is usually very slow.

⁷¹ CDC, Strategies for Optimizing the Supply of N95 Respirators, Center for Disease Control and Prevention (updated April 2, 2020). For Non-NIOSH Approved Respirator Emergency Use Authorization see <https://www.fda.gov/media/136664/download>

⁷² Commission Recommendation 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat, [2020] OJ L 79/1.

⁷³ Correia de Brito, Kauffmann and Pelkmans (n 55).

⁷⁴ Lorand Bartels, ‘The Legality of the EC Mutual Recognition Clause Under WTO Law’ (2005) 8 Journal of International Economic Law 691.

⁷⁵ Susanne K Schmidt, ‘Mutual Recognition as a New Mode of Governance’ (2007) 14 Journal of European Public Policy 667.

⁷⁶ Jacques Pelkmans, ‘Mutual Recognition in Goods and Services: An Economic Perspective’ in Fiorella Kostoris Padoa Schioppa (ed), *The Principle of Mutual Recognition in the European Integration Process* (Palgrave Macmillan UK 2005).

⁷⁷ ASEAN, ASEAN Cooperation on Standards and Conformance to Facilitate Trade in the Region <https://asean.org/asean-economic-community/sectoral-bodies-under-the-purview-of-aem/standards-and-conformance/>

Measures taken by China, the EU and the US, although they are temporary in nature and only valid in emergency situations, recognize conformity assessment as well as relevant technical regulations in other jurisdictions. However, unlike the US that refers to acceptable standards from certain listed jurisdictions, the EU Recommendation refers to the WHO recommendations on the appropriate selection of PPE.⁷⁸ In most of the cases, the WHO recommendation refers to only the US standard and the EU standard and uses the term “or equivalent” in the technical specification column. Without explicitly listing other equivalent standards in either the EU or the WHO Recommendations, most of the notified bodies, in practice, still require conformity assessment to be done according to the relevant EU standards and even to provide test reports against relevant EU standards as a prerequisite to initiating the conformity assessment procedures. This requirement places a huge burden for the PPE suppliers from third countries, especially from top exporters including China, Thailand and Malaysia.⁷⁹

2. Mutual Recognition of Conformity Assessment

Compared to mutual recognition of rules, mutual recognition of conformity assessments is much less ambitious and does not imply cooperation on the content of the rules. It refers to the recognition of each other’s competence to perform testing and certification that is of no less quality than as it would be if performed by authorities in the importing country. MRAs that facilitate mutual market access by eliminating duplicative testing and certification have emerged in the international trade regime. To date, there are over 160 Free Trade Agreements (FTAs) that incorporate MRAs in the agreement,⁸⁰ and most of them promote the conclusion of mutual recognition of conformity assessments as one amongst several options.⁸¹ In the case of COVID-related PPE, there are only some successful cases of MRAs. The US has only concluded an MRA in the field of medical devices with the EU, while the EU has clearly demonstrated its preference for negotiating MRAs, including those with Australia, New Zealand, Switzerland, and the US on medical devices and when it comes to legally defined PPE with Switzerland.⁸² The ASEAN Agreement on Medical Device Directive is another landmark MRA that achieves the goal of “one test and registration, accepted everywhere”.⁸³

It is worth noting that the TBT Agreement encourages the use of MRAs when appropriate, without providing any rules with regard to the origin of the product. Most of the MRAs remain silent on whether origin-based bias exists. The Medical Devices Annex to the EU-US MRA explicitly expressed the aim of facilitating bilateral trade and the interest of SMEs in the EU and the US.⁸⁴ However, it does not directly touch upon the issue of where the products are manufactured. The scope of the agreement applies only to the exchange and endorsement of

⁷⁸ WHO, Rational Use of Personal Protective Equipment for Coronavirus Disease 2019 (COVID-19) https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPPE_use-2020.1-eng.pdf. For PPE specification, see WHO, Disease Commodity Package - Novel Coronavirus (COVID-19), WHO, WHO/2019-nCoV/DCPv3/2020.4 (2020) [https://www.who.int/publications-detail/disease-commodity-package--novel-coronavirus-\(ncov\)](https://www.who.int/publications-detail/disease-commodity-package--novel-coronavirus-(ncov)).

