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STANDARDS, REGULATIONS AND COVID-19 – WHAT ACTIONS TAKEN BY WTO MEMBERS?

INFORMATION NOTE[1]

KEY POINTS

- Around two-thirds of notifications by WTO members in response to COVID-19 are related to standards and regulations (i.e. technical barriers to trade and sanitary and phytosanitary measures). These have been notified by 27 members.
- The standards, regulations and related measures notified by WTO members mainly affect trade in personal protective equipment (PPE), food, live animals and medical equipment.
- The notified measures fall into four broad categories: streamlining certification procedures; ensuring that medical goods are safe; making food available by relaxing technical regulations; and addressing COVID-19 risks from international trade in live animals.

1 INTRODUCTION

This information note describes the standards and regulations that members have notified to the WTO in response to the COVID-19 pandemic.[2] These have been submitted under the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), which set out disciplines for standards and regulatory measures used, for example, to protect human, animal and plant life and health and the environment, and to ensure product safety.

For instance, to expedite and broaden access to PPE on a temporary basis, Brazil has eased its authorization requirements, while Canada has loosened its bilingual labelling rules. Several members (including Argentina, Australia, Chile, Costa Rica, the European Union, Indonesia, Japan, Mexico, the Philippines, the Russian Federation, South Africa and Chinese Taipei) are accepting scanned copies or electronic SPS certificates, in light of the disruptions caused by COVID-19. Switzerland is relaxing certain food labelling requirements to deal with COVID-19-related supply shortages.

2 NOTIFICATIONS AND COMMUNICATIONS

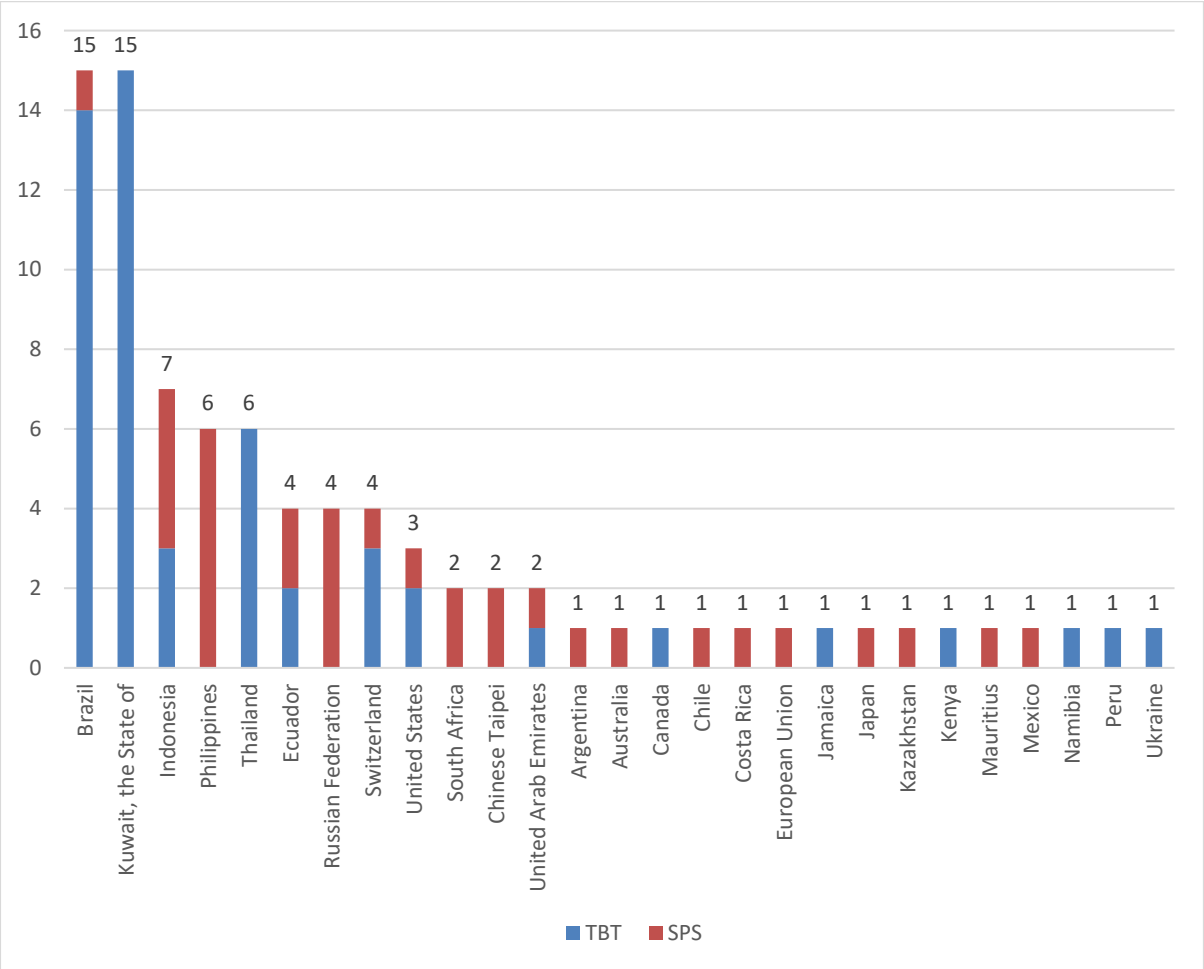
As of 8 May 2020, two-thirds of all notifications/communications submitted by WTO members on COVID-19 are related to standards and regulations. Twenty-seven WTO members have submitted 85 such notifications/communications (52 TBT and 33 SPS) on COVID-19 (see Figure 1).[3] The first of these notifications was received on 3 February 2020, and the majority in April 2020.

