ETHIOPIAN CIVIL AVIATION AUTHORITY

TRANSPORTATION OF VACCINES USING DRY ICE

February 2021

APPROVAL

DIRECTIVE (DIR).REF.:	ECAA/DG/DIR/001/2021
Subject:	Safe Transportation of COVID-19 Vaccines on Commercial Aircraft
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Applicability:	This Directive is applicable to all Aircraft Operators intending to transport COVID-19 Vaccines using dry ice on commercial aircraft.

This Directive contains mandatory information regarding operational safety. This Directive is published to provide guidance that can be used by operators to support the safe transport of COVID-19 Vaccines on Commercial Aircraft due o the special situation resulting from the COVID-19 pandemic.

Air Operators must ensure that this document is copied to all members of their staff who need to take appropriate action or who may have an interest in the information.

This Directive is approved by the undersigned for use by all to whom it applies and will remain in effect until further notice.

By:.....
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1. Background and Scope

Worldwide demand for COVID-19 vaccines will result in a significant increase in the volume of vaccines offered for air transport. It is expected that large quantities of COVID-19 vaccines will be transported by airfreight, which may introduce challenges for the supply chain as well as for the airline operators.

Some COVID-19 vaccines may need to be maintained at sub-zero temperatures during transport, and some may even require a temperature-controlled environment of below -70°C. The cooling can reliably be ensured by the use of dry ice (frozen CO2). Dry ice, however, is classified as a dangerous good.

The use of dry ice in large quantities on board an aircraft may raise hazard particularly when transported on the main (passenger/cargo) deck of a large aeroplane.

Compliance with the requirements for the transport of dangerous goods on board the aircraft and ICAO Doc 9284 'Technical Instructions for the Safe Transport of Dangerous Goods by Air') is the responsibility of each operator.

The transport of vaccines must comply with the detailed provisions of the Technical Instructions where the vaccines are classified as dangerous goods, or the vaccines are shipped with dry ice as a refrigerant, or data loggers and cargo tracking devices are included in packages or attached to packages or overpacks. A risk-based assessment, in addition to the prescriptive requirements in the Technical Instructions, for operators transporting items in the cargo compartment is required.

The purpose of this document is to provide guidance and recommendations to operators for the transport of dry ice in excess of that already permitted in the operators' operations manual or other applicable manuals or documents (e.g. aircraft TCH/OEM Service Letter; regulatory AC) in order to reduce the introduction of additional risks (safety and health) to the aircraft systems and its occupants.

Most aircraft OEM provided revised information on their aircraft maximum capabilities to transport dry ice. It is the operator's responsibility to assess the risks associated with the transportation of increased quantities of dry ice.

2. Definitions and Abbreviations

'Dangerous goods' – articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in the Technical Instructions or which are classified according to those Instructions (as per ICAO annex 18 definition).
'Dry ice' – solidified carbon dioxide (CO_2).
'Occupants' – in this context any person on board, be it flight crew, cabin crew or supernumerary. 'OEM' – Original Equipment Manufacturer.
'Sublimation' – the process of converting a solid substance (dry ice, solid C02) into a gas (C02 gas).

3. Chemical and Toxicity Aspects of Dry Ice

Dry ice sublimates at -78°C to gaseous carbon dioxide (CO_2). Carbon dioxide is heavier than air, colour- and odourless.

Carbon dioxide at low concentration (below 0.5%) has little, if any, toxicological effects. At higher concentrations (>5%), it causes the development of hypercapnia and respiratory acidosis. Concentrations of more than 10% carbon dioxide may cause convulsions, coma, and death by affecting the respiratory function and causing excitation followed by depression of the central nervous system.

Consequently, dry ice is classified as dangerous goods. The use of dry ice as refrigerant raises technical and operational challenges on board of the transport-category aeroplanes. The conversion rate of dry ice to gaseous CO_2 will vary depending on package insulation, dry ice particle/pellets size, surrounding temperature, and cabin pressure.

4. Safety Standards

As per certification specification for large aeroplanes, the carbon dioxide concentration during flight must be shown not to exceed 0.5 % by volume (sea level equivalent) in compartments normally occupied by passengers or crewmembers. For the purpose of this sub- paragraph, "sea level equivalent" refers to conditions of 25° C (77° F) temperature and 1,013.2 hPa (760 millimetres of mercury) pressure.

