THE GLOBAL SCRAMBLE FOR PPE AMID COVID-19: LESSONS FROM THE EU EXPORT RESTRICTIONS AND IMPORT FACILITATION THROUGH REGULATORY COOPERATION ON PPE

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ABSTRACT

As the COVID-19 pandemic continues to spread around the world, unprecedented disruption to the global economy and international trade have prompted widespread fears especially when it comes to the scramble for personal protective equipment (hereinafter "PPE"), as a result of critical shortages. Government officials around the world have raised concerns about how to ensure that their countries have adequate access to PPE. Many governments have introduced trade-related measures, such as restricting exports of critical PPE and medical supplies. Governments are also mounting special efforts including temporarily revising import procedures and easing technical barriers to ensure the supply of PPE in response to a crisis-within-a-crisis. Such trade-related measures on both export restrictions and import facilitation in response to COVID-19 have brought considerable attention to the role of the multilateral trading system in promoting stability and predictability of international trade flows in a time of global crisis and have also exposed the existing limits of

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international trade law. This article presents an overview of both the European Union's export restrictions and import facilitation measures on PPE, as an example, and provides analyses of issues associated measures in the international trade law regime.

KEYWORDS: *export restriction, mutual recognition, trade facilitation, COVID-19, PPE regulation*

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I. INTRODUCTION

Since the outbreak of COVID-19 was identified in Wuhan in December 2019, it has rapidly progressed to become an ongoing global pandemic, causing an unprecedented, far-reaching impact on human health, social well-being and economic growth around the world. The pandemic is also causing major disruption to global logistics and supply chains, in particular, the supply of personal protective equipment (hereinafter "PPE"). Such disruption creates a high level of risk for medical and other frontline personnel as the virus rapidly spreads. For example, it was reported that more than 3,000 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.[1] PPE supplies have become a key concern around the world. The ongoing coronavirus pandemic has exposed the vulnerabilities of supply chains across many industries and the global supply chain is suffering from significant disruptions. The high geographic concentration of PPE manufacturers, in conjuncture with factory shutdowns and bans on travel and PPE and medical device exports have all put a significant strain on the supply chain.[2]

Many governments have been compelled to respond with measures that affect the delivery of such critical supplies. Governments swiftly enacted temporary trade measures to restrict exports of vital PPE and medical supplies and to liberalize imports of such products. The information thus far suggests that there have been over 260 trade-related measures taken in the context of COVID-19.[3] Over seventy countries have introduced export curbs on PPE and medical supplies.[4] As most governments were not properly prepared, many of them scrambled to acquire supplies wherever they could especially in March and April. Additional measures have also been introduced to facilitate imports. The European Commission has, among competent authorities in other jurisdictions, introduced export controls on PPE and some medical supplies and issued an accompanying Guidance Note for the implementation of export controls. It also published a recommendation on conformity assessment and market surveillance

[1] *COVID-19: Protecting Health-Care Workers*, 395 LANCET 922, 922 (2020).
[2] *Global Shortage of Personal Protective Equipment amid COVID-19: Supply Chains, Bottlenecks, and Policy Implications*, 130 ADB BRIEFS 1, 3 (Apr., 2020), https://www.adb.org/sites/default/files/publication/579121/ppe-covid-19-supply-chains-bottlenecks-policy.pdf.
[3] *COVID-19: Measures Affecting Trade in Goods*, WORLD TRADE ORG. [hereinafter WTO], https://www.wto.org/english/tratop_e/covid19_e/trade_related_goods_measure_e.htm (last visited Jan. 15, 2021). *See also* WTO, EXPORT PROHIBITIONS AND RESTRICTIONS: INFORMATION NOTE 7 (2020), https://www.wto.org/english/tratop_e/covid19_e/export_prohibitions_report_e.pdf.
[4] Maddy White, *World Bank Urges Against Export Bans amid Covid-19 Medical Supply Chain Mayhem*, GTR (Apr. 21, 2020), https://www.gtreview.com/news/global/world-bank-urges-against-export-bans-amid-covid-19-medical-supply-chain-mayhem/.

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procedures and now accepts PPE that has been manufactured following technical solutions, other than harmonized European Union (hereinafter "EU") standards, in the "war of PPE", as a result of the COVID-19 threat.

International Organizations, including the World Trade Organization (hereinafter "WTO"), the World Health Organization (hereinafter "WHO") and the World Bank, have urged leaders against hoarding critical supplies, and not to use shortages as a reason to step up protectionist measures. Not surprisingly, the EU's export restrictions have been the subject of criticism from its key trading partners that rely heavily on supplies from the EU, and they claim that the measures adversely affect the international trade climate at a time when international cooperation is most needed.[5] In the meantime, the EU recommend that the fast cross-border movements of PPE and medical device suppliers should be facilitated through quicker conformity assessments for new requests and derogations from standard conformity assessment procedures. These measures also face implementation challenges in practice.

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 EU's export restrictions and import facilitation measures in the context of COVID-19, as an example, and to analyze the issues associated with both export and import measures on essential supplies in the international trade law regime. Section II details the EU export restrictions on PPE and the potential issues associated with the measures in the context of the WTO. Section III examines the EU import facilitation measures, their resemblance to mutual recognition principles and the implementation issues associated with such measures. Section IV concludes on global solidarity and cooperation in battling COVID-19 and the Mutual Recognition Agreements (hereinafter "MRAs") that are required in future trade negotiations with a focus on the PPE and medical device sectors.

II. EXPORT RESTRICTIONS

This section examines the restrictions imposed by the EU to cope with the shortage of PPE arising from the arrival of COVID-19 in Europe from the initial fragmented response to the introduction of EU export restrictions before examining the relevant WTO disciplines, which includes an assessment of the WTO-compatibility of the EU measures before concluding on the development of EU policy in this area.

[5] André Sapir, *What the EU Should Do and Not Do on Trade in Medical Equipment*, BRUEGEL (Mar. 25, 2020), https://www.bruegel.org/2020/03/what-the-eu-should-do-and-not-do-on-trade-in-medical-equipment/.

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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:[6]

> 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 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.[7] 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.[8] 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 a products subject to authorisation "to prevent a critical situation from arising on account of a shortage of essential products."[9] 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*

[6] Ursula von der Leyen, President, European Comm'n Speech, Speech by President von der Leyen at the European Parliament Plenary on the European Coordinated Response to the COVID-19 Outbreak (Mar. 26, 2020).