[1] This document has been prepared under the WTO Secretariat's own responsibility and is without prejudice to the positions of members or to their rights and obligations under the WTO.

[2] For further discussion of the importance of transparency and notification in the context of the COVID-19 pandemic, see the information note of 7 April 2020, titled "Transparency – why it matters at times of crisis".

[3] We classify TBT and SPS notifications as COVID-19-related if they contain the terms "coronavirus", "COVID", "SARS-COV-2" and "nCoV" and were issued as of 8 May 2020. This includes 15 revisions, addenda and corrigenda to previous notifications.

Figure 1: COVID-19-related notifications by member, TBT/SPS



Most of the notifications were submitted under the emergency/urgent notification provisions of the SPS and TBT Agreements[4] in response to the pressing health problems posed by the pandemic. Under these provisions, WTO members can adopt measures directly and immediately notify them to the WTO, without providing the usual 60-day comment period (or six-month transition period prior to entry into force).

However, emergency measures still need to comply with the other provisions of the SPS and TBT Agreements, such as avoiding discriminatory or unnecessary barriers to trade, ensuring a scientific basis for measures, and harmonizing with international standards. The SPS/TBT notification alert system, ePing, facilitates swift access to these notifications by both public and private stakeholders so that they can react and adjust as necessary to the evolving requirements and procedures.[5]

With respect to TBT, around half the notified measures were reported as temporary, often applying for a period of six months. With regard to SPS measures, almost two-thirds of these were notified as emergency measures, and half were reported as temporary measures. The remaining one-third of the SPS notifications were submitted as regular notifications. Of these, 90 per cent were identified as trade-facilitating measures. According to the SPS Committee's Recommended Transparency

