# Transportation of COVID-19 Vaccines by Air

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Deputy Regional Director ICAO EUR/NAT Office

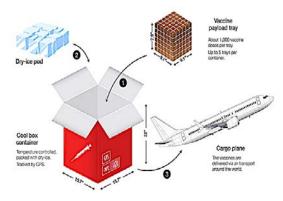
ICAO EUR/NAT DGCA teleconference 24 February 2021



# Vaccine delivery

- Now a reality.
- Is aviation ready?
- We know how to do it.
- Volume and timing is a challenge.
- 8,000 jumbo jets needed to deliver. (source – IATA)





- 1. Coordination with multiple authorities Vaccine delivery is a multifunctional area.
- 2. Operational flexibility for flights carrying vaccines (question of traffic rights, approvals for charters, etc.).
- 3. Cargo security Maintain continued security of air cargo from acts of unlawful interference.
- 4. Facilitation Coordinate between CAAs, health authorities, and industry for faster border processes and the rapid adoption of digital technologies to improve supply chain safety, efficiency and resilience.
- 5. Cargo safety Proper classification of vaccines; provide guidance on use of refrigerants, data loggers.
- 6. Mutual recognition of vaccine records and certificates adoption of policies and processes for issuance of secure vaccine certificates that will be accepted as widely as necessary.

Presented by Cortney Robinson,
Air Transport Officer (Air Cargo)
Economic Regulatory Framework Section (ERF)

#### **ECONOMICAL CONSIDERATIONS**

### Grant of 7th Freedom Traffic Right

- LACAC uses multilateral:
  - ✓ Established through an MoU 7<sup>th</sup> freedom for all-cargo flights without route/capacity restrictions in Dec 2020;
  - ✓ Existing regional multilateral provides basis for the MoU;
  - ✓ In force for a maximum of two years;
  - ✓ Intention is COVID-19 vaccine transport.
- Uzbekistan uses unilateral in its new provision:
  - ✓ Unilateral action in June 2020 by granting extra-bilateral rights to foreign carriers for both passengers and cargo;
  - ✓ Restrictions;
  - ✓ In force until winter 2023:
  - ✓ Intention is trade facilitation, tourism, and broader air connectivity.
- Many regions are seeking guidance and beginning active discussions.
- A global solution is strongly preferred; regional solutions represent progress, but could fall short in regions lacking air cargo capacity.
- The unilateral approach avoids many of the challenges of multilaterals, however States must move forward together in implementing such policies to realize their benefits.



## Collaboration on Air Cargo Digitalization

- Support UNECE in the UN Development Account project for the UN COVID-19 Rapid **Response:** Transport and Trade Connectivity in the Age of Pandemics: Contactless, Seamless and Collaborative UN Solutions
- Relevant project components that will benefit air cargo stakeholders:
  - ✓ Reducing physical contacts among the participants of international trade and transport operations (aligned with ICAO Public Health Corridor concept); and
  - ✓ Pursuing collaborative rather than unilateral solutions on transport response to the pandemic.
- Deliverables relevant to ICAO: technical specifications for data exchange for the e-Airwaybill, e-CSD, Dangerous Goods Declaration. EUR/NAT, SAM and NACC will provide support; additional support from IATA, TIACA, IPCSA and others on technical work.

# Helpful links on Air Cargo Economics, Digitalization and Supply Chain

- Guidance on Economic and Financial Measures to Mitigate the Impact of the Coronavirus
   Outbreak on Aviation (Dec 2020): <a href="https://www.icao.int/sustainability/Documents/COVID-19">https://www.icao.int/sustainability/Documents/COVID-19</a>
   Economic and Financial Measures/ICAO Guidance on Economic and Financial Measures.pdf
- UNDA *Transport and Trade Connectivity in the Age of Pandemics* project profile: <a href="http://www.un.org/development/desa/da/wp-content/uploads/sites/52/2020/08/2023X">http://www.un.org/development/desa/da/wp-content/uploads/sites/52/2020/08/2023X</a> Transport-and-Trade-Connectivity-in-the-Age-of-Pandemics.pdf

Presented by Lynn McGuigan Technical Officer, Cargo Safety, ICAO

#### **OPERATIONAL SAFETY**

- Classification of vaccines as dangerous goods
- Tracking
  - Data loggers and tracking devices (lithium batteries)
- Temperature control
  - Refrigerants (dry ice)





