EUROPEAN COMMISSION
DIRECTORATE-GENERAL
TAXATION AND CUSTOMS UNION
Customs
**Risk management and security**
**Protection of citizens and enforcement of IPR**

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TAXUD.A.5.002

**NOTE FOR THE ATTENTION OF THE PARCS DELEGATES AND THE MEMBERS OF THE CUSTOMS CRISIS MANAGEMENT NETWORK**

**Subject:** **COVID-19 (note 04): prohibitions & restrictions (P&R) in the customs field**

In the context of the current COVID-19 global outbreak, I would like to draw your attention on the enclosed Annex, which provides information on the impacts of the COVID-19 outbreak in relation to:

– various prohibitions & restrictions (P&R) aspects in the customs field and

– other internal border measures to protect health and preserve the Single Market.

This document will be regularly updated in view of new developments.

Lina PAPAMICHALOPOULOU
Head of Unit TAXUD.A3

Valérie LEDURE
Head of Unit TAXUD.A.5

Enclosure: Annex A: COVID-19: prohibitions & restrictions (P&R) in the customs field

c.c.: Mr Quest, Ms Dzhumalieva, Mr Biebel, Mr Kermode, Ms Cassan, Ms Ledure, Ms Nicolle, Mr De Meyer, Mr Demoulin, Mr Burbulea, Ms Rottiers, Ms Aignier, Mr Gooreman, Ms Papamichalopoulou, Ms Segers, Mr Suortti, Mr Lazzaroni, DG TAXUD
Mr Ingels, Ms Martinez Felix, Mr Roeland, DG GROW
Mr Michiels, Ms Silna, Ms Van Kampen, DG TRADE

# Annex A: COVID-19: prohibitions & restrictions (P&R) in the customs field

**Disclaimer: As a general remark, it should be underlined that this document is not legally binding. It does not create rights and obligations and is of an explanatory nature only. Its purpose is to provide a tool to facilitate the correct and uniform application of relevant legislation by the Member States and to improve compliance by economic operators.**

## 1. CONFORMITY OF PRODUCTS

### 1.1. [20.3.2020] Recommendation on conformity assessment

– Recommendation (EU) 2020/403 of 13 March on conformity assessment and market surveillance procedures within the context of the COVID-19 threats – C/2020/1712
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H0403

– Summary: The Recommendation intends to allow non CE-marked PPE products that comply with the necessary health and safety standards to enter the EU market. The objective is to ensure that all authorities treat as a matter of priority shipments from third countries containing personal protective equipment (PPE) such as face masks, gloves, protective coveralls or eyewear protection, as well as for medical devices such as surgical masks, exploration gloves and some gowns, to avoid increasing shortages in Member States in need.

### 1.2. [20.3.2020] European standards for medical supplies made freely available

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/IP_20_502

– Summary: Upon the urgent request of the Commission, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), in collaboration with all their members, have agreed to immediately make available a number of European standards for certain medical devices and personal protective equipment. This action will help both EU and third-country companies willing to manufacture these items to swiftly start production and place products on the internal market more easily while ensuring a high degree of safety.

### 1.3. [30.3.2020] Guidance to help increase production of safe medical supplies

– Press release of 30.3.2020 on questions and answers to help increase production of safe medical supplies
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_558

– Summary: The guidance assists manufacturers in ramping up production of essential medical equipment and material in three areas: the production of masks and other personal protective equipment (PPE), leave-on hand cleaners and hand disinfectants and 3D printing in the context of the coronavirus outbreak. These documents also aim to assist manufacturers and market surveillance authorities in making sure these products comply with necessary safety standards and are effective.

### 1.4. [30.3.2020] Guidance on conformity assessment procedures for protective equipment

– Conformity assessment procedures for protective equipment
https://ec.europa.eu/docsroom/documents/40521

– Summary: The guidance helps manufacturers to assess the applicable legal and technical requirements before importing new products to the EU or launching new or reconverting existing facilities to produce protective equipment like masks, gloves and surgical gowns to satisfy the unprecedented demand in the wake of the coronavirus outbreak. It explains the role of national authorities, in particular market surveillance authorities in ensuring an adequate level of health and safety of equipment originating in third-countries, which is placed on the EU market.

**1.5. [30.3.2020] Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.)**

– Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.)
https://ec.europa.eu/docsroom/documents/40523

– Summary: The document provides guidance to economic operators including small and medium-sized enterprises on the applicable legal framework for the placing on the EU market of hydro-alcoholic gel (i.e. the Cosmetic Products Regulation or the Biocidal Products Regulation) and the claims which can be made to the user. It aims at responding to frequent questions the Commission is receiving from operators of the cosmetic and of other sectors, which are heavily engaged in increasing or converting their production capacity towards these products.