In case of main deck cargo compartments that are intended to be accessible during flight or the transport of cargo in the passenger compartment, the above-mentioned criterion is considered applicable.

For cargo compartments that are fully segregated from the passenger compartment and non- accessible during flight.

However, an excessive CO2 concentration in the specific cargo compartments, if not detected, could be unsafe for the personnel on ground (loading/unloading processes).

5. Dedicated Risk Assessment

For the transport of vaccines using dry ice in excess of the limit specified in the operations manual or other applicable documents (e.g. aircraft TCH/OEM Service Letter or similar), the operator should perform a specific risk assessment. Such risk assessment may require getting in contact with the TC and/or STC holder and should propose appropriate operating procedures in order to adequately mitigate the identified risks. This risk assessment should at least cover:

(1) The vaccine and its characteristics for transport as cargo (i.e. packaging, handling, etc);

(2) The data trackers and loggers.

(3) The amount and effects of dry ice to be carried (including weight and balance considerations) and the associated sublimation rate with validation of the assumed rates vs. all operational scenarios.

(4) The possible need for CO2 detectors to mitigate the identified risks;

(5) The aircraft ventilation system's operational characteristics, performance, controls, selections- settings in all operational procedures for normal/abnormal/emergency operational scenarios and phases of operation (including applicable MEL provisions);

(6) All other relevant aircraft and systems configurations (including applicable MEL provisions);

(7) The location of the cargo on board and the interaction with other cargo;

(8) The aircraft occupancy (whether occupants are allowed on board or not);

(9) The procedures and training of on-board occupants, ground handling and other relevant staff;

(10) The analysis of ambient temperatures on the ground (at departure and arrival), which may lead to a higher sublimation rate (particularly when flying to warm areas);

(11) The potential pressure build-up as a result of gas released from the packaging;

(12) The impact of potential departure delays, extended taxi-in/out and additional time needed on the ground (e.g. for de-icing);

(13) The consequences of diversion and specific airport ground-handling consideration;

(14) The possible diversion times and the need to use alternative routes where necessary;

(15) The extended loading time needed in case of transport in the passenger cabin, which may result in excessive CO_2 concentration.

The risk assessment should ensure that all relevant technical and operational aspects have been taken into account.

6. Technical Considerations – Safety of Flight

Vaccines cooled by dry ice should preferably be transported in the existing lower-deck cargo compartments. In case vaccines, cooled by dry ice, need to be transported on the main (passenger/cargo) deck, additional technical aspects should be considered.

6.1 Ventilation and Pressurization System

6.1.1 MEL considerations

For aircraft dispatch, the air conditioning, air supply and the distribution/ventilation system should use configurations recommended by the manufacturer.

6.1.2 AFM considerations.

The AFM procedures for ventilation should be reviewed and adapted in the operator's standard operating procedures to consider carriage of dry ice under normal and failure cases.

To mitigate the risk of higher concentrations of CO_2 (above 0.5%), it is recommended that the ventilation and pressurization system is fully operational, i.e. all air-conditioning packs should be running at all times.

In case of partial failure of the ventilation system in flight, the situation has to be carefully evaluated in order to decide if the flight may continue to destination. The OEM guidance should account for a single next critical failure to enable continuation of the flight, while total failure of the

ventilation system in flight should lead to an immediate diversion to the nearest suitable airport.

Note 1: Running the air-conditioning systems at maximum volume may lead to an additional risk when opening the doors due to potential residual overpressure. The operator should consider this hazard when drafting the operational procedures for the transportation of vaccines.

Note 2: The operator should consider the case of build-up of CO_2 concentration in the cabin as a possible emergency situation and should develop a procedure to require the donning of oxygen masks for the remaining duration of the flight.

6.2 Oxygen System

6.2.1 MEL considerations

For aircraft dispatch the crew oxygen systems should be fully operative.