[7] Measures were taken by countries where production of personal protective equipment (PPE) is concentrated, such as Germany, France, Poland, Bulgaria and the Czech Republic. *See* Paulette Vander Schueren et al., *EU and EU Member States Impose COVID-19-Related Export Restrictions on Medical and Protective Equipment*, MAYER BROWN (Mar. 17, 2020), https://www.mayerbrown.com/en/perspectives-events/publications/2020/03/eu-and-eu-member-states-impose-covid-19-related-export-restrictions-on-m edical-and-protective-equipment.

[8] *See* Commission Implementing Regulation (EU) 2020/402 of 14 March 2020, Making the Exportation of Certain Products Subject to the Production of an Export Authorisation, 2020 O.J. (L 77 I) 1. The Regulation was amended by Commission Implementing Regulation 2020/426 of 19 March 2020, Amending Implementing Regulation (EU) 2020/402 Making the Exportation of Certain Products Subject to the Production of an Export Authorisation, 2020 O.J. (L 84 I) 1.

[9] Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on Common Rules for Exports, 2015 O.J. (L 83) 34, 35.

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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."[10]

In April 2020 the Commission issued a new Implementing Regulation, Implementing Regulation 2020/568, replacing the initial Regulation, as amended.[11] The Preamble makes it clear that:[12]

> 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 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.[13]

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 (hereinafter "EFTA") (i.e. Iceland, Liechtenstein, Norway and Switzerland) and the Western Balkans (Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia and

[10] *Coordinated Economic Response to the Covid-19 Outbreak*, at 3, COM (2020) 112 final (Mar. 13, 2020). It also noted that national measures created a domino effect. *See also* COVID-19 Guidelines for Border Management Measures to Protect Health and Ensure the Availability of Goods and Essential Services, 2020 O.J. (C 86 I) 1, 2.

[11] Commission Implementing Regulation (EU) 2020/568 of 23 April 2020, Making the Exportation of Certain Products Subject to the Production of an Export Authorisation, 2020 O.J. (L 129) 7.

[12] *Id.* at 8.

[13] *Id*. Recital 14 acknowledges the principle of international solidarity. See also article 2(6) of the Regulation.

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Serbia).[14] 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:[15]

> 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. 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.[16] As of 30 April,

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[14] *Id.* art. 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.

[15] *Coronavirus: Commission Adjusts Export Authorisation Scheme for Personal Protective Equipment to Suit Current Needs*, EUR. COMM'N (Apr. 24, 2020), https://trade.ec.europa.eu/doclib/press/index.cfm?id=2139.

[16] *DG Azevêdo Requests WTO Members to Share Information on Trade Measures Related to COVID-19*, WTO (Mar. 25, 2020), 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 (2020), https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf. *See generally* Council for Trade in Goods, *Decision on Notification Procedures for Quantitative Restrictions*, WTO Doc. G/L/59/Rev.1 (July 3, 2012).

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the EU has notified the various Implementing Regulations along with the amended guidelines for their implementation.[17] Their notifications are among the forty-six WTO Members who have introduced export prohibitions or restrictions.[18] The G20 Ministerial Statement of 30 March 2020 noted: "[w]e 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."[19] The relevant WTO rules are contained in Article XI of the General Agreements on Tariffs and Trade (hereinafter "GATT") on quantitative restrictions and, if there has been a breach of a GATT provision, Article XX of the GATT on general exceptions.

Article XI:1 of the GATT provides that: "[n]o 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 Article XI:2(a) of the GATT makes it clear that this does not extend to "export . . . restrictions temporarily applied to prevent or relieve critical shortages of . . . other products essential to the exporting contracting party."[20]

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:[21]

> 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

[17] WTO, *supra* note 3. *See also* Committee on Market Access, *Notification Pursuant to the Decision on Notification Procedures for Quantitative Restrictions (G/L/59/REV.1)*, WTO Doc. G/MA/QR/N/EU/4/Add.1 (Apr. 8, 2020); Committee on Trade Facilitation, *Notifications Under Articles 1.4, 10.4.3, 10.6.2 and 12.2.2 of the Agreement on Trade Facilitation*, WTO Doc. G/TFA/N/EU/1/Rev.2 (Apr. 9, 2020).

[18] WTO, *supra* note 3, at 6.

[19] *G20 Trade and Investment Ministerial Statement 30 March 2020*, WTO Doc. WT/L/1089 (Apr. 14, 2020).

[20] General Agreement on Tariffs and Trade art. XIII:1, Oct. 30, 1947, 61 Stat. A11, 55 U.N.T.S. 194 provides: "[n]o prohibition or restriction shall be applied by any contracting party . . . on the exportation of any product destined for the territory of any other contracting party, unless . . . the exportation of the like product to all third countries is similarly prohibited or restricted." This suggests that there should be a non-discriminatory administration of quantitative restrictions.

[21] Appellate Body Report, *China — Measures Related to the Exportation of Various Raw Materials*, ¶ 319, WTO Doc. WT/DS394/AB/R, WT/DS395/AB/R, WT/DS398/AB/R (adopted Feb. 22, 2012).

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> condition or regulation", and thus refers generally to something that has a limiting effect.

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."[22] 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 (i.e. they fall outside the scope of Article XI of the GATT), there would be no scope for the application of Article XX of the GATT.[23]

In the event that Article XX of the GATT was relevant (i.e. there is a breach of a GATT obligation) the jurisprudence of the GATT and the WTO suggest 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 of the GATT.[24] 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:[25]

> 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."[26]

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[22] *Id.* ¶¶ 323-24, 326.
[23] *Id.* ¶ 334.
[24] *See, e.g.*, Appellate Body Report, *United States — Standards for Reformulated and Conventional Gasoline* [hereinafter *US — Gasoline*], at 22, WTO Doc. WT/DS2/AB/R (adopted May 20, 1996).
[25] Appellate Body Report, *Brazil — Measures Affecting Imports of Retreaded Tyres*, ¶ 156, WTO Doc. WT/DS332/AB/R (adopted Dec. 17, 2007).
[26] *Id.* ¶ 179.