#### Classification of COVID-19 Vaccines

- Most are not hazardous during transport
  - Not dangerous goods as defined by the **Technical Instructions**
- Some contain genetically modified organisms (GMOs) or micro-organisms (GMMOs)
  - Low risk to transport
  - Not subject to Technical Instructions WHEN AUTHORIZED FOR USE BY THE APPROPRIATE NATIONAL AUTHORITIES of the States of Origin, transit and destination.
  - Obtaining authorization by States of Origin, transit and destination complicated
  - Without authorization subject to Packing Instruction 959

"WHO and ICAO urge all Member States to exempt GMMO vaccines from dangerous goods provisions when the vaccine is in authorized clinical trial stage prior to final authorization by the national regulatory authorities"

57<sup>th</sup> Session of the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods 30 November to 8 December 2020



#### Amendment to 2021-2022 Edition of Technical Instructions: GMMOs

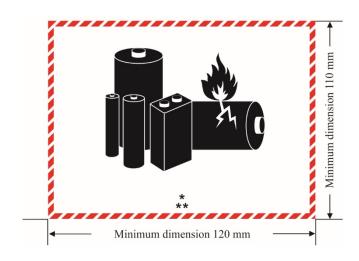
- Addendum No. 1
- Applicable 1 January 2021
- Part 2, Chapter 9, Table 2-16

"COVID-19 vaccines containing GMOs or GMMOs, including those in clinical trials, are not subject to these Instructions."



### Data Loggers and Tracking Devices

- Hazards
  - Electromagnetic interference
  - Lithium batteries
    - Ignition source
    - Fuel
- Subject to Technical Instructions
  - Lithium battery mark





# COVID-19 Vaccines and Data Loggers/Tracking Devices

- Used to monitor the temperature and location of vaccines during transport.
- Potential delays with lithium battery mark.
- Packaging and devices subject to robust medical standards.
- Guidance:
  - www.icao.int/safety/OPS/OPS Normal/Pages/Vaccines-Transport.aspx



# Amendment to 2021-2022 Edition of Technical Instructions: Data Loggers and Tracking Devices

- Addendum No. 1
- Applicable 1 January 2021
- Special provision applicable to lithium ion and lithium metal batteries contained in equipment.
- Further amendment for return of boxes and broader scope (COVID-19 pharmaceuticals)?

"Packages containing COVID-19 vaccines accompanied by data loggers and/or cargo tracking devices containing lithium batteries are not subject to the marking and documentation requirements of Section II of Packing Instruction 967 or 970, as applicable."



#### Solid Carbon Dioxide (Dry Ice)

- Commonly transported as refrigerant
- Hazards
  - Sublimation of dry ice/ displacement of oxygen
- Subject to Technical Instructions
- Additional limitations based on specific aircraft, its systems, sublimation rate, capability to vent CO<sub>2</sub>





#### COVID-19 Vaccines and Dry Ice

- Challenges
  - Larger quantities than normal
  - Using smaller aircraft for remote locations
- Communication
  - Operator, CAA, manufacturers (airframe, vaccine, packaging)
- Existing guidance
  - FAA, EASA, ICCAIA
- ICAO guidance on vaccines
  - www.icao.int/safety/OPS/OPS-Normal/Pages/Vaccines-Transport.aspx



#### Conclusion

- States should help facilitate transport of COVID-19 vaccines without compromising safety.
- Vaccines are routinely transported, so caution against fixing what is not broken.
- Helpful guidance:
  - Safety transport of COVID-19 vaccines on commercial aircraft:
    - √ <a href="https://www.icao.int/safety/OPS/OPS-Normal/Pages/Safety-transport-vaccines.aspx">https://www.icao.int/safety/OPS/OPS-Normal/Pages/Safety-transport-vaccines.aspx</a>
  - ➤ Guidance for Safe Operations Involving Aeroplane Cargo Compartments (Doc 10102)
  - Safety Management Manual (Doc 9859)
  - Handbook for Civil Aviation Authorities (CAAs) on the Management of Aviation Safety Risks related to COVID-19 (Doc 10144)
    - √ <a href="https://www.icao.int/safety/SafetyManagement/Pages/COVID-19-Safety-Risk-Management.aspx">https://www.icao.int/safety/SafetyManagement/Pages/COVID-19-Safety-Risk-Management.aspx</a>