⁷⁹ ADB, ‘Global Shortage of Personal Protective Equipment amid COVID-19: Supply Chains, Bottlenecks, and Policy Implications’ (2020).

⁸⁰ WTO, *Regional Trade Agreements Database* <https://rtais.wto.org/UI/PublicMaintainRTAHome.aspx>.

⁸¹ Correia de Brito, Kauffmann and Pelkmans (n 55)..

⁸² Medical device and PPE are listed as the priority sector for EU-Canada MRA. See Annex 2 of the Protocol on Mutual Acceptance of the Results of Conformity Assessment in the Comprehensive Economic and Trade Agreement. For the MRA with Switzerland on PPE, [2007] OJ L 32.

⁸³ ASEAN Medical Device Directive, articles 5 and 6.

⁸⁴ EC-US MRA, Preamble.

quality evaluation system, product evaluation and post-market vigilance reports produced by the EU CABs against the US regulatory requirements, and *vice versa*.⁸⁵

There are some nuances when it comes to the scope and coverage in the Annex on medical devices to the EU-New Zealand MRA, which explicitly limits products to specific origin. Conformity assessment procedures can only be recognized for medical devices manufactured in the EU for export to New Zealand and those manufactured in New Zealand for export to the EU.⁸⁶ In this case, surgical masks from China, India and Vietnam, for instance, that follow the EU-type examination carried out by an accredited CAB in New Zealand would not get similar access to the EU market as products manufactured in New Zealand, even if they are fully compliant with the MD Directive and PPE Regulation and could pass relevant EU-type examinations.

Such origin-based bias might lead to a conflicting regime to Article I:1 of the GATT on most-favored-nation (MFN), which “immediately and unconditionally” accords “like products” from all WTO members the same treatment as the most advantageous treatment granted by any Member to any product originating in or destined for any other country.⁸⁷ Nevertheless, the GATT provides justifications for MFN-inconsistent measures under the regional integration clause (Article XXIV of the GATT). The application of the Article XXIV of the GATT exception of MRAs is not favored by some scholars who repeatedly questioned the legality of MRAs.⁸⁸

The origin-based restriction limits the benefit of recognized conformity assessment to products from Contracting Parties only and provides restrictions for products manufactured in the non-preferential area. This is more likely to create WTO-inconsistency as the “advantage” is explicitly based the origin of the products rather than the applicable rules or the capacity and credibility of CABs for undertaking relevant conformity assessment. This can further be backed by the Appellate Body’s finding in the *Canada-Auto* dispute that differential treatment of products originating from different Members violated Canada’s obligations under Article I:1 of the GATT.⁸⁹ The Appellate Body also emphasized the objective of the prohibition of discrimination in Article I:1 of the GATT, which serves as an incentive for concessions, negotiated reciprocally, to be extended to all other Members on an MFN basis to support its interpretation.⁹⁰ Given the pervasive character of the MFN principle of non-discrimination, any advantage that treat “like products” differently due to recognition arrangement might be problematic.

The EU-Canada Comprehensive Economic and Trade Agreement (CETA) contains a protocol on mutual acceptance of the results of conformity assessments (EU-Canada MRA), with eleven sectors incorporated and an additional six sectors, including both PPE and medical devices, identified as being priority categories of goods for consideration for inclusion, making it the

⁸⁵ Medical Devices Annex to the EC-US MRA, article 2.

⁸⁶ Sectoral Annex on Medical Device to EU-New Zealand MRA, [2012] OJ L/356/10.

⁸⁷ Article I:1 GATT (emphasis added).