**1.6. [30.3.2020] Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context**

– Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19
https://ec.europa.eu/docsroom/documents/40522

– Summary: The guidance aims to detail the applicable EU legal frameworks for those products and sets out examples of technical standards which manufacturers may use in order to place compliant products on the EU market.

**1.7. [NEW: 3.4.2020] Proposed postponement of the Medical Devices Regulation**

– Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions – COM(2020) 144
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020PC0144

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_589

– Summary: The document proposes to postpone the application of the Regulation by one year - until 26 May 2021. This proposal will not affect the date of application of the In Vitro Diagnostics Medical Devices Regulation, which becomes applicable from 26 May 2022.

### 1.8. [NEW: 8.04.2020] Guidelines on the optimisation of supply of medicines

– Communication from the Commission – Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak – C(2020) 2272
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0408(03)

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_622

– Summary: The guidelines focus on the rational supply, allocation and use of vital medicines to treat coronavirus patients as well as medicines which may be at risk of shortage due to the pandemic. The proposed actions should allow for a more coordinated approach across the EU, preserving the integrity of the Single Market whilst protecting public health.

### 1.9. [NEW: 10.4.2020] Regulatory expectations for medicinal products for human use

– Questions and answers on regulatory expectations for medicinal products for human use
https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf

– Summary: The document explains some regulatory flexibilities that can be applied to help pharmaceutical companies cope with the consequences of the pandemic, while ensuring a high level of quality, safety and efficacy for medicinal products made available to patients in the EU. The measures introduced cover different areas of the regulation of medicines, incl. importation of active pharmaceutical ingredients (APIs) and finished products and labelling and packaging requirements.

### 1.10. [FUTURE: TBD] Guidance on medical devices

– [REFERENCE TO COME]

– [LINK TO COME]

– Summary: A guidance on medical devices will be made available within the coming days.

## 2. EXPORT AUTHORISATION OF PERSONAL PROTECTIVE EQUIPMENT (PPE)

### 2.1. [1.4.2020] FAQ on PPE export authorisation

– Frequently Asked Questions (FAQ) on export authorisation for personal protective authorisation
https://ec.europa.eu/trade/import-and-export-rules

– Summary: All relevant information on this subject is made publicly available under a joint TRADE-TAXUD FAQ on DG TRADE website

## 3. FIGHT AGAINST COUNTERFEIT PRODUCTS

### 3.1. [27.3.2020] TAXUD note Ares(2020)1795618

- The Coronavirus outbreak has offered new opportunities for fraudsters to profit from the high market demand for medical, personal protection, and hygiene products. MS have been requested by TAXUD via the crisis alert on COVID 19 (created on 4.02.2020 in the Customs Risk Management System/Crisis Management (CRMS/CM)) to ensure that the risk of substandard or counterfeit medical products are properly addressed.

- MS have Regulation (EU) 608/2013 at their disposal to enforce IPR at the EU external borders (actions potentially possible on goods suspected of infringing an IPR under all customs procedures).

- MS were also recalled to share in CRMS via a RIF (Risk Information form) any case of dangerous, substandard or counterfeit goods related to COVID-19.

- In the framework of the EU IPR action plans with China and Hong Kong, DG TAXUD:

  - recalled the participating MS to the Action Plans to pay attention to this specific issue,

  - already exchanged concrete information with HK customs (concerning masks)

  - contacted China customs to ask appropriate attention.

- On 19 March 2020, OLAF opened a case in relation to the imports of fake products used in the fight against the COVID-19 infection, such as masks, medical devices, disinfectants, sanitisers and test kits.

- At the crisis CPG of 1st April, MS were urged to actively cooperate in it.

## 4. INTERNAL BORDER MANAGEMENT & GREEN LANES

**Remark: this topic is not directly related to customs issues and is included for information only.**

### 4.1. [NEW] General Websites

- Commission measures
  https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/travel-and-transportation_en

- National measures
  https://ec.europa.eu/transport/coronavirus-response_en

### 4.2. [16.3.2020] Temporary restriction on non-essential travel to the EU

– Communication from the Commission to the European Parliament, the European Council and the Council – COVID-19: Temporary Restriction on Non-Essential Travel to the EU – COM/2020/115
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0115

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_20_477

### 4.3. [16.3.2020] Guidelines for border measures to protect health and keep goods and essential services available

– Guidelines for border management measures to protect health and ensure the availability of goods and essential services – C(2020) 1753
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0316(03)

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_468

– Summary: The aim is to protect citizens' health, ensure the right treatment of people who do have to travel, and make sure essential goods and services remain available. Commissioners Kyriakides and Johansson presented the guidelines to EU ministers of Health and of Home Affairs at their first joint video meeting on 16.3.2020.