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Although not cited by any Member in their notifications, another possible paragraph which could be used to justify the export restrictions is paragraph (j) which 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."[27] 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".[28] As for the analysis inherent in the phrase "products in general or local short supply", the Appellate Body concluded that such analysis:[29]

> [M]ay, 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

[27] See also decision in Panel Report, *European Union and Its Member States — Certain Measures Relating to the Energy Sector*, ¶ 7.247, WTO Doc. WT/DS476/R (circulated Aug. 10, 2018).
[28] Appellate Body Report, *India — Certain Measures Relating to Solar Cells and Solar Modules*, ¶¶ 5.60, 5.62, WTO Doc. WT/DS456/AB/R (adopted Oct. 14, 2016).
[29] *Id.* ¶ 5.83.

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of that provision.[30] 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.[31]

One further potentially applicable provision is Article XXI:2(b)(iii) of the GATT which provides that: "[n]othing 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 GATT i.e. it was not self-judging (non-justiciable) as argued by Russia.[32] As for the interpretation of the provision at issue (Article XXI(b)(iii) of the GATT), 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."[33] The Panel continued to note that there is an "obligation to interpret and apply Article XXI(b)(iii) . . . 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."[34] In January the WHO Director General, Dr. Tedros Adhanom Ghebreyesus, declared the COVID-19 outbreak a Public Health Emergency of International Concern.[35] The question arises whether this characterisation of COVID-19 is sufficient to meet the requirement in Article XXI of the GATT i.e. an "emergency in international relations" in the sense of a situation of "heightened tension or crisis, or of general instability engulfing or surrounding a State." It seems that it would not be sufficient.

[30] *See, e.g.*, Appellate Body Report, *United States — Import Prohibitions of Certain Shrimp and Shrimp Products*, ¶¶ 157-59, WTO Doc. WT/DS58/AB/R (adopted Nov. 6, 1998).
[31] *US — Gasoline*, *supra* note 24, at 25.
[32] Panel Report, *Russia — Measures Concerning Traffic in Transit*, ¶¶ 7.57-.58, WTO Doc. WT/DS512/R (adopted Apr. 26, 2019).
[33] *Id.* ¶ 7.130.
[34] *Id.* ¶¶ 7.76, 7.132.
[35] *WHO Director-General's Statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV)*, WHO (Jan. 30, 2020), https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ihr-emergency-committee-on-novel-coronavirus-(2019-ncov).

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C. Reflections on Export Restrictions

The introduction by Members States 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. That notification indicated that the justification for the measure was Article XX(b) of the GATT (the protection of human life or health).[36] However, when the Regulation was amended through the introduction of Implementing Regulation 2020/426, the introduction of provisions excluded countries from export authorisations (e.g. member states of EFTA). It could be argued that this created a WTO-incompatible element. The incompatibility could arise from the requirement of Article XIII of the GATT for the non-discriminatory application of quantitative restrictions which, if proven, would require justification under Article XX of the GATT. Whilst still being necessary to protect public health under Article XX(b) of the GATT, it may be doubted whether the measure could satisfy the terms of the chapeau of that Article given that it introduced an element of discrimination. Thus, Implementing Regulation 2020/426 and its successor, Implementing Regulation 2020/568, which extended the geographical discrimination, could fail to satisfy the requirement of Article XX GATT. However, such a possibility is now moot given that Implementing Regulation expired on 25 May 2020 and was not extended or replaced.[37]

Irrespective of the merits of adopting export restrictions to deal with the shortage of PPE,[38] COVID-19 revealed shortcomings in the integrity of the single market. To ameliorate possible problems, in March the Member States endorsed "Guidelines for border management measures" in order to ensure the smooth passage of goods, particularly food, and medical and health supplies across EU Member States' borders.[39] To preserve the free circulation of goods within the single market, these Guidelines recommended that the Members States should not impose additional certification requirements, particularly on basic need products, such as

[36] *See* Committee on Market Access, *supra* note 17. *See also* Committee on Market Access, *Notification Pursuant to the Decision on Notification Procedures for Quantitative Restrictions (G/L/59/REV.1)*, WTO Doc. G/MA/QR/N/EU/4/Add.2 (May 7, 2020).

[37] *Notification Pursuant to the Decision on Notification Procedures for Quantitative Restrictions (G/L/59/REV.1)*, WTO Doc. G/MA/QR/N/EU/4/Add.3 (June 10, 2020). This notification did, however, notify measures taken by some Member States (Cyprus, Estonia, France, Greece, Romania and the, Slovak Republic) to protect human health in relation to the COVID-19 pandemic.

[38] *See, e.g.*, Simon J. Evenett, *Sicken Thy Neighbour: The Initial Trade Policy Response to COVID-19*, 43(4) WORLD ECON. 828, 828 (2020).

[39] COVID-19 Guidelines for Border Management Measures to Protect Health and Ensure the Availability of Goods and Essential Services, *supra* note 10, at 1.

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medicines, medical equipment and food products. Beyond economic policy and trade, there is a limit to EU action in the health field for although Article 168(1) of the Treaty on the Functioning of the EU provides that "[a] high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities", EU competence is subordinate to that of the Member States and is limited to "incentive measures" designed to protect and improve human health.[40] The early imposition of export restrictions by some Member States emphasises that they are in control when it comes to health policy. To mitigate supply chain bottlenecks, the EU Commission has also launched several joint procurements for PPE, medical equipment and vaccination to help member countries get more essential supplies. These measures are introduced pursuant to Article 5 of Decision 1082/2013 on serious cross-border threats to health provides for the joint procurement of medical countermeasures,[41] and the Joint Procurement Agreement for medical countermeasures ("JPA"),[42] which laid down common rules for practical organization of joint procurement procedures and the role of joint procurement. Action was also taken under Decision 1313/2013 which established an EU Civil Protection Mechanism to create a strategic stockpile of medical equipment such as ventilators and protective masks.[43] Looking ahead, strategic stocks could be a more effective and cost efficient solution to matching crisis demand in lieu of encompassing the whole value chain and introducing export restrictions in times of crisis. In late March, European standards for medical supplies were made freely available to facilitate production increases for these

[40] *See*, *e.g.*, Scott Greer & Anniek de Ruijter, *EU Health Law and Policy in and After the COVID-19 Crisis*, 30(4) EUR. J. PUB. HEALTH 623, 623 (2020); Andrea Renda & Rosa Castro, *Towards Stronger EU Governance of Health Threats After the COVID-19 Pandemic*, 11(2) EUR. J. RISK REG. 273, 276 (2020).