⁸⁸ See, e.g. Bartels (n 74). Lorand Bartels, ‘WTO Dispute Settlement Practice on Article XXIV of the GATT’, *The WTO Dispute Settlement System 1995-2003* (Kluwer Law International BV 2004). See also, Joel P.

Trachtman, ‘Embedding Mutual Recognition at the WTO’ (2007) 14 *Journal of European Public Policy* 780.

⁸⁹ Appellate Body Report Canada – Certain Measures Affecting the Automotive Industry, WTO/DS139/AB/R, WT/DS 142/AB/R, Para 85.

⁹⁰ *Id*, para 84.

largest MRA in the world.⁹¹ As an innovation, the EU-Canada MRA, makes it clear that the procedure for mutual recognition is not limited to products from the other contracting party, but applies to products regardless of their origin. It states that:⁹²

A Party shall accept the result of conformity assessment activities performed by conformity assessment bodies established in the other Party's territory ... no less favorable than those applied to the result of conformity assessment activities performed by recognized conformity assessment bodies in its territory. The Party shall accept these results regardless of the nationality and location of the supplier or manufacturer, or of the country of origin of the product for which the conformity assessment activities are performed.

In other words, PPE produced in other countries, including those used in the medical setting, can also be tested by the authorities on both sides of the Atlantic after the inclusion of PPE and medical device in the annex. This provision, on the one hand, avoids the risk of violating the MFN clause by granting preferences to products originating from the MRA contracting party, and on the other hand, reaffirms the non-discrimination principle embedded in MFN.

The prohibition of origin-based restrictions when it comes to conformity assessment activities has significant implications for the future negotiation of MRAs. The time and source-intensive registration and conformity assessment procedures for PPE market access amid the COVID-19 pandemic and failures to complete PPE deals within a short period provide lessons that will prepare us for the future. It is envisaged that the global community will work closely on the harmonization of relevant technical regulations for essential goods, or at least will accelerate the incorporation of MRAs on PPE and medical devices in bilateral or regional trade agreements in the post-pandemic future.

It is important to make a clear “origin-neutral” statement and not to impose origin-based bias in future MRAs. From a legal point of view, such clarification can avoid the risk of violating the MFN clause. On a practical level, this provides multiple channels for products that meet the technical regulations of an importing country to apply for relevant conformity assessment procedures with designated CABs. This is particularly important during the time of regional or global pandemic time, when access to CABs in the importing country might be difficult. On the legal level, similar provisions can avoid the risk of violating the MFN clause.

c. Concluding Remarks

In the context of COVID-19, many countries have introduced an “emergency use authorisation” of products from other jurisdictions to meet the surge in demand for PPE during the presence of the coronavirus public health emergency. These temporary measures reflect, to varying degrees, principles of mutual recognition, either recognition of rules, or recognition of conformity assessment. It would appear that it is not easy to achieve mutual recognition of diverging technical regulations for safeguard reasons of protection of life and health. That being said, MRAs of conformity assessment in the essential goods sectors are expected in our post-pandemic future.

⁹¹ Iulianna Romanchyshyna, ‘Tackling Technical Barriers to Trade in EU “New Generation” FTAs: An Example of Open or Conflicting Regionalism?’ in Wolfgang Weiß and Cornelia Furculita (eds), *Global Politics and EU Trade Policy: Facing the Challenges to a Multilateral Approach* (Springer International Publishing 2020).

⁹² EU-Canada MRA, Article 9, [2017] OJ L 11/23.