6.2.2 AFM considerations

The AFM procedures for the use of oxygen should be reviewed and adapted in the Operator Standard Operating Procedures to consider carriage of dry ice under normal and failure cases (e.g. failure of the ventilation systems), including the case of detection of dangerous concentration of CO_2 (if applicable).

6.3 CO_2 Detectors

Based on the risk assessment (see Section 5 above), the operator should determine whether CO_2 detectors should be used for the flight deck and any other occupied area of the aircraft (e.g. passenger cabin).

If the amounts of dry ice to be transported (refer to aircraft OEM specifications, supplier packaging details and other guidance material) is in excess of that specified in the operations manual or other relevant manuals and in the guidance provided by the OEM, or if dry ice is loaded on the main (passenger/cargo) deck, the use of CO_2 monitors/detectors is recommended in all compartments in which dry ice is being transported. Such detectors should be adequately located and should timely and reliably detect dangerous concentrations of CO_2 in the aircraft. If the detectors are power supplied by lithium ion batteries, the additional fire risk must be assessed and mitigated accordingly.

Note 1: "Use" in this context means physically installed in the aircraft or – alternatively – portable devices. If CO_2 sensors and monitoring systems are used, the operator should ensure that these devices do not interfere with the aircraft systems and do not affect the safe operation of the aircraft. Portable CO_2 detectors are considered Portable Electronic Devices (PED). Recent/frequent calibration of CO_2 detectors must be ensured. At least two sensors should be available in case of a sensor disagree.

6.4 Cargo Locations (Lower and Main Deck Cargo Compartments and Passenger Cabin)

Vaccines cooled with dry ice should preferably be transported in lower-deck cargo compartments. It is recommended to use the cargo compartment that is located to the next outflow valve, in order to effectively ensure that even in the case of partial or complete failure of the ventilation and pressurization system during flight, the CO_2 will be ventilated overboard.

ECAA published specific conditions for the potential transportation of cargo in passenger compartments (see **Civil Aviation Safety Circular - TRANSPORT OF CARGO IN PASSENGER COMPARTMENT**). A minimum number of occupants should be onboard for fire detection and fire-fighting purposes. Vaccines cooled with dry ice may be transported in the passenger cabin when the associated risks are sufficiently mitigated. Details are addressed below in paragraphs 6.5 and 6.6.

6.5 Occupants on Board (Their Roles and Location, Equipment, etc.)

6.5.1 Flight crew

The operator should take all necessary steps to avoid that the flight crew is harmed by carbon dioxide incapacitation or intoxication.

Flight crews should have been properly trained prior to the flight on the hazards and risks of transporting dry ice and on the procedures related to the operation.

6.5.2 Other occupants

Passengers should not be allowed onboard if dry ice is transported in excess of the limit specified in the operations manual or other applicable documents (e.g. aircraft TCH/OEM Service Letter or similar). Any other occupants onboard should only be allowed if required under demonstrated urgent operational needs (e.g., additional flight crew for the return flight or additional persons needed for the cargo handling).

If occupants, that are not considered flight crew, need to be onboard, they should be protected against a potential CO_2 intoxication by the following means:

(1) Have access during all phases of flight to approved supplemental oxygen equipment ready to be used.

(2) Have been properly trained prior to the flight on the use of that oxygen equipment.

(3) Have been properly trained prior to the flight on the hazards and risks of transporting dry ice and on the procedures related to the operation. And

(4) In addition, CO_2 detectors should be available in the cabin (see paragraph 6.4).

Any seating position identified for a potential occupancy during any phase of the flight should pose no additional risk to its occupants, in particular in case of a CO_2 incapacitation/intoxication.

6.6 Interaction with Other Cargo

Live animals may not be transported in cargo compartments if dry ice is also transported therein at the same time. Any interaction with other cargo should be assessed and mitigated by the operator and the shipper.

7 Technical Considerations – Ground Handling

When loading and unloading boxes filled with dry ice, awareness should be raised that there can be carbon dioxide present in concentrations that potentially endanger human health. Staff engaged in the loading and unloading process should be properly trained and prepared for this. They should be trained on the specific risks and hazards and the special procedures related to this cargo. The operator and the ground-handling provider should implement special procedures to ensure that there is no health or safety risk for the staff performing the loading and unloading of dry ice packages. In doing this, the operator and ground-handling provider should consider, as a minimum, the following:

(1) Loading:

  (a) Methods to ensure that only packaging compliant with the applicable regulations is loaded on board;

  (b) Procedures for reporting and addressing damaged/leaking packages.