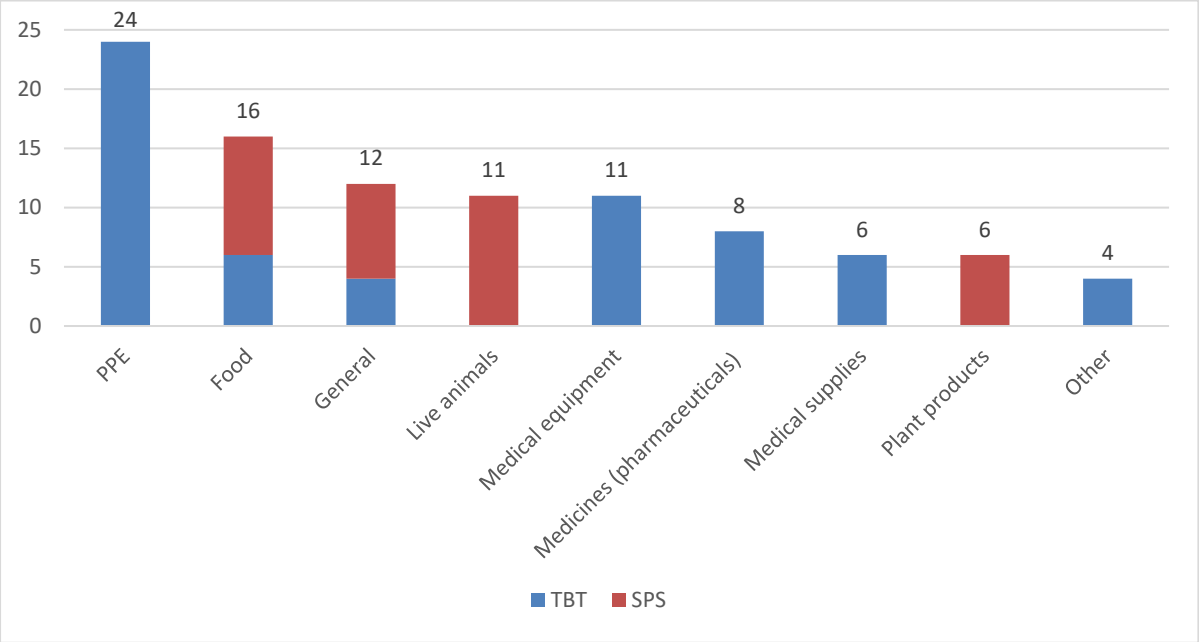
[4] Under the SPS Agreement – Article 7, and Annex B(2) and B(6); under the TBT Agreement – Articles 2.10, 2.12, 5.7, and 5.9.

[5] A new video clip explains how to receive daily or weekly alerts on COVID-19 related notifications. The ePing platform also assists SPS/TBT Enquiry Points in reaching out to domestic stakeholders or other members to seek further information and discuss these notifications.

Procedures, the entry into force of such trade-facilitating measures should not be unnecessarily delayed, and no comment period and transitional period needs to be provided.[6]

The TBT and SPS notifications cover a range of products,[7] including PPE,[8] food, live animals, medical equipment,[9] medicines (pharmaceuticals),[10] plant products, medical supplies[11] and general coverage[12] (see Figure 2).

Figure 2: Product coverage of notifications



The notified measures fall into four main categories: streamlining certification procedures; ensuring that medical goods are safe; making food available by relaxing technical regulations; and addressing COVID-19 risks from international trade of live animals.

Streamlining certification and related procedures

A range of temporary actions have been notified by members to streamline certification, authorization and other procedures for medical goods, to allow a wider range of products to enter the market more quickly, while still ensuring continued health and safety protection.

For instance, Brazil is taking a series of actions on a temporary basis, including: exempted PPE (including surgical masks, N95, PFF2 or equivalent particulate respirators, goggles, face shields, disposable hospital gowns, caps and props, valves, circuits and respiratory connections) and related medical equipment from usual authorization requirements and consolidated PPE product

[6] See WTO official document G/SPS/7/Rev.4. WTO official documents may be searched for at https://docs.wto.org/

[7] With respect to medical goods, this note adopts the product categories developed in "Trade in Medical Goods in the Context of Tackling COIVD-19" (WTO, 2020), page 2 and Annex 1.

[8] Personal protective equipment includes hand soap and sanitizer, face masks and protective spectacles (*ibid).*

[9] Medical equipment includes a range of medical devices (*ibid).*

[10] Medicines (pharmaceuticals) includes both dosified and bulk medicines (*ibid*).

[11] Medical supplies refer to consumables for hospital and laboratory use (e.g. alcohol, syringes, gauze, reagents, etc.) (*ibid*).

[12] The category of "General" includes, for instance, notifications on "goods subject to veterinary or phytosanitary inspection or control" (e.g. WTO official documents G/SPS/N/TPKM/526 and G/SPS/N/RUS/184), or "conformity assessment activities" (e.g. WTO official document G/TBT/N/BRA/978). "Other" includes, for instance, clothing, textiles and tobacco products.

requirements;[13] suspended compulsory certification of medical gloves;[14] relaxed authorization and production requirements for sanitizers and antiseptics;[15] and introduced facilitated procedures for conditional approval for registration (and post-registration changes) of drugs and biological products.[16] Canada is temporarily allowing hand sanitizers, disinfectants and PPE into its market that do not fully meet its (bilingual) labelling or packaging requirements.[17] Switzerland is temporarily lifting its authorization requirements for medicines and disinfectants, as well as its certification requirements for medical devices and PPE.[18] Ukraine notified temporary and exceptional procedures that broaden market access for PPE and medical devices which otherwise would not comply with its technical regulations, but the use of which is considered necessary to protect health due to the pandemic.[19] Thailand announced temporary facilitated registration approval for PPE, medical devices and pharmaceuticals.[20]