### 4.4. [23.3.2020] Guidance to ensure continuous flow of goods across EU via green lanes

– Communication from the Commission on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services – C/2020/1897
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0324(01)

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_510

– Summary: To keep freight moving freely and efficiently across the EU, the European Commission has issued practical advice on the implementation of ‘green lanes’ – border crossings open to all freight vehicles carrying goods where any checks or health screenings should not take more than 15 minutes.

### 4.5. [26.3.3030] Guidelines on facilitating air cargo

– Communication from the Commission - European Commission Guidelines on facilitating Air Cargo Operations during COVID-19 outbreak – C/2020/2010
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0327(03)

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_533

– Summary: The new guidance recommends operational and organisational steps to keep essential transport flows moving, including medical supplies and personnel.

**4.6. [30.3.2020] Guidance on implementing the temporary restriction on non-essential travel to the EU**

– Communication from the Commission - Guidance on the implementation of the temporary restriction on non-essential travel to the EU, on the facilitation of transit arrangements for the repatriation of EU citizens, and on the effects on visa policy – C/2020/2050
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0330(02)

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_543

– Summary: This guidance, which will assist border guards and visa authorities, provides advice on the implementation of the temporary restriction at the border, on facilitating transit arrangements for the repatriation of EU citizens, and on visa issues.

**4.7. [30.3.2020] Guidance to ensure the free movement of critical workers**

– Communication from the Commission - COVID-19 - Guidance on the implementation of the temporary restriction on non-essential travel to the EU, on the facilitation of transit arrangements for the repatriation of EU citizens, and on the effects on visa policy – C/2020/2051
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0330(03)

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_545

– Summary: The guidelines identify a range of workers that exercise critical occupations, and for which continued free movement in the EU is deemed essential.

**4.8. [NEW: 31.3.2020] Ensuring waste shipments across the EU**

– https://ec.europa.eu/environment/waste/shipments/pdf/waste_shipment_and_COVID19.pdf

– Summary: The guidance aims at ensuring a common approach is taken in the EU for securing the continuation of waste shipments across the EU via the green lanes. It is essential to prevent and reduce any possible obstacles to cross-border movements of waste within the EU. The guidance is addressed to Member States authorities, economic operators and relevant stakeholders.

**4.9. [NEW: 8.4.2020] Guidelines on seafarers, passengers and other persons on board ships**

– Communication from the Commission – Guidelines on protection of health, repatriation and travel arrangements for seafarers, passengers and

other persons on board ships – C/2020/3100
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0414(01)

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_619

– Questions & Answers
https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_632

– Summary: From cruise ship passengers to cargo vessel crew, many have found themselves stranded since the coronavirus pandemic first took hold. The guidelines support these individuals, providing recommendations on health, repatriation and travel arrangements. They also call on Member States to create a network of ports where crew changes can take place without delays.

### 4.10. [NEW: 8.4.2020] Extension of the temporary restriction on non-essential travel to the EU

– Communication from the Commission to the European Parliament, the European Council and the Council – COVID-19: Temporary Restriction on Non-Essential Travel to the EU – COM(2020) 148
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0148

– Questions & Answers
https://ec.europa.eu/info/files/questions-answers-people-travelling-and-eu-during-pandemic_en

– Press release
https://ec.europa.eu/commission/presscorner/detail/en/ip_20_616

– Summary: The Commission invited Schengen Member States and Schengen Associated States to prolong the temporary restriction on non-essential travel to the EU until 15 May. The experience of Member States and other countries exposed to the pandemic shows the measures applied to fight the spread of the virus require more than 30 days to be effective. The Commission calls for a coordinated approach to the prolongation, as action at the external borders can only be effective if implemented by all EU and Schengen States at all borders, with the same end date and in a uniform manner. The travel restriction, as well as the invitation to extend it, applies to the 'EU+ area', which includes all Schengen Member States (including Bulgaria, Croatia, Cyprus, and Romania) and the 4 Schengen Associated States (Iceland, Liechtenstein, Norway, and Switzerland) – 30 countries in total.

### 4.11. [NEW: 08.4.2020] Frequently Asked Questions

– Frequently Asked Questions – Communication COM(2020)115 on Temporary restriction on non-essential travel to the EU and Communication C(2020)2050 Guidance on the implementation of the temporary restriction on non-essential travel
https://ec.europa.eu/home-affairs/sites/homeaffairs/files/20200408_faqs-communications-non-essential-travel.pdf