Presented by Inga Jgenti, Consultant - AVSEC/FAL

#### **CARGO SECURITY**

#### **Aviation Security Aspects**

- State letter AS 8/7-21/6 of 27 January 2021 "The distribution of COVID-19 vaccines and Air Cargo Security" contains references and guidance to assist States in their efforts to ensure robust security for vaccine transportation while supporting facilitation.
- Annex 17 requires that Air Cargo and Mail shipments must be secured and protected from unauthorized interference before being loaded on board a commercial aircraft. Aviation Security Procedures include:
  - Screening where practicable;
  - Secure Supply Chain Procedures based on Regulated agents and Known consignors regimes;
  - Exemptions (e.g. BIOM).
- Guidance material ICAO Security Manual Doc 8973 Chapter 13 and Appendix 30;

#### Additional Annex 17 SARPs to be considered:

- ✓ Risk Assessment 3.1.5 and 3.1.4;
- Landside Security 4.8.1, 4.8.2 and 4.8.3;
- Cybersecurity 4.9.1.



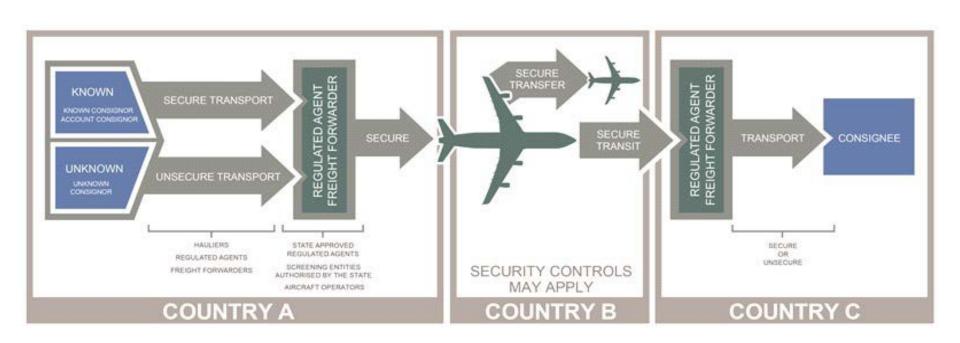
### Suggested actions by States

Securing of COVID-19 vaccines through State's supply chain security process

- Identify manufactures, handling and transportation entities and assist them by providing information on Known Consignors/Regulated Agents approval process.
- Consider granting Known Consignor status urgently to approved production facilities for COVID-19 vaccines, taking into consideration other existing supply chain regimes overseen by other national authorities (e.g. Pharmaceuticals regulators, Customs Authorities).
- Until Known Consignor status is granted, Consider alternative measures/temporary exemptions from screening of COVID-19 shipments based on national risk assessment.



### Air Cargo Secure Supply Chain Process





### Suggested actions by States

#### Securing of COVID-19 vaccines by applying alternative security procedures

- Where a secure supply chain process cannot be provided, alternative security procedures such as temporary exemption from screening (strictly limited, based on the NCASP provisions) may be applied in accordance with a State's own risk assessment.
- The nature of the consignment should be properly declared (BIOM/COVID-19 vaccine) on the shipping documentation (airway bill) and subject to documentary and physical checks to ensure that the cargo matches the description and shows no signs of tampering.
- The consignment needs to be issued with a security status (either in electronic format or in writing) and continually protected against unauthorized interference.
- Transfer Cargo should be protected from unauthorized interference during all steps of transportation and have a security status, Transit consignments should be clearly indicated in the accompanying airway bills.
- If signs of tampering are identified, States should apply the security measures stipulated by the NCASP.

#### Other considerations

- States should consider COVID-19 vaccines as high-value cargo and facilitate the implementation of measures aimed at protecting such shipments from non-aviation security-related threats (e.g. criminal threats).
- The Appropriate Authority should ensure that the ability of aviation security measures applied to safeguard civil aviation against acts of unlawful interference is not compromised.
- ▶ Different national authorities and stakeholders should address different risks in coordination with one another (e.g. via NCASC/NATFC) a robust communication process between all entities is vital.
- States should consider establishing plans to accommodate contingency situations (e.g. diversion of aircraft carrying shipments of COVID-19 vaccines).
- States should consider leveraging/implementing additional instruments e.g. Pre-Loading Advance Cargo Information (PLACI) programme.