Remote/electronic procedures

In the context of the disruptions caused by COVID-19, a related group of notifications set out alternative procedures to enable compliance to be checked by remote or electronic means. For instance, Brazil notified temporary and emergency changes to its conformity assessment procedures to allow for remote inspection (through videoconference technologies and transmission of data) and verification through documentary analysis,[21] including for good manufacturing practices of pharmaceutical and medical devices.[22] The United Arab Emirates has activated the use of visual technology programmes (video meetings) in place of onsite visits, for instance for the renewal of accreditation.[23] Ecuador has developed online tools for verification of certificates of free sale.[24]

In the SPS area, several members have temporarily eased their certification requirements and are moving towards more electronic processes: eleven members accept copies or scanned documents instead of requiring originals, six have implemented electronic signatures, and three have also set up dedicated websites for the verification of documents. For instance, the European Union has allowed alternative methods for the performance of official controls and other activities, including the use of electronic copies and electronic formats of certificates and attestations. It has also authorized any designated laboratory to undertake analyses, testing or diagnoses. The United Arab Emirates is developing alternative solutions such as electronic health certificates and agreeing to verification procedures of certificates in order to reduce the use of paper health certificates.[25] Overall, there seems to be a trend towards electronic certification, in line with the e-Phyto Solution being implemented by the International Plant Protection Convention (IPPC), and supported by the Standards and Trade Development Facility (STDF).[26] These notified measures apply to live animals and food,[27] plant products,[28] and in some cases to a more general range of products.[29]

It remains to be seen whether the use of electronic or remote processes will be continued after the pandemic, based on experiences with their use.

[13] See WTO official document G/TBT/N/BRA/993/Add.1.
[14] See WTO official document G/TBT/N/BRA/992.
[15] See WTO official documents G/TBT/N/BRA/989 and G/TBT/N/BRA/996
[16] See WTO official document G/TBT/N/BRA/990.
[17] See WTO official document G/TBT/N/CAN/609.
[18] See WTO official documents G/TBT/N/CHE/244 and G/TBT/N/CHE/245.
[19] See WTO official document G/TBT/N/UKR/162.
[20] See WTO official documents G/TBT/N/THA/569 and G/TBT/N/THA/570.
[21] See WTO official documents G/TBT/N/BRA/978 and G/TBT/N/BRA/991.
[22] See WTO official documents G/TBT/N/BRA/984 and G/TBT/N/BRA/988.
[23] See WTO official documents G/SPS/GEN/1774 and G/TBT/GEN/294.
[24] See WTO official document G/TBT/GEN/293.
[25] See WTO official documents G/SPS/GEN/1774 and G/TBT/GEN/294.
[26] See also the STDF webpage on electronic SPS certification, including the STDF e-Phyto project.
[27] See WTO official documents G/SPS/N/CRI/230, G/SPS/N/ZAF/67, G/SPS/N/PHL/458, G/SPS/N/PHL/459 and G/SPS/N/JPN/755.
[28] See WTO official documents G/SPS/N/JPN/755, G/SPS/N/ZAF/66, G/SPS/N/BRA/1642, and G/SPS/N/PHL/460
[29] See WTO official documents G/SPS/GEN/1770, G/SPS/N/EU/380, G/SPS/N/RUS/184, G/SPS/N/USA/3135/Add.2, and G/SPS/N/TPKM/526.

Regulatory cooperation

Some members are choosing to rely on regulatory cooperation with other members as a basis for easing procedures and expediting access to essential medical equipment.