(2) Unloading:

(a) Instructions on precautions to be taken when opening cargo or cabin doors;

(b) A second person always outside the cargo bay or cabin to monitor entrance and trigger the alarm in case of an incident;

(c) Procedures for reporting and addressing damaged/leaking packages.

(3) Ensure proper ventilation before entering a cargo compartment containing dry ice.

(4) Minimize ground time without ventilation.

(5) Carry a CO2 detector when entering cargo compartments.

(6) Develop emergency procedures in case of an incident or accident.

8 Operational Considerations

Operators transporting dry ice must have an approval for the transport of dangerous goods in accordance with ICAO Annex 6, Part I, Chapter 14 and Ethiopian Civil Aviation Rules and Standards (ECARAS) **Part 9 Section 9.5 and Part 8 Section 8.5.1.29**. In accordance with such requirements, operators shall have specific training and procedures for the transport of dangerous goods. The training and procedures have to be approved by the ECAA and shall be in accordance with ICAO Annex 18 and ICAO Doc 9284, Technical Instructions for the Safe Transport of Dangerous Goods. This should all be reflected in the Operations Manual.

It is possible to obtain an approval for the transport of certain dangerous goods. Thus, an operator may hold an approval to transport only dry ice. The scope of the approval needs to be taken into consideration before accepting any shipment of the vaccine.

Additionally, operators need to perform a risk assessment which includes the specificities of dangerous goods transport. The operator shall establish policies and procedures for the transport of items in the cargo compartment, which include the conduct of a specific safety risk assessment. The risk assessment shall include at least the:

a) Hazards associated with the properties of the items to be transported;
b) Capabilities of operator
c) Operational considerations (e.g. area of operations, diversion time);
d) Capabilities of the aeroplane and its systems (e.g. cargo compartment fire suppression capabilities);
e) Containment characteristics of unit load devices;
f) Packing and packaging;

g) Safety of the supply chain for items to be transported; and
h) Quantity and distribution of dangerous goods items to be transported.

To ensure the transport is done safely, operators transporting quantities of dry ice in excess of that specified in the operations manual or other applicable documents (e.g. OEM/TCH Service Letter or equivalent) should consider additional mitigation actions. The training, procedures and risk assessment mentioned above must take into consideration the specific conditions of this transport. These must also include all the technical considerations mentioned before and apply to all the staff involved and all the stages of the operation, from the acceptance to the unloading.

The operator may additionally consider the following:

(1) Lower the temperature in the cargo compartment as much as possible to minimize the sublimation rate;

(2) Evaluate the potential for cargo containing dry ice to be loaded as late as possible and unloaded as early as possible to minimize the potential exposure of ground staff to elevated levels of CO_2 in the cargo compartment.

The following key issues have been identified in relation to the carriage of COVID-19 vaccines. These issues shall be considered by all operators involved in transporting COVID-19 Vaccines on Commercial Aircraft.

1. Data loggers and cargo tracking devices (batteries & quantities)

Data loggers and cargo tracking devices may be required to monitor the temperature and location of vaccines during transport. Most such devices are powered by lithium batteries and the packages need to be properly identified as such. The following table identifies the hazards associated with the data loggers and trackers transported, and the considerations for the operators risk assessments.

2. Data loggers and cargo tracking devices (EMI)

Inclusion of transmitting/receiving devices in packages for the purposes of tracking and data logging (e.g. of temperature) has the potential for electromagnetic interference with aircraft systems. The potential risk to the operations needs to be assessed.

3. Requirement for carriage of quantities of dry ice in excess of that previously specified by operator for the aircraft type

At present, many of the vaccines need to be transported in temperature controlled conditions. These conditions are specific to the vaccine itself. For example, some of the vaccines need to be kept at temperatures that require dry ice (carbon dioxide, solid) for cooling purposes. The volume of vaccine to be transported means that the quantity of dry ice proposed for carriage exceeds that previously specified for the aircraft type in the operator's manuals. A review of the risk assessment based on the considerations provided may be needed.