Presented by Cornelia Ludorf, Regional Officer, Aviation Security

#### **FACILITATION**

#### **Facilitation Aspects**

- Article 22 of the Chicago Convention expresses the obligation accepted by each Contracting State "To adopt all practicable measures, through the issuance of special regulations or otherwise, to facilitate and expedite navigation by aircraft between the territories of contracting States, and to prevent unnecessary delays to aircraft, crews, passengers and CARGO, especially in the administration of the laws relating to immigration, quarantine, customs and clearance".
- Standards and Recommended Practices Annex 9.
- Guidance material:
  - ✓ Doc 9957 Facilitation Manual;
  - ✓ Doc 10042 Model National Air Transport Facilitation Programme.

- Facilitation of entry and departure of aircraft (Annex 9, Chapter 2, Section "F"):
  - Standards 2.37 and 2.38 Establishment of efficient procedures for prior authorization for non-scheduled/additional flights for air cargo operators:
  - ✓ No requirement for notifications be applied for through diplomatic channels, unless the flight is diplomatic in nature;
  - ✓ Establishment of procedures whereby such application will be dealt with promptly;
  - ✓ Requirement to make such permission effective for a specific length of time or number of flights wherever possible; and
  - ✓ Impose no fees, dues or charges for the issue of such permission.
- Implementation of international health regulations and related provisions (Annex 9, Chapter 8, section "E") and facilitation of the entry of Crew members (Annex 9, Chapter 3, section "N"):
  - ✓ Recommended Practice 8.15.1 States are recommended to use systematically the Passenger Locator Form (Appendix 13) for Crew members to facilitate tracing, consider digitalizing the form for ease of use and effective submission and States may additionally apply sanitary measures (e.g. testing) to exempt crews from mandatory quarantine regime.

- Facilitation of entry and departure of Cargo (Annex 9, Chapter 4):
  - ✓ Coordinated and simultaneous application of release/clearance procedures by various entities (the principle of a single entry window) (Standard 4.5);
  - ✓ Application of Risk management (Standard 4.6);
  - ✓ Digitalization of documents and information submission processes (RP 4.10; 4.20);
  - ✓ Promotion of standardization and harmonization of information formats and procedures (paper or electronic) (Standard 4.16; 4.17);
  - ✓ Introduction of interoperable electronic communication standards (Standard 4.17; RP 4.10; 4.17.1; 4.17.2);
  - ✓ Providing awareness and guidance material necessary to streamline the distribution of vaccines to manufacturers and entities engaged in vaccine shipping (e.g. ICAO, IATA, ACI guidance).

- Establishment of a National Air Transport Facilitation Programme (NATFP) (Annex 9, Chapter 8, Section "G")
  - ✓ Standard 8.17 Obligation to establish a National Air Transport Facilitation Programme based on the facilitation requirements of the Chicago Convention and of Annex 9 thereto.

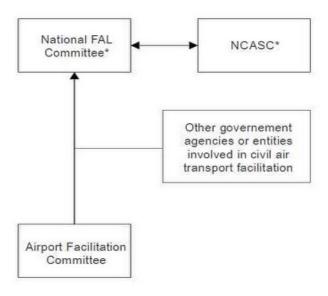
#### The objectives of the programme are:

- ✓ To adopt all practicable measures to facilitate the movement of aircrafts, crews, passengers, cargo, mail and stores, by removing unnecessary obstacles and delays;
- ✓ To define the mandates of various national stakeholders involved in implementation of facilitation standards and procedures (ref. standard 8.18).