[41] Decision No 1082/2013/EU, of the European Parliament and of the Council of 22 October 2013 on Serious Cross-border Threats to Health and Repealing Decision No 2119/98/EC, art. 5, 2013 O.J. (L 293) 1, 8. *See also Proposal for a Regulation of the European Parliament and of the Council on Serious Cross-border Threats to Health and Repealing Decision No 1082/2013/EU*, at 9, COM (2020) 727 final (Nov. 11, 2020).

[42] For details, see European Commission Press Release IP/20/523, Coronavirus: Commission Bid for PPE Successful (Mar. 24, 2020), https://ec.europa.eu/commission/presscorner/detail/en/ip_20_523. On the Joint Procurement Agreement (JPA), see European Commission, Commission Decision of 10.4.2014 on Approval of the Joint Procurement Agreement to Procure Medical Countermeasures Pursuant to Decision 1082/2013/EU, C (2014) 2258 final (Apr. 10, 2014).

[43] *See* Decision No 1313/2013/EU, of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism, 2013 O.J. (L 347) 924. For details of the stockpile, see European Commission Press Release IP/20/476, COVID-19: Commission Creates First Ever RescEU Stockpile of Medical Equipment (Mar. 19, 2020), https://ec.europa.eu/commission/presscorner/detail/en/ip_20_476.

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products.[44] This particular initiative was in response to a Commission Recommendation to which the discussion now turns.

III. IMPORT FACILITATION THROUGH RECOGNITION OF STANDARDS AND CONFORMITY ASSESSMENTS IN OTHER JURISDICTIONS

In the context of the unprecedented levels of demand for PPE, in addition to the export restrictions, governments have also taken dozens of measures to facilitate imports of COVID-19 related PPE, including cutting import duties, curbing customs clearance processes and streamlining licensing and approval requirements. The EU has also published a recommendation on conformity assessment and market surveillance procedures for PPE such as face masks, gloves, protective gowns, as well as for medical devices such as surgical masks, exploration gloves and some gowns to allow suppliers to bring PPE quicker to those who need them the most.[45] In view of the shortage of PPE supplies for the EU market, the stringent requirements of harmonized EU technical regulations, and the long period needed to complete the full conformity assessment procedures, the Commission is encouraging notified bodies to process applications for Conformité Européenne (hereinafter "CE") marking swiftly and to consider non-harmonized standards for certification. There will also be derogations from conformity assessment procedures in order to enable sufficient PPE and medical devices to be placed on the EU market more quickly and to reduce the risks for medical professionals and other frontline responders.

A. EU Technical Regulations and Conformity Assessment on COVID-19 PPE

The current coronavirus situation has led to a growing demand for face masks, protective suits, safety glasses, surgical masks and examination gloves. Most of the PPE falls within EU Regulation 2016/425 on personal

[44] *Coronavirus: European Standards for Medical Supplies Made Freely Available to Facilitate Increase of Production*, EUR. COMM'N (Mar. 23, 2020), https://ec.europa.eu/growth/content/coronavirus-european-standards-medical-supplies-made-freely-available-facilitate-increase_en#:~:text=Publications-,Coronavirus%3A%20European%20standards%20for%20medical%20supplies%20made%20freely,to%20facilitate%20increase%20of%20production&text=In%20the%20context%20of%20the,gowns%20and%20other%20medical%20supplies.

[45] Commission Recommendation (EU) 2020/403, of 13 March 2020 on Conformity Assessment and Market Surveillance Procedures Within the Context of the COVID-19 Threat, 2020 O.J. (L 79 I) 1 [hereinafter Recommendations EU 2020/403]. By a strict legal interpretation, some PPE such as surgical masks, surgical exploration gloves fall into the definition of "medical device" in the EU Medical Device Directive.

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protective equipment (hereinafter "PPE Regulation").[46] 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 mask and medical gowns, for instance), and therefore fall into the purview of Directive 93/42—the Medical Devices Directive (hereinafter "MD Directive").[47] Both pieces of legislation lay down very demanding requirements for the technical design, manufacture and sale of the equipment, in particular high standards when it comes to health and safety requirements.

PPE imported from outside the EU (including EFTA and other participants in the single market) has to undergo a conformity assessment system, in this case, CE marking, in order to determine whether the products comply with the relevant harmonized EU technical standards. Only after the completion of this procedure can the product be affixed with the CE marking, which is a prerequisite for lawfully placing the product on the market. For cases featuring higher levels of risk, CE marks can only be affixed after third party certification by a so-called "notified body", accredited *via* the European Co-operation for Accreditation system ("EA"), designated by Members States, and listed by the European Commission.[48]

PPE regulated by the PPE Regulation, and 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.[49] In this case, products from third countries need to go through a review of their submitted technical documentation,[50] the "EU-type examination Module B", for initial product approval in order to ensure the products meet all relevant essential health and safety requirements,[51] and on-going surveillance through testing (Module C2) or factory auditing (Module D) by a designated notified body to ensure that the

[46] *See* 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, 2016 O.J. (L 81) 51, 57 [hereinafter PPE Regulation] (if it is to protect the doctor from the patient, it is PPE).

[47] *See* Council Directive 93/42/EEC, of 14 June 1993 Concerning Medical Devices, 1993 O.J. (L 169) 1 [hereinafter Directive 93/42/EEC]. 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. *Parliament Decides to Postpone New Requirements for Medical Devices*, EUR. PARL. (Apr. 17, 2020, 4:21 PM), https://www.europarl.europa.eu/news/en/press-room/20200415IPR77113/parliament-decides-to-postpone-new-requirements-for-medical-devices.

[48] Anabela Correia de Brito et al., *The Contribution of Mutual Recognition to International Regulatory Co-Operation* 19 (OECD, OECD Regulatory Policy Working Papers No. 2, 2016), https://www.oecd.org/regreform/WP2_Contribution-of-mutual-recognition-to-IRC.pdf.

[49] PPE Regulation, *supra* note 46, Annex I.

[50] *Id.* Annex III.

[51] *Id.* Annex II.

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production versions of the item continue to comply with the sample that was approved by the EU-type examination,[52] all of which means that it takes months to complete the entire conformity assessment system.

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. 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).[53] Secondly, a certificate 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 (hereinafter "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.