4. Guidance to support the operators risk assessment process

The specific safety risk assessment on the transport of items in the cargo compartment is part of Safety Management System, and may be based on the safety risk management guidelines. Hazards should be identified, risks assessed, and specific mitigation measures established, according to predicted probability and the severity of the consequences based on the worst foreseeable situation. The following tables provide guidance the air operator to facilitate an understanding of the requirements. It is structured around each element the operator is required to consider as part of its specific safety risk assessment and based on Guidance for Safe Operations Involving Aeroplane Cargo Compartments (Doc 10102). However, where the vaccine supply chain requires use of smaller aircraft without cargo compartments, this material can still be used as some guidance to develop the associated risk assessments for these types of operations. Different mitigation strategies may need to be developed depending upon the type of aircraft and operation considered.

Packages of vaccines may contain multiple elements such as:

- the vaccine component itself;
- data loggers and cargo tracking devices powered by lithium batteries, and that emit electromagnetic radiation that have the potential to interfere with aircraft systems; and
- dry ice.

For each identified element in the package, the following considerations will need to be addressed, to maintain safe operations.

The tables should not be considered as an exhaustive or limiting list and each

operator is expected to tailor the tables as necessary for the individual case and context.

A) Data loggers and cargo tracking devices (batteries & quantities)

a) hazards associated with the properties of the items to be transported;	
Hazard Description	**Information to support hazard assessment**
Increased quantities of data loggers and cargo tracking devices containing lithium batteries.	• Operator may not know the contents of the package – most vaccine packages will contain a data logger even if not marked as such • Lithium batteries can enter a thermal runaway and become a potential ignition source as a result of failure due to damage or internal quality issues. • Lithium batteries generally contain an electrolyte that can become a fuel source for a fire. • Capabilities of the aircraft fire suppression systems - see section d) could be exceeded Specific considerations: • Packages with data loggers and trackers powered by lithium button cells which meet the limits specified in the Technical Instructions, Section II of Packing Instruction 967 or Packing Instruction 970 are not required to bear the lithium battery mark. • Manufacturer testing (38.3 of UN manual of tests and criteria) still applies. • The number of lithium battery devices within the package should be taken into consideration.
b) capabilities of the operator	
	• Identification by the operator of the contents of the package may not be possible from inspection – there is a need to ensure operator has full knowledge of contents regardless of

	marking or labelling • Acceptance for transport should be only by operators with specific approval for carrying dangerous goods as cargo and with suitable training • Training and procedures are required to ensure damaged items are not accepted for transport, regardless of whether the label indicates lithium battery contents or not.
c) operational considerations;	
	• Operators need to ensure they are provided with the information regarding the content of the packaging and can take measures to ensure the type and quantity is consistent with the capabilities of the aircraft cargo compartment (see section d) and the procedures of the operator • Loading of packages must not exceed maximum quantities identified by the operator for the carriage of lithium batteries in the cargo compartment
d) capabilities of the aircraft and its systems;	
	Size, type and quantities of batteries needs to be assessed to ensure the capabilities of the cargo compartment, and in particular of its fire protection or suppression system, are not exceeded.
e) containment characteristics of unit load devices;	
	• None
f) packing and packaging;	
	• Compliance with packing requirements detailed in the Technical Instructions is still essential even where marking of the contents (lithium batteries) may not be mandated • Design of package needs to minimize the risk of damage to the contained lithium cells

g) safety of the supply chain for items to be transported;	
	• None
h) quantity and distribution of dangerous goods items to be transported	
Operators should consider the risks of loading these shipments with other flammable dangerous goods.	