For example, instead of conducting its own inspections of pharmaceuticals manufacturers, Brazil has decided to accept information directly from other regulators that participate in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the Medical Device Single Audit Program (MDSAP).[30] Brazil will also directly accept certification of ventilators and other medical devices under MDSAP,[31] and will accept novel medical devices and PPE not regulated in Brazil but that are authorized in jurisdictions of other members of the International Medical Devices Regulators Forum (IMDRF).[32]

In a similar vein, Canada is allowing hand sanitizers, disinfectants and PPE that are authorized in other jurisdictions with similar regulatory frameworks.[33]

Ensuring safe medical goods

Several members have adopted new health, safety or quality requirements for medical goods in response to the pandemic. For instance, Kuwait[34] adopted a series of new standards covering respirators, disinfectants and antiseptics, medical devices and PPE, while Namibia[35] and Jamaica[36] adopted requirements for hand sanitizers, and Peru[37] for face masks for community use. Adopting such standards enables the domestic production of essential medical goods. The United States updated regulatory requirements for testing and approving air-purifying particulate respirators, which establish a new class of performance standards to relieve the current high demand for particulate filtering facepiece respirators in healthcare and emergency medical response settings.[38] Brazil introduced import procedures for products used for *in vitro* diagnosis of COVID-19.[39]

Making food available by relaxing technical regulations

A number of members have notified that they are temporarily relaxing certain aspects of technical regulations for some food products, while still ensuring health protection. For example, Indonesia is temporarily suspending fortification and quality requirements for food staples (flour, cooking oil, sugar) to ensure availability.[40] Switzerland is relaxing its food labelling requirements for six months, to respond to shortages of certain food ingredients and packaging material arising from the pandemic.[41]

Addressing COVID-19 risks from international trade of live animals

In the first stages of the pandemic, in the context of the SPS Agreement, a few members imposed temporary restrictions on the importation, and sometimes transit, of live animals and animal products, or on certain species, such as exotic and decorative animals, including insects, arthropods, amphibians, reptiles and live fish; other members' measures also included plants and aquatic organisms in addition to fish.[42, 43] While, initially, some measures targeted imports from China, later measures were broadened to other affected areas, including Italy, Iran, the Republic of Korea,

[30] See WTO official document G/TBT/N/BRA/984
[31] See WTO official document G/TBT/N/BRA/988
[32] See WTO official document G/TBT/N/BRA/993/Add.1
[33] See WTO official document G/TBT/N/CAN/609
[34] See WTO official documents G/TBT/N/KWT/538, G/TBT/N/KWT/539, G/TBT/N/KWT/540, G/TBT/N/KWT/541, G/TBT/N/KWT/542, G/TBT/N/KWT/543, G/TBT/N/KWT/544, G/TBT/N/KWT/546, G/TBT/N/KWT/547, G/TBT/N/KWT/548 and G/TBT/N/KWT/549.
[35] See WTO official document G/TBT/N/NAM/2.
[36] See WTO official document G/TBT/N/JAM/93.
[37] See WTO official document G/TBT/N/PER/120.
[38] See WTO official document G/TBT/N/USA/1602.
[39] See WTO official document G/TBT/N/BRA/1000.
[40] See WTO official documents G/TBT/N/IDN/1/Add.4, G/TBT/N/IDN/70/Add.1 and G/TBT/N/IDN/77/Add.5.
[41] See WTO official documents G/TBT/N/CHE/246 and G/SPS/N/CHE/84. This measure also pursues consumer protection and environmental objectives.
[42] See WTO official documents G/SPS/N/RUS/178 and G/SPS/N/RUS/Corr.1. The measure has already been lifted (G/SPS/N/RUS/178/Add.1).
[43] See WTO official document G/SPS/N/KAZ/59.

Switzerland, Réunion Island and member states of the European Union.[44] Some members also notified COVID-19-related certification requirements for any importation and/or movement of mammals and pets from Hong Kong, China,[45] or for all goods subject to veterinary and phytosanitary control.[46]

3 CONCLUSION

Standards and regulatory measures (SPS and TBT) make up two-thirds of notifications submitted by WTO members in response to COVID-19. Around half of these measures are reported as temporary. With respect to TBT, most measures ease conformity assessment applying to PPE and other essential medical equipment, to expedite access and increase supply. In the case of SPS, most measures aim to facilitate trade through the increased use of electronic certificates, mainly for plant products, but also for animal products, building on currently on-going e-certification initiatives by the IPPC and the World Organisation for Animal Health (OIE).

[44] See WTO official document G/SPS/N/MUS/18.
[45] See WTO official document G/SPS/N/IDN/132.
[46] See WTO official document G/SPS/N/RUS/184.