Some protective equipment such as surgical face masks and 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.

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 will be considered to have a dual purpose. According to the guidelines from the 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] The manufacturer only needs to affix one CE mark to the device. That being said, it will be almost impossible for a new market supplier to obtain the CE marking within a short period of time in order to supply the EU market. As of 13 March 2020, the WHO considered Europe the active centre of the

[52] *Id.* art. 19.
[53] *COVID-19: Suspicious Certificates for PPE*, ESF (Jan. 18, 2021), https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe.
[54] EUR. COMM'N, 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 50 (1st ed. 2018), https://ec.europa.eu/docsroom/documents/29201.

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COVID-19 pandemic and the reported number of confirmed cases in Europe has exceeded over 1.3 million by early May.[55] However, estimates show that the "traditional" supply lines will only be able to serve 10% of the demand.[56] As a result, the EU has been scrambling to acquire crucial PPE from outside Europe since the epidemic spread to the continent. 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. Measures have been taken to ramp up PPE imports from outside Europe.

In its Recommendation 2020/403, the European Commission set out a series of measures on regulatory flexibility to ensure availability and faster delivery of PPE onto the market. Based on the Recommendation, in the first situation, Member States can authorize the placing of PPE the market, if products are found to conform with the essential health and safety requirements of the relevant legislation even though the conformity assessment procedures with the relevant notified bodies are not even finalized.[57] In the second case, relevant PPE for COVID-19 can be placed on the market even if the certification procedures have not been initiated and no CE marking is present on the product.[58] It should be noted, however that, in this case, the PPE shall be part of a purchase organized by the relevant Member State authorities and it is only designated for protecting healthcare professionals and only for the duration of the current COVID-19 threat.[59] In other words, they cannot be placed in the normal distribution channels and thus made available to private customers. In both cases, other technical specifications other than the harmonized EU standards (hereinafter "EN") can be acceptable. The Commission, in the Recommendation explicitly refers to:

> [T]he WHO recommendations on the appropriate selection of PPE, [which] may be used as a potential source of reference for such technical solutions, provided that the said technical solutions ensure an adequate level of protection corresponding to the applicable essential health and safety requirements laid down in [the PPE Regulation].[60]

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[55] *COVID-19 Situation Update Worldwide, as of 4 May 2020*, ECDC, https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases.
[56] Francesco Guarascio, *Exclusive: EU States Need 10 Times More Coronavirus Equipment—Internal Document*, REUTERS (Mar. 25, 2020, 6:56 PM), https://www.reuters.com/article/us-health-coronavirus-eu-supplies-exclus-idUSKBN21C1JC.
[57] Recommendations EU 2020/403, *supra* note 45, at 4.
[58] *Id.*
[59] *Id.*
[60] *Id.*

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B. Mutual Recognition Under International Trade Law to Facilitate PPE Imports

The European Commission's recommendation on considering non-harmonized standards and allowing derogations from conformity assessment procedures reflects the principle of mutual recognition. Indeed, the idea of "mutual recognition" is derived from the premises of EU free movement, first seen in the landmark *Cassis-de-Dijon* ruling of the Court of Justice (without mentioning the term), and later becoming a cornerstone of the EU internal market.[61] Mutual recognition is further strengthened as a principle in the Technical Barriers to Trade (hereinafter "TBT") Agreement that addresses TBTs from the point of view of diverging technical regulations and facilitates market access without affecting domestic risk regulations.

1. Mutual Recognition in International Trade Law — Mutual recognition in many areas and on different levels requires different forms of engagement.[62] Above all, there are two types of mutual recognition: mutual recognition of rules and mutual recognition of conformity assessments. The TBT Agreement requires Members to 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.[63] In addition to mutual recognition of rules, which often requires not only sufficient knowledge but, more importantly, close integration between different regulatory systems, the TBT Agreement also explicitly implies recognition of conformity assessment procedures undertaken by designated conformity assessment bodies (hereinafter "CABs") in the territory of another WTO Member in accordance with applicable technical regulations. It provides that "[m]embers shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted . . . provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures."[64]

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

[61] Case 120/78, Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein, 1979 E.C.R. 660. *See also* Iulianna Romanchyshyna, *Mutual Recognition as a Method to Deal with Regulatory Divergence: What Is Its Reach in EU FTAs?*, 15(1) GLOBAL TRADE & CUSTOMS J. 6, 8 (2020).
[62] *See* de Brito et al., *supra* note 48, at 48.
[63] Agreement on Technical Barriers to Trade art. 2.7, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120.
[64] *Id.* art. 6.1.

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quality than it would be if performed by authorities in the importing country. The MRAs that facilitate mutual market access by eliminating duplicative testing and certification have emerged in the international trade regime. To date, there are 176 Free Trade Agreements (FTAs) that incorporate MRAs in the agreement,[65] and most of them promote the conclusion of mutual recognition of conformity assessments as one amongst several options.[66] The EU, among other regions, has conspicuously demonstrated its preference for negotiating MRAs in its FTAs.

MRAs, in their classic form, enable CABs that are designated by one party to perform certification and testing in accordance with the other party's regulations on market access.[67] This type is pronounced in the EU–Canada Comprehensive and Economic Trade Agreement (hereinafter "CETA"), where the protocol on the mutual acceptance of the results of conformity assessment entitles authoritative bodies to perform conformity assessment that is to be recognized in the sectors that are covered.[68] The CETA, in its TBT Chapter, encourages accreditation and conformity assessment bodies of both parties to participate in cooperation arrangements that promote the acceptance of conformity assessment results in order to strengthen cooperation in the areas of technical regulations. The EU has also concluded this kind of classic MRA with the United States (hereinafter "US"), Japan, Australia, and New Zealand.[69]

"Enhanced" MRAs also deal with recognition of testing and certification, but are based on equivalents or the alignment of underlying regulations.[70] For instance, the EU MRA with the US on marine equipment accepts results of conformity assessments issued by the CABs of the other party and such recognition is based on relevant international standards (in this case, the rules of the International Maritime Organization).[71] The EU MRA with Switzerland is, in part, another example of an MRA that is based on a number of bilateral sectoral agreements by specialized committees looking to align rules,[72] as with Switzerland's strong links to the EU and its

