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

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Scope of Paper

• Background: Global Scramble for PPE amid COVID-19
• Technical barriers to PPE trade
• Mutual Recognition Agreements (MRAs) as a potential pathway to close the loophole
• Issues with existing MRAs
• Proposed provision in future MRAs
TBT in PPE sector

- Technic regulations/product standards

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Filter performance – (must be ≥ X% efficient)</td>
<td>≥ 95%</td>
<td>≥ 94%</td>
<td>≥ 95%</td>
<td>≥ 94%</td>
<td>≥ 94%</td>
<td>≥ 95%</td>
</tr>
<tr>
<td>Test agent</td>
<td>NaCl</td>
<td>NaCl and paraffin oil</td>
<td>NaCl</td>
<td>NaCl</td>
<td>NaCl and paraffin oil</td>
<td>NaCl</td>
</tr>
<tr>
<td>Flow rate</td>
<td>85 L/min</td>
<td>95 L/min</td>
<td>85 L/min</td>
<td>95 L/min</td>
<td>95 L/min</td>
<td>85 L/min</td>
</tr>
<tr>
<td>Total inward leakage (TIL)* – tested on human subjects each performing exercises</td>
<td>N/A</td>
<td>≤ 8% leakage (arithmetic mean)</td>
<td>≤ 8% leakage (arithmetic mean)</td>
<td>≤ 8% leakage (individual and arithmetic mean)</td>
<td>≤ 8% leakage (arithmetic mean)</td>
<td>Inward Leakage measured and included in User Instructions</td>
</tr>
<tr>
<td>Inhalation resistance – max pressure drop</td>
<td>≤ 343 Pa</td>
<td>≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)</td>
<td>≤ 350 Pa</td>
<td>≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)</td>
<td>≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)</td>
<td>≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)</td>
</tr>
<tr>
<td>Flow rate</td>
<td>85 L/min</td>
<td>Varied – see above</td>
<td>85 L/min</td>
<td>Varied – see above</td>
<td>Varied – see above</td>
<td>40 L/min</td>
</tr>
<tr>
<td>Exhalation resistance – max pressure drop</td>
<td>≤ 245 Pa</td>
<td>≤ 300 Pa</td>
<td>≤ 250 Pa</td>
<td>≤ 120 Pa</td>
<td>≤ 300 Pa</td>
<td>≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)</td>
</tr>
<tr>
<td>Flow rate</td>
<td>85 L/min</td>
<td>160 L/min</td>
<td>85 L/min</td>
<td>85 L/min</td>
<td>160 L/min</td>
<td>40 L/min</td>
</tr>
<tr>
<td>Exhalation valve leakage requirement</td>
<td>Leak rate ≤ 30 mL/min</td>
<td>N/A</td>
<td>Depressurization to 0 Pa ≤ 20 sec</td>
<td>Leak rate ≤ 30 mL/min</td>
<td>visual inspection after 300 L/min for 30 sec</td>
<td>Depressurization to 0 Pa ≤ 15 sec</td>
</tr>
<tr>
<td>Force applied</td>
<td>-245 Pa</td>
<td>N/A</td>
<td>-1180 Pa</td>
<td>-250 Pa</td>
<td>N/A</td>
<td>-1470 Pa</td>
</tr>
<tr>
<td>CO₂ clearance requirement</td>
<td>N/A</td>
<td>≤ 1%</td>
<td>-1180 Pa</td>
<td>-250 Pa</td>
<td>N/A</td>
<td>-1470 Pa</td>
</tr>
</tbody>
</table>

Source: 3M Technical Bulletin
TBT in PPE sector

• **Conformity Assessments** (CA Process EU as an example)

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2-6 weeks (depending on when the test report can be issued)

- Complete and submit Application Form, complete Technical File and Test Reports.
- Test report may cost additional 4-5 weeks at the moment.
- Review of Technical Documentation by assessor; report of findings sent to manufacturer.
- Findings to be addressed by manufacturer and additional evidence submitted.

Within one week

- Review amended technical documentation — if additional amendments are required, consult manufacturer. If not, send draft certificate.
- Confirm all information on draft is present.
- Temporary Certificate Issued (valid for 3 months).
- Finalise Docs and place products on the market.

Within 3 months

- Prepare Docs of a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.
- Confirm all EHSRs are met by manufacturer.
- Certificate Issued (valid for 5 years).
- Continue to place products on the market. Complete Module C2 or D.

Within one year

- Confirm all information on draft is present.
- Temporary Certificate Issued (valid for 3 months).
- Finalise Docs and place products on the market.
MRAs to facilitating PPE trade

• Recognition of Rules
  ➢ Examples: EU, AUS-NZ – require sufficient knowledge and close integration

Temporary recognition of PPE standards amid COVID-19 – many not enforced in practice

➢ EU Recommendation 2020/403
➢ US Emergency Use Authorisation (a list of countries and their relevant standards)
➢ China Measures on Emergency Imports of Medical Products
MRAs to facilitate PPE trade

- **Recognition of Conformity Assessment** – less ambitious but only some successful cases on COVID-related PPE

  ➢ Examples: MD: US-EU, EU-AUS, EU-NZL, EU-CHE, ASEAN
  PPE: EU-CHE

- **Origin-based restriction in MRAs?** – Most MRAs remain silent on this
Existing MRA provisions

• Medical Devices Annex to US-EU MRA:
  Silent, and expresses the aim of facilitating bilateral trade and the interest of SMEs in the EU and the US

• EU-NZL MRA: limits products to specific origin

• CETA (PPE+MD not included but identified as priority)
  ✓ Makes it clear that procedure for MR is not limited to products from other contracting party
Proposed model provision

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

• Temporary measures during COVID-19 crisis reflect same approach to mutual recognition ➔ convert to long term measures (incorporated in future MRAs)

• Envisage increased MRAs in future trade negotiations
  ➢ Endeavor to reach MR of rules based on International standards and short-term measures
  ➢ For negotiation of MR of CA ➔ eliminate origin-based bias in future MRA clauses
THANK YOU!