- Establishment of coordinating bodies (Annex 9, Chapter 8, section "G"):
  - ✓ Standard 8.19 Obligation to establish a National Air Transport Facilitation Committee, and Airport Facilitation Committees, or similar coordinating bodies, for the purpose of coordinating facilitation activities between departments, agencies, and other organizations of the State.
- ➤ The National Air Transport Facilitation Committee (NATFC) is a vehicle for coordinating the implementation of the NATFP. The chair of the NATFC should be a top-management official in the CAA (details of composition ref. Doc 9957 and attachment 2 of Doc 10042).
- ➤ It is recommended to establish coordination between the NCASC and NATFC certain members of the FAL Committee should also be members of the Security Committee.
- ➤ The Airport Facilitation Committee is a vehicle for coordinating the implementation of the facilitation programme at the operational level. The Airport Facilitation Committee should coordinate with the NATFC and provide information regarding their challenges and progress.

In the light of the pandemic and in anticipation of extensive COVID-19 vaccine transport and distribution globally, coordination and cooperation between various stakeholders, including public health authorities at national and airport levels is essential.

# Establishment of National coordination bodies – Coordination Framework



Presented by Sven Halle, Regional Officer, Air Navigation Systems Implementation (ATM)

# AIR NAVIGATION CAPACITY AND EFFICIENCY

#### Air Navigation Capacity and Efficiency related issues

- ➤ IATA Guidance for Vaccine and Pharmaceutical Logistics & Distribution, 2<sup>nd</sup> update December 2020;
- ACI Advisory Bulletin regarding airport preparedness for COVID-19 vaccine distribution, December 2020;
- ➤ ICAO discussion on additional guidance which resulted in State Letter 21/06 (Distribution of COVID-19 Vaccines and Air Cargo Security) from 21 January 2021.





... helping States and Industry apply aviation security measures while facilitating a smooth flow of vaccines throughout the supply chain and to the final destination.

# Coordinated Air Traffic Management (ATM) approach for specific flights transporting COVID-19 vaccines which may require special handling and/or priority

The routine transport of COVID-19 vaccine and pharmaceutical products should still be a business-as-usual task which follows the existing provisions.

- However...
- when considering specific aspects of the COVID-19 vaccine delivery process, there could be special circumstances for a flight which would then require special or priority handling, so that the vaccines will not be put at risk.

#### **Air Navigation Aspects**

#### Example A

✓ A flight which has to be able to arrive at the destination airport before the end of the operating hours or before a local curfew (avoiding the potential diversion to an alternate aerodrome) so that the vaccine can still be uplifted and further distributed.

#### Example B

✓ A flight has accumulated several delays during the day, or would receive Air Traffic Flow Management measures which would now have a direct impact on the connecting flights when the vaccine shipment will be distributed onto several flights at a hub airport towards different destinations.



#### Example C

✓

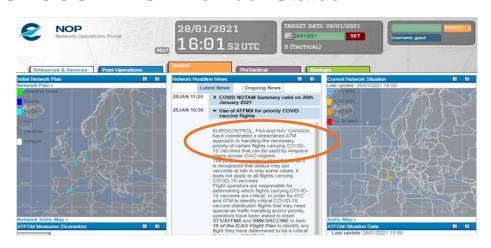
#### ATM approach for critical COVID-19 vaccines flights

- > In order for Air Traffic Management and Air Traffic Control Units to identify critical COVID-19 vaccine distribution flights that may need special air traffic handling and/or priority, aircraft operators have been asked to insert STS/ATFMX and RMK/VACCINE in Item 18 of the ICAO Flight Plan to identify any flight they have determined to be a critical flight due to the COVID-19 vaccine transport.
- > Aircraft operators are responsible for determining which flights carrying COVID-19 vaccines are critical and it must be understood that this process/procedure does NOT apply to all flights carrying COVID-19 vaccines.



#### ATM approach for critical COVID-19 vaccines flights

This coordinated process/procedure was implemented on 28 January 2021 by the United States FAA, NAV Canada and in all EUROCONTROL Member States.