[65] *Regional Trade Agreements Database*, WTO, https://rtais.wto.org/UI/PublicSearchByCr.aspx (with search entry RTA provisions on "mutual recognition" across all RTAs) (last visited Jan. 25, 2021).
[66] de Brito et al., *supra* note 48, at 48.
[67] Romanchyshyna, *supra* note 61, at 11.
[68] Comprehensive Economic and Trade Agreement (CETA) Protocol on the Mutual Acceptance of the Results of Conformity Assessment, Can.-EU, art. 3, Oct. 30, 2016, 2017 O.J. (L 11) 567, 568.
[69] *Commission Staff Working Paper: Priorities for Bilateral/Regional Trade Related Activities in the Field of Mutual Recognition Agreements for Industrial Products and Related Technical Dialogue*, at 4, SEC (2004) 1072 (Aug. 25, 2004), https://ec.europa.eu/docsroom/documents/6802/attachments/1/translations/en/renditions/native.
[70] Romanchyshyna, *supra* note 61, at 12.
[71] *Id.*
[72] *Id.*

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strong interests in getting access to the EU market in the areas covered by the MRA.

In addition, MRAs are, in most cases, limited in sectoral scope, and parties focus on a select number of sectors where agreements may be more easily reached such as telecommunication and electrical equipment.[73] Sectoral-specific provisions in MRAs can be found in a number of FTAs. The EU–Korea Agreement, for example, contains provisions that facilitate access to high-quality pharmaceutical products and medical devices through increased cooperation and requires parties to consider requests by the other party to accept conformity assessments of that party when performed in accordance with good laboratory and manufacturing practices based on international practice.[74] In some cases sectoral agreements also include some specific requirements with which designated CABs shall assess compliance. This is represented in the Sectoral Annex on Automotive Products in the EU-Australia MRA.[75]

2. Recognition in the Context of COVID-19 — "Recognition" is embedded in various policies, and to varying degrees, in different jurisdictions in order to deal with critical shortages of PPE. For instance, the US has accepted the use of respirators approved under standards used in other countries that are similar to the National Institute for Occupational Safety and Health-approved respirators, and considers products certified by an authorized test laboratory indicating their conformity with relevant standards to be suitable alternatives when it comes to providing protection during the COVID-19 response and when supplies are short. The US also explicitly lists countries such as Australia, Brazil, China, Japan, Korea and Mexico, their relevant technical standards and the acceptable product classification to be used in lieu of relevant National Institute for Occupational Safety and Health-certified products.[76] China, in the early

[73] Mahesh Sugathan, *Mutual Recognition Agreement on Conformity Assessment: A Deliverable on Non-Tariff Measures for the EGA?* 19 (ICTSD, Issue Paper No. 21, 2016), https://ictsd.iisd.org/themes/environment/research/mutual-recognition-agreement-on-conformity-assessment-a-deliverable-on.

[74] Council Decision of 16 September 2010 on the Signing, on Behalf of the European Union, and Provisional Application of the Free Trade Agreement Between the European Union and its Member States, of the One Part, and the Republic of Korea, of the Other Part, Annex 2-D, 2011 O.J. (L 127) 1154, 1156.

[75] Decision No 1/2005, of the Joint Committee Established Under the Agreement on Mutual Recognition in Relation to Conformity Assessment, Certificates and Markings Between the European Community and Australia of 11 November 2005 Related to Giving Effect to the Listing of a Conformity Assessment Body Under the Sectoral Annex on Automotive Products (2005/916/EC), 2005 O.J. (L333) 51.

[76] *Strategies for Optimizing the Supply of N95 Respirators*, CDC (Nov. 23, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html. For Non-NIOSH Approved Respirator Emergency Use Authorization, see *Stakeholders for Non-NIOSH-Approved Imported FFRs Manufactured in China*, FDA (Oct. 15, 2020), https://www.fda.gov/media/136664/download.

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stage of the outbreak of the coronavirus, issued guidelines on emergency imports of PPE and medical devices in the context of COVID-19. It allows relevant products from US, the EU, Korea and Japan which are not yet registered with the China Food and Drug Administration to be used provided that manufacturers can provide test results according to their relevant domestic technical regulations, and provide a Declaration of Conformity as a written assurance of conformity to their individual applicable technical regulations.[77] Both policies, although they are temporary in nature and are only valid in emergency situations, reflect a similar approach to "enhanced MRAs" that recognize conformity assessment as well as relevant technical regulations in other jurisdictions.

Measures provided in the Recommendation 2020/403, to some extent, also reflect principles of "recognition", especially recognition of rules. It accepts technical solutions other than EN standards, provided that such standards can afford an adequate level of protection to the EU standards. It also refers to the WHO recommendations on the appropriate selection of PPE, which lists multiple widely accepted standards in different scenarios.[78] In most of the cases, the WHO recommendation refers to both the US standard and the EU standard and also uses the term "or equivalent" in the technical specification column. This makes it possible to give consideration to standards that could offer equivalent protection from other jurisdictions that are able to guarantee a stable supply of PPE.[79]

3. Practical Issues with Temporary/Emergency Recognition — Temporary/emergency recognition in response to the COVID-19 crisis, by nature promotes regulatory cooperation and facilitate trade. However, such measures face several practical challenges.

Firstly, temporary/emergency recognition measures introduced by many countries did not specifically identify a list of standards in other jurisdictions, but rather used vague terms such as "other equivalent standards". For example, this is the case in the EU Recommendation 2020/403. In practice, without a clear list of recognized standards, most of the EU notified bodies still require conformity assessment to be done according to the relevant EN

[77] *Luse Yingji Tungdao: Jinji Jinkou Weizai Zhongguo Zhuce Yiliao Qixie* [*Green Lane: Emergency Imports of Medical Devices Unregistered with Chinese Food and Drug Administration (CFDA)*], MEDTEC (Feb. 11, 2020), https://www.medtecchina.com/zh-cn/RegulationDetail/newsid/2475.

[78] WHO, RATIONAL USE OF PERSONAL PROTECTIVE EQUIPMENT FOR CORONAVIRUS DISEASE 2019 (COVID-19) (2020), https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPPE_use-2020.1-eng.pdf. For PPE specification, see *Disease Commodity Package—Novel Coronavirus (COVID-19)*, WHO (Mar. 6, 2020), https://www.who.int/publications-detail/disease-commodity-package---novel-coronavirus-(ncov).

