Transportation of Vaccines Using Dry Ice

Guidelines in relation to the COVID-19 pandemic

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1. Background and Scope

Several COVID-19 vaccines have been developed in the past months by the pharmaceutical industry and are now close to final approval from the regulatory health authorities. Within a short timeframe, the COVID-19 vaccines will be ready to be distributed worldwide.

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 CO_2). 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 (Regulation (EU) No 965/2012 and ICAO Doc 9284 'Technical Instructions for the Safe Transport of Dangerous Goods by Air') is the responsibility of each operator.

The purpose of this document is to provide guidance and recommendations to national competent authorities (NCAs) and 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

'Dry ice' – solidified carbon dioxide (CO_2).

'NCA' – National Competent Authority, i.e. the national aviation authority with the power for the relevant aviation domain.

'Sublimation' – the process of converting a solid substance (dry ice, solid C02) into a gas (C02 gas).

'Occupants' – in this context any person on board, be it flight crew, cabin crew or supernumerary.

'*OEM'* – Original Equipment Manufacturer.

'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).

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 in CS-25

As per certification specification for large aeroplanes CS-25, article 25.831(b)(2), 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, there is no such requirement specified in CS-25. However, an excessive CO_2 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 (see link in chapter 10);

(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 CO_2 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 Pressurisation 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 pressurisation 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 chapter 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, see also chapter 10) 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 pressurisation system during flight, the CO_2 will be ventilated overboard.

EASA published specific conditions for the potential transportation of cargo in passenger compartments (see also link in chapter 10). 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 chapters 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 chapter 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 CO_2 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 with Part SPA.DG of Regulation (EU) 965/2012. In accordance with the requirements established in such regulations, operators shall have specific training and procedures for the transport of dangerous goods. The training and procedures have to be approved by the NCA and should 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, as mandated by ORO.GEN.200(a)(3) of Regulation (EU) No 965/2012 on air operations (as from November 2020, ICAO Annex 6, Chapter 15 also calls for such a risk assessment).

Additional guidance contained in ICAO Doc 10102 may also be considered.

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 minimise 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 minimise the potential exposure of ground staff to elevated levels of CO_2 in the cargo compartment.

9. Liaison with EASA

NCAs engaged in the approval of transportation of large amounts of dry ice for the cooling of vaccines may request more information from EASA by sending an email to RNO@easa.europa.eu.

10. Useful Links

Major aircraft manufacturers have specified the maximum allowable amount of dry ice to be loaded on their aircraft models. Furthermore, ICAO, IATA and the FAA have also published relevant guidance material.

10.1 EASA Guidelines

https://www.easa.europa.eu/the-agency/coronavirus-covid-19

- EASA guidelines for the transportation of cargo in the passenger cabin (issue 5): https://www.easa.europa.eu/newsroom-and-events/news/easa-publishes-issue-5-guidelines-transport-cargo-passenger-compartments
- EASA generic deviation on the transportation of cargo in large aeroplane passenger cabins: https://www.easa.europa.eu/document-library/product-certification-consultations/deviation-transportation-cargo-passenger

- EASA Guidelines for the use of Cargo Tracking Devices in relation to the COVID-19 pandemic: https://www.easa.europa.eu/newsroom-and-events/news/easa-published-guidelines-use-cargo-tracking-devices-relation-covid-19

10.2 Aircraft Manufacturer Guidelines

Airbus

- Website: https://w3.airbus.com/
- Guidance: ISI (In Service Information) Reference 25.50.00011

Boeing

- Website: https://www.myboeingfleet.com/ReverseProxy/Authentication.html
- Guidance:
  - 707-SL-21-006-(Latest Revision) - Service Letter – "Recommended Allowable Dry Ice Carriage Limits"
  - 727-SL-21-020--(Latest Revision) - Service Letter – "Recommended Allowable Dry Ice Carriage Limits"
  - 737-SL-21-033--(Latest Revision) - Service Letter – "Recommended Allowable Dry Ice Carriage Limits"
  - 747-SL-21-055--(Latest Revision) - Service Letter – "Recommended Allowable Dry Ice Carriage Limits"
  - 757-SL-21-036--(Latest Revision) - Service Letter – "Recommended Allowable Dry Ice Carriage Limits"
  - 767-SL-21-044--(Latest Revision) - Service Letter – "Recommended Allowable Dry Ice Carriage Limits"
  - 777-SL-21-001--(Latest Revision) - Service Letter – "Recommended Allowable Dry Ice Carriage Limits"
  - 787-SL-21-002--(Latest Revision) - Service Letter – "Recommended Allowable Dry Ice Carriage Limits"
  - MOM-MOM-20-0053-01B (Latest Revision) - Multi-Operator Message – "Information – 2019-nCov Coronavirus Infection Control Guidance as Related to Commercial Aircraft"
  - MOM-MOM-20-0239(Latest Version) - Multi-Operator Message – "Information – All Model Guidelines for Passenger Airplane Carriage of Cargo"
  - MOM-MOM-20-0863-01B (Latest Revision) – Multi-Operator Message – "Dry Ice Carriage during the COVID-19 Coronavirus Pandemic"

Embraer

- Website: https://www.flyembraer.com
- Guidance: Airplane Operations Manual (AOM) - Dry Ice Transportation.

10.3 Additional Guidance

- FAA Advisory Circular 91-76A, "*Hazard Associated with Sublimation of Solid Carbon Dioxide (Dry Ice) Aboard Aircraft*"
- IATA guidance for Vaccine and Pharmaceutical Logistics and Distribution

  https://www.iata.org/en/pressroom/pr/2020-11-16-01/
  https://www.iata.org/en/programs/cargo/