B) Data loggers and cargo tracking devices (EMI)

a) hazards associated with the properties of the items to be transported;	
Hazard Description	**Information to support hazard assessment**
Data loggers and cargo tracking devices used in monitoring the transport of the vaccine	• Operator may not know the contents of the package • Specific details regarding acceptable transmissions not known by the operator • Potential for the electromagnetic radiation from such devices to interfere with the aircraft systems •
b) capabilities of the operator	
• Identification by the operator of the contents of the package may not be possible from inspection – there is a need to ensure operator has full knowledge of contents regardless of marking or labelling • Operator approves the carriage of data loggers and cargo tracking devices based on information from the device manufacturer confirming compliance with applicable standards and airframe manufacturer regarding the Portable Electronic Device (PED) tolerance of the aircraft.	
c) operational considerations;	
	• Portable Electronic Devices that have a transmitting function should meet the requirements of the State of Design such FAA AC 91.21-1D and EASA AMC1 CAT.GEN.MPA.140.

d) capabilities of the aircraft and its systems;	
• aircraft systems susceptibility to electromagnetic interference; the relevant information and documents from the aircraft OEM and/or Operator should be considered; • Additional guidance specific to each aircraft type and model (if any), should be obtained from the aircraft manufacturer.	
e) containment characteristics of unit load devices;	
	• None
f) packing and packaging;	
	• None
g) safety of the supply chain for items to be transported;	
	• None
h) quantity and distribution of dangerous goods items to be transported	
	• See c) & d) • Type and quantity of data loggers and cargo tracking devices may be limited • Loading on the aircraft may be subject to specific restrictions in terms of location

C) Requirement for carriage of quantities of dry ice in excess of that previously specified by operator for the aircraft type

a) hazards associated with the properties of the items to be transported;	
Hazard Description	**Information to support hazard assessment**
Carriage of large quantities of dry ice (CO_2, solid)	• The sublimation of dry ice may result in significant concentrations of gaseous CO2 in aircraft • Gaseous CO2 will replace oxygen in aircraft compartments and may interfere with the breathing abilities of the occupants • High concentrations of CO2 can lead to unrecognized degradation of cognitive functioning

	and asphyxiation. It causes suffocation by displacing and diluting the amount of oxygen in the air, leading to hypoxia (lack of oxygen) and is toxic to brain functioning
b) capabilities of the operator	
	• Operators must ensure that their dangerous goods training programme, operational procedures and safety management system address the requirements applicable to transport of dry-ice (including the acceptance, handling, loading and carriage of cargo containing dry ice) during both ground and flight operations. • Pilot and crew training on specific conditions and procedures can improve pilot decision-making in the event of a CO2 detector alert or other system abnormalities • Training for loading and unloading precautions for ground/service crews
c) operational considerations;	
	• The operators' determination of the maximum amount of dry ice it will allow in a cargo compartment based on the aircraft manufacturer's recommendations, operational considerations for the air conditioning system, and the sublimation rate • An accurate determination of the dry ice sublimation rate is necessary to determine the quantity of dry ice that may be safely transported • Sublimation rate can be affected by ambient compartment temperature and pressure, amount of insulation surrounding the dry ice, type of container, amount of surface area of the dry ice, and the temperature of the cargo being cooled by the dry ice • As the dry ice sublimates, a loss of weight occurs that may affect the aircraft center of gravity • CO2 sensors installed or carried in the aircraft to recognize hazardous concentrations of CO2 and to

	implement effective risk controls • Aircraft ventilation during normal procedures, to include engine start, less than all engine taxi, aircraft de-icing, and with MEL deferred items • Aircraft ventilation during abnormal and emergency procedures to include abnormal and emergency operations and flight during air system component failure.
d) capabilities of the aircraft and its systems;	
• The environmental control system on the aircraft must be suitable for the quantity of dry ice intended to be carried, including flow mode, air recirculation control, MEL deferred items, and possible malfunctions en-route. • Additional guidance specific to each aircraft types and models, if any, should be obtained from the aircraft manufacturer.	
e) containment characteristics of unit load devices;	
	• None.
f) packing and packaging;	
	• Compliance with packing requirements detailed in the Technical Instructions • Information on the sublimation rate of vaccine packing.
g) safety of the supply chain for items to be transported;	
	• None
h) quantity and distribution of dangerous goods items to be transported	
	As determined by the operators' safety risk assessment taking into considerations of items a) to g)

REFERENCE MATERIAL

1) ICAO - SAFE TRANSPORT OF COVID-19 ON COMMERCIAL AIRCRAFT

2) EASA - Transportation of Vaccines Using Dry Ice