#### ATM approach for critical COVID-19 vaccines flights

A NOTAM text was prepared as a template for all involved States:

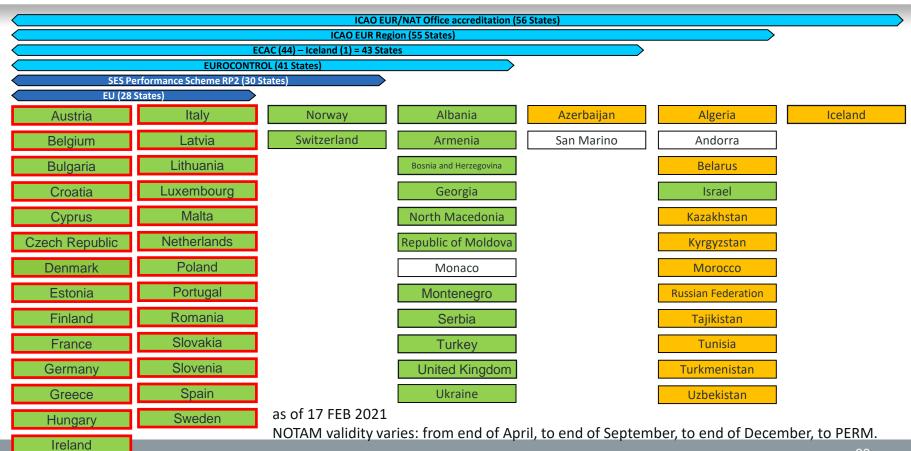
#### NOTAM Text:

Effective Date – 28<sup>th</sup> January 2021 Published by – 25<sup>th</sup> January 2021

To ensure safe and expeditious delivery of COVID-19 vaccines, aircraft operators of flights carrying such vaccines should ask approval from (mention relevant State Authority) for exemption from ATFM measures for each flight deemed critical. Upon approval, STS/ATFMX and RMK/VACCINE shall be inserted in Item 18 of the flight plan. Aircraft Operators carrying COVID 19 vaccines regularly may request approval in advance for all flights involved.

The ICAO EUR/NAT Office issued a State Letter (Ref: EUR/NAT 21-0011 of 19 January 2021) which invited the States in the EUR Region which are also operating an Air Traffic Flow Management Centre to consider the implementation of this harmonized process/procedure.

#### **Air Navigation Aspects**



Presented by Berk Bozkurt, Regional Officer, Air Navigation Systems Implementation (ATM)

# PUBLIC HEALTH CORRIDORS AND MUTUAL RECOGNITION

### Public Health Corridor (PHC)

- CAPSCA Experts Group developed the PHC concept ICAO Council approved and included it in the CART and TOGD.
- A key to ensure continued flight operations with minimal restrictions, prevent the spread of COVID-19, protect the health of crew and passengers.
- To establish this, mutual recognition of the implemented public health mitigation measures on one or more routes agreed between States is needed.
- States are encouraged to have bilateral or multilateral discussions with each other to establish PHCs.
- A dedicated ICAO Application is developed to support the States.

#### Vaccine Certificates - the latest

- The leading UN organization working on this topic is WHO.
- WHO established the Smart Vaccination Certificate Expert Group.
- ICAO is contributing to the WHO ongoing work with a multidisciplinary team of 9 experts.
- WHO Emergency Committee, 15 January 2021:
  - No requirements of proof of vaccination for international travel;
  - An internationally recognized solution for certification of testing results for travel is urgently needed;
  - The need for a solution enabling the certification of vaccination status for travel is planned to be developed in the short to medium term.



#### Vaccine Certificates - the latest

- ICAO is urged to support the Aviation Industry partners ASAP.
- There are both Medical and Technical Aspects to consider.
- Multi-disciplinary working methodology also within ICAO.
- CAPSCA Experts Group has recommended the data elements needed for standardized testing certificates, elements for vaccination certificate will be determined by WHO.
- Proposed way forward: Use the CAPSCA med specifications and of the specifications for Visible Digital Seal (VDS) – a 2D barcode for reading and authenticating testing/vaccine certificates. Similar specifications are already used for ICAO travel documents such as electronic visas.
- The policy decision will be at the State level implementation of all Public Health guidelines are subject to State authorities' approval (State sovereignty).

# ICAO Doc 10152

- ICAO published in November 2020: Doc 10152, Manual on Testing and Cross-border Risk Management Measures;
- This guidance is intended for use by State regulators, service providers and other concerned entities and addresses cross-border risk management in commercial air transport operations;
- The objective of the guidance is to inform States about public health risk management strategies to reduce the probability of translocation of the disease from one region to another;
- Version 2 of ICAO Doc 10152 will include: Validation of testing certificates, a new section on vaccination and a new chapter on PHCs;
- Version 2: expected to be completed end of March 2021.