[79] For instance, for particulate respirator, grade N95 or higher, it specifically lists, "minimum 'N95' respirator according to FDA Class II, under 21CFR 878.4040, and CDC NIOSH (42CFR84), or, minimum 'FFP2' according to EN 149, EU PPE Regulation 2016/425 Category III, or equivalent". *Disease Commodity Package—Novel Coronavirus (COVID-19), supra* note 78.

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standards. During surges in demand, some EU notified bodies even require exporters to provide test reports against relevant EN standards issued by exporting countries as a prerequisite to initiating the conformity assessment procedures. This requirement places a huge burden on third country PPE suppliers, especially those from top exporters such as China, Thailand and Malaysia.[80] This is despite a technical comparison indicating that standards for respirators in major jurisdictions are largely equivalent to each other with only minor differences in certain specifications.[81] In other words, respirators certified as meeting most current standards can be expected to function in a very similar way to each another. Without implementation of temporary/ emergency recognition on the ground, differentiated but essentially similar technical standards will only lead to excessive testing, thus delaying the supply of essential goods.

Secondly, there are a very limited number of laboratories capable of testing against EN Standards outside Europe. To look at the case of masks again, there were only five internationally accredited (under the International Laboratory Accreditation Cooperation (hereinafter "ILAC")) laboratories in China that were capable of conducting tests according to the PPE standards (EN 149) and only three capable of testing the medical device standards (EN 14683) for surgical masks in April.[82] Mask production in China since the coronavirus emerged has expanded by nearly twelve-fold and represents a large proportion of the world's PPE supply. [83] However, the limited availability of testing against relevant EN standards, and the waiting period for conducting a self-assessment, even prior to the EU-type examination, has become a barrier to supplying the European PPE market.

Thirdly, the European Commission, while accepting equivalent technical solutions in its Recommendation, did not recognize conformity assessment carried out by any additional authoritative CABs in third countries, as done by the US and China in their emergency measures. To

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[80] *See Global Shortage of Personal Protective Equipment amid COVID-19: Supply Chains, Bottlenecks, and Policy Implications*, *supra* note 2, at 3.

[81] 3M, the world's leading supplier of particulate respirators across the world compared the regulatory standards of N95/FFP2 respirators in some major jurisdictions, notably N95 (United States NIOSH-42CFR84), FFP2 (Europe EN 149-2001), KN95 (China GB2626-2006), P2 (Australia/New Zealand AS/NZA 1716:2012), Korea 1st class (Korea KMOEL - 2017-64), and DS2 (Japan JMHLW-Notification 214, 2018) respectively. *See* 3M, COMPARISON OF FFP2, KN95, AND N95 AND OTHER FILTERING FACEPIECE RESPIRATOR CLASSES (2020), https://multimedia.3m.com /mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf.

[82] Numbers of accredited laboratories increased to thirty-one for EN 149 and twelve for EN 14683 in September 2020. *See Laboratories Accredited by CNAS for Testing of Masks, Gloves, Medical Protective Clothing and Other Personal Protective Equipment*, CNAS (Sept. 22, 2020), https://www. cnas.org.cn/english/photonews/06/903064.shtml.

[83] Keith Bradsher & Liz Alderman, *The World Needs Masks. China Makes Them, But Has Been Hoarding Them*, N.Y. TIMES (Apr. 2, 2020), https://www.nytimes.com/2020/03/13/business/masks-china-coronavirus.html.

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date, the EU has only concluded MRAs concerning the conformity assessment of medical devices with Australia, New Zealand, Switzerland and the United States, plus one agreement on PPE with Switzerland.[84] These MRAs entitle authoritative bodies in those countries to perform EU conformity assessments in their medical device or PPE sectors. However, none of these countries can supply the in-demand PPE, on account of export bans and their own acute domestic shortages of PPE during the COVID-19 crisis. Without additional MRAs on conformity assessment or similar provisions to recognize the results of conformity assessment from other third countries, PPE manufacturers in third countries can only go through the time-consuming conformity assessment procedures with the designated EU CABs if they want to gain market access.

The following example of China's PPE exports to the EU might further illustrate the situation where no MRA on PPE exists. Prior to the pandemic, the EU supplied its own PPE regionally, with sources in Belgium, France, Germany, Italy, the Netherlands, and Poland. But after supply chain disruptions, factory shutdowns and export bans among major raw material suppliers, the EU seems unlikely to be able to meet its own surging demand.[85] With virus restrictions in China lifted and economic activity beginning to recover, the country has directed its manufacturing might toward making PPE, becoming the most important supplier in the global PPE trading network.[86] However, many manufacturers are new to the EU market and need to go through the long application procedures with CABs. As the obligation to carry out the complete EU conformity assessment procedure remains solely that of the applicants, this places a huge regulatory compliance burden (information costs, conformity assessment costs, specification costs and administrative costs, to name a few) on Chinese PPE manufacturers used to their domestic standards, not being able to complete the EU conformity assessment for exports within a limited time frame in the crisis situation.

Lastly, despite Recommendation 2020/403, although allowing PPE to enter the EU market even if it does not bear a CE mark (provided

[84] The Mutual Recognition Agreements (hereinafter "MRA") that contain medical device sector are signed between the EU and Australia, New Zealand, Switzerland, and United States. For the MRA with Switzerland on PPE, see Decision No. 2/2006, of 13 December 2006 of the Committee Established Under the Agreement Between the European Community and the Swiss Confederation on Mutual Recognition in Relation to the Listing of a Conformity Assessment Body Under the Sectoral Chapter on Personal Protective Equipment, 2007 O.J. (L 32) 135.

[85] *Global Shortage of Personal Protective Equipment amid COVID-19: Supply Chains, Bottlenecks, and Policy Implications*, *supra* note 2, at 3.

[86] Jim Axelrod & Michael Kaplan, *As World Turns to China for PPE, U.S. Buyers Risk Knock-offs and Price Gouging*, CBS NEWS, (Apr. 13, 2020, 10:00 AM), https://www.cbsnews.com/news/china-ppe-us-buyers-knock-offs-price-gouging/.

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manufacturers can demonstrate conformity with applicable EU regulations), PPE suppliers still wish to apply for the complete CE marking conformity assessment, which offers a more formal assurance on product reputation and the supplier's position in the value chain,[87] and avoids ex-post product liabilities due to free-riding. In addition, the recommendation is non-binding, meaning its implementation varies across Member States. Under such circumstances, members endeavor to source the most ideal products available—in other words, products that have gone through the formal and entire conformity assessment with a competent notified body.