The existence of an MRA does not automatically mean that products approved by one party will necessarily be accepted by another contracting party but, rather, independent systems can be maintained for regulating relevant products while at the same time benefiting manufacturers with CABs in their own country in a more efficient manner. Whether an MRA can impose origin-based bias on products manufactured in other WTO members remains arguably unclear due to the absence of WTO precedents. This concern is more pronounced in a time of global crisis. An open regionalism, as reflected in the EU-Canada MRA, can avoid MFN-inconsistent risk and more importantly facilitate conformity assessment activities for gaining market access by providing more open options in a time of crisis. The provision that allows products, regardless of their origin, to access conformity assessment procedures prescribed in an MRA could potentially serve as a model for future MRA negotiations. Based on the language used in the CETA, future MRAs on essential products can consider incorporation of the proposed provision on the acceptance of results of conformity assessment below:

“A Party shall accord the result of conformity assessment performed by designated conformity assessment bodies established in the other Party’s territory no less favorable than those applied to the result of conformity assessment performed by recognized conformity assessment bodies in its territory. The Party shall accept these results regardless of the nationality and location of the supplier or manufacturer, or of the country of origin of the product for which the conformity assessment activities are performed.”

IV. Conclusion

PPE is vital to protect healthcare professionals fighting COVID-19. Faced with acute shortages of PPE, many governments introduced export curbs on PPE. The cycle of protectionism spread as fast as the coronavirus itself. It is not surprising to see export restrictions on PPE during the pandemic. Economists have almost universally condemned the recent surge in export restrictions. However, by looking at the relevant WTO discipline, international trade law offers a great deal of carve-outs for Members to enact export restrictions during the current pandemic and seems inadequate as a basis for international cooperation in times of emergency.

The global PPE supply chain is highly integrated. The export restrictions can endanger economies that rely heavily on PPE supplies in the time of global public health emergency. On the other hand, restrictions can also lead to retaliation across major economies, which will irreversibly affect the global supply chain.

Import facilitation measures have also been used widely across countries to facilitate market access of PPE and ensure supply availability. Many of these measures, although applied temporarily and non-binding in nature, reflect the same approach to the Mutual Recognition. Some major economies have recognised different technical regulations, provided that such technical solutions provide an adequate level of protection, and accepted results of conformity assessment performed by relevant institutes in other jurisdictions. This is a big step forward, contrary to what happens in the export regime, where international cooperation is most needed. The COVID-19 pandemic has also highlighted the need for greater cooperation and efforts to reduce barriers to trade, including through increased MRAs on essential goods in the future trade negotiations. It is worth noting that the EU-Canada MRA, which has eliminated origin-based bias of conformity assessment could potentially serve as a model for future MRA negotiations, especially when it comes to the MRAs on essential goods.

The COVID-19 pandemic not only imposes threat to global public health, but also brings out protectionist instinct. A virtual G20 Leaders' summit organized with a view to advancing a coordinated global response to the COVID-19 pandemic noted, "the unprecedented COVID-19 pandemic is a powerful reminder of our interconnectedness and vulnerabilities. The virus respects no borders. Combatting this pandemic calls for a transparent, robust, coordinated, large-scale and science-based global response in the spirit of solidarity."⁹³ This statement was accompanied by one from the G20 Trade and Investment Ministers set out a series of short-term measures to alleviate the impact of COVID-19 (e.g. on trade regulation and trade facilitation), it also set out a number of longer term measures that would "support the necessary reform of the WTO and the multilateral trading system, build resilience in global supply chains, and strengthen international investment."⁹⁴ A new Director-General will lead the WTO response to the contribution it can make to the global economic recovery from the COVID-19 pandemic which should include measures taken on export restrictions and import facilitation.⁹⁵

⁹³ *G20 Leaders' Statement*,

[https://g20.org/en/media/Documents/G20_Extraordinary%20G20%20Leaders%E2%80%99%20Summit_State%20ment_EN%20\(3\).pdf](https://g20.org/en/media/Documents/G20_Extraordinary%20G20%20Leaders%E2%80%99%20Summit_State%20ment_EN%20(3).pdf).

⁹⁴ Available at <https://www.marketscreener.com/news/G20-Trade-and-Investment-Ministerial-Meeting-Statement--30607832/>.

⁹⁵ *DG Azevêdo Announces He Will Step Down on 31 August*
https://www.wto.org/english/news_e/news20_e/dgra_14may20_e.htm.