C. Potential Solutions Through Regulatory Cooperation

It is envisaged that continued work on mutual recognition of standards and conformity assessments of PPE will be on trade negotiators' agendas in the post-pandemic future. Indeed, the EU has already successfully reached MRAs with other developed countries on medical devices and pharmaceuticals, which serve as good starting points. Conversely, there are no multilateral or regional trade agreements with temporary or emergency provisions on regulatory cooperation during crisis situations. A few regional trade agreements refer to regulatory cooperation activities on sanitary and phytosanitary (SPS) measures when an emergency (such as disease outbreak) arises.[88] In light of the considerable number of emergency recognition and equivalence measures being introduced as a result of the global scramble for PPE amid COVID-19 and to think beyond the immediate crisis, we recommend temporary or emergency provisions on regulatory cooperation (including harmonization, recognition and equivalence) to be included in regional trade agreements. Such provisions should also provide clear guidelines on temporary authorization and recognition of other standards and CABs and enable contracting parties to be better prepared for future crises.

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[87] de Brito et al., *supra* note 48, at 22.

[88] For instance, Comprehensive and Progressive Agreement for Trans-Pacific Partnership [CPTPP] provides that:

> The Party that adopts the emergency measure shall take into consideration any information provided by other Parties in response to the notification. If a Party adopts an emergency measure, it shall review the scientific basis of that measure within six months and make available the results of the review to any Party on request.

Comprehensive and Progressive Agreement for Trans-Pacific Partnership, GOV'T CAN., art. 7.14, https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/text-texte/cptpp-ptpgp.aspx?lang=eng (last visited Feb. 10, 2021). *See also* Divya Prabhakar et al., *Strengthening International Regulatory Cooperation for Medical Supplies in Times of Medical Emergencies* 37-38 (ESCAP, Policy Hackathon Series, 2020), https://www.unescap.org/sites/default/d8files/142%20Final-Team%20Divya%20Prabhakar-Switzerland_0.pdf.

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Likewise, conformity assessment, delivered by numerous CABs, has a vital role in delivering assurance to quality of PPE and ensuring necessary protection of human life and health. This is particularly the case for imports from countries with lower standards which could have inferior quality. Key organizations such as the International Accreditation Forum (IAF) and ILAC and others could provide a reliable tool to support the continuous delivery of the conformity assessment services in spite of several lockdowns, travel restrictions and services shut-downs. Although there are limited numbers of laboratories accredited, both to perform testing against relevant EN standards and under ILAC in major PPE exporting countries such as China, Vietnam and Thailand, their geographic proximity to the suppliers can significantly save time in terms of communicating conformity assessment procedures and in sending samples to a EU-based CAB during a crisis. The ILAC Mutual Recognition Arrangement can be leveraged to provide proficient testing and deliver confidence in accepting results across national borders.

D. Reflections on Import Facilitation

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 classic MRAs that recognise conformity assessment performed by authorised CABs or enhanced MRAs that recognise conformity assessment on the basis of regulatory alignment or relevant international standards. The EU Commission, by introducing Recommendation 2020/403, exceptionally accepts PPE products that do not bear a CE marking and encourages notified bodies to temporarily process applications for CE marking swiftly and to consider non-harmonized standards for certification in order to ensure continuation of supply. However, there are also important implementation challenges to Recommendation 2020/403. Without a specific list of jurisdictions whose technical regulations provide an adequate level of protection, notified bodies, in practice, still use EN standards and member states are still in fierce competition to source PPE from the limited number of suppliers that have obtained accreditation from an EU CAB and are thus entitled to affix the CE marking on the products. In addition, without accepting results from CABs from third countries, the EU cannot deal with the significant shortages of PPE effectively. Therefore, the authors recommend including temporary or emergency provisions on regulatory cooperation in regional trade agreements and leveraging ILAC Mutual Recognition Arrangement in accepting testing results from countries where MRAs on PPE cannot be reached.

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IV. CONCLUSION

PPE is vital to protect healthcare professionals fighting COVID-19. Faced with acute shortages of PPE, many governments have introduced export curbs on PPE. The cycle of protectionism spread as fast as the coronavirus itself. It is not surprising that the European Commission adopted an Implementation Regulation restricting PPE exports outside EU. 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. That said, the EU measures which introduced geographic discrimination between third countries may be problematic.

The global PPE supply chain is highly integrated. The EU is both an exporter and an importer of the PPE products that is now subject to export restriction.[89] The export restrictions can endanger economies that rely heavily on PPE supplies from the EU in the time of global public health emergency. On the other hand, restrictions can also endanger the EU, as retaliation across major economies will have an irreversible effect on the global supply chain, which in turn endangers EU itself, when it comes to products it cannot produce sufficiently.

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 MRAs. Some major economies have recognised different technical regulations, provided that such technical solution provides 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, when 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 negations.

The COVID-19 pandemic not only imposes a threat to global public health, but also brings out a 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

[89] Chad P. Bown, *How the G20 Can Strengthen Access to Vital Medical Supplies in the Fight Against COVID-19*, PIIE (Apr. 15, 2020, 9:00 AM), https://www.piie.com/blogs/trade-and-investment-policy-watch/how-g20-can-strengthen-access-vital-medical-supplies-fight.

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respects no borders. Combatting this pandemic calls for a transparent, robust, coordinated, large-scale and science-based global response in the spirit of solidarity."[90] This statement was accompanied by one from the G20 Trade and Investment Ministers that 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."[91] 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.[92]

[90] G20, G20 LEADERS' STATEMENT (2020), https://reliefweb.int/sites/reliefweb.int/files/resources/G20_Extraordinary%20G20%20Leaders%E2%80%99%20Summit_Statement_EN%20%283%29.pdf.

[91] *G20 Trade and Investment Ministerial Meeting—Statement*, MARKET SCREENER (May 14, 2020, 11:10 AM), https://www.marketscreener.com/news/G20-Trade-and-Investment-Ministerial-Meeting-Statement--30607832/.

[92] *DG Azevêdo Announces He Will Step Down on 31 August*, WTO (May 14, 2020), https://www.wto.org/english/news_e/news20_e/dgra_14may20_e.htm.

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