PARLIAMENTARY JOINT COMMITTEE ON LAW ENFORCEMENT

Inquiry into COVID vaccine related fraud and security risks

Who we are

The Australian Food Cold Chain Council

The Australian Food Cold Chain Council (AFCCC) is a non-for-profit group of industry leaders committed to reducing food wastage and improving innovation, compliance and food safety for the Australian community. Its members are a vertical slice of the cold food chain and include companies involved in food production, refrigeration, transport (including trailers) and other equipment manufacturers.

Refrigerants Australia

Refrigerants Australia is the peak body of the refrigerants industry in Australia. It represents companies that sell more than 90% of all refrigerants in Australia (HFCs, ammonia, CO_2 and hydrocarbons), wholesaling companies, contracting organisations (representing the people on the tools), importers and manufacturers of equipment, as well as Australia's award-winning program recovering and destroying used refrigerants. Refrigerants Australia is focused on ensuring Australia benefits from a technologically advanced industry that provides efficient cooling at least cost and with as little environmental impact as possible to support the Australian community and economy.

Background to our response

We recognise that the request for submissions relate to the terms of reference listed below:

a) telecommunications and internet fraud relating to COVID vaccinations

b) criminal activity around the supply of fake vaccines, black market vaccines and/or fake vaccine certifications and the acquisition of certificates

c) risks to Australia regarding fraud and integrity of COVID vaccines in South Pacific nations and support for these nations to address issues relating to fraud and integrity risks

d) physical security in the production, transport and supply of COVID vaccines in Australia

e) measures to prevent and protect against COVID vaccine-related fraud and security risks

f) any related matters.

Our area of expertise obviously relates most specifically to the cold chain and item d) on this list. However, other fraud and security risks are addressed in any discussion about a compliant cold chain, which is the essence of our response.

We understand, and would like the committee to be aware, that the broader cold chain in Australia covering both food and pharmaceutical goods is in need of better compliance to achieve world's best practices and standards. This uplift will require a major shift in management and training to achieve implementation of proper cold chain practices.

The comments and advice we provide have prevailed for a number of years and predate the Covid Pandemic. It is unfortunate, but worth pointing out, that some stakeholders are seeking to take advantage of the current crisis for commercial gain or public attention. We support a longer-term constructive approach for industry and government to work collaboratively to resolve ongoing issues.

About the cold chain

1. The cold chain is a temperature-controlled supply chain of separate refrigerated events sufficient to achieve continuous temperature control of perishable goods. An unbroken, or compliant cold chain is an uninterrupted series of these events used to store and transport perishable products from one destination to another.

2. A compliant cold chain is treated as a Quality Management System (QMS) where verification and validation at each step in that process or system is required.

3. There are principally two types of cold chains:

    i) Closed loop – goods are transported in a single asset or assets which return to base (circular to the beginning of the chain) with no change of custody during the delivery journey or before delivery is made.

    ii) End to end – goods are transported from one point to another in multiple assets where change of custody occurs between third party logistics providers (3PL) causing multiple journeys before delivery is made.

4. The modern cold chain QMS can be based on different platforms derived from principles to suit different industry requirements. Major examples used globally are:

    <u>HACCP – Hazard analysis critical control point</u>

    The steps in a HACCP process are separated into control points and critical control points. A cold chain control point (CP) is where the food temperature and the environment is controlled, such as inside a warehouse or in a monitored refrigerated transport.

    A cold chain critical control point (CCP) is where there is no temperature control, which typically are those areas of the chain where the goods are handled from one control point to the next or transported in an asset with inadequate controls.

HARPC - Hazard analysis and risk-based preventive controls

An upgrade of HACCP as a food safety system, mandated in the United States by the FDA Food Safety Modernization Act (FSMA) of 2010 for the use of preventive control systems to emphasise prevention of hazards before they occur rather than their detection after they occur.

GAMP – Good automated manufacturing practice

A set of guidelines for manufacturers and other automation users that maintains operational efficiency and reliability. GAMP is also a sub-committee of the International Society for Pharmaceutical Engineering (ISPE). GAMP guidelines are used heavily by the pharmaceutical industry to ensure that drugs are manufactured with the required quality through quality testing (not batch control) as an integral part of each stage of manufacturing, including facilities, equipment, materials acquisition, transport and staff hygiene. GAMP Community of Practice (COP) is a pharmaceutical professionals' forum that ensures continued development and adoption of best practices in the field.

CAPA - Corrective action and preventive action (ISPE APQ Guide)

This most recent Advancing Pharmaceutical Quality (APQ) initiative by the International Society for Pharmaceutical Engineering (ISPE) published in November 2020 is part of a comprehensive program for assessing and improving an organisation's quality management maturity and providing a quality management framework for assessing and advancing CAPA systems.

FMEA - Failure mode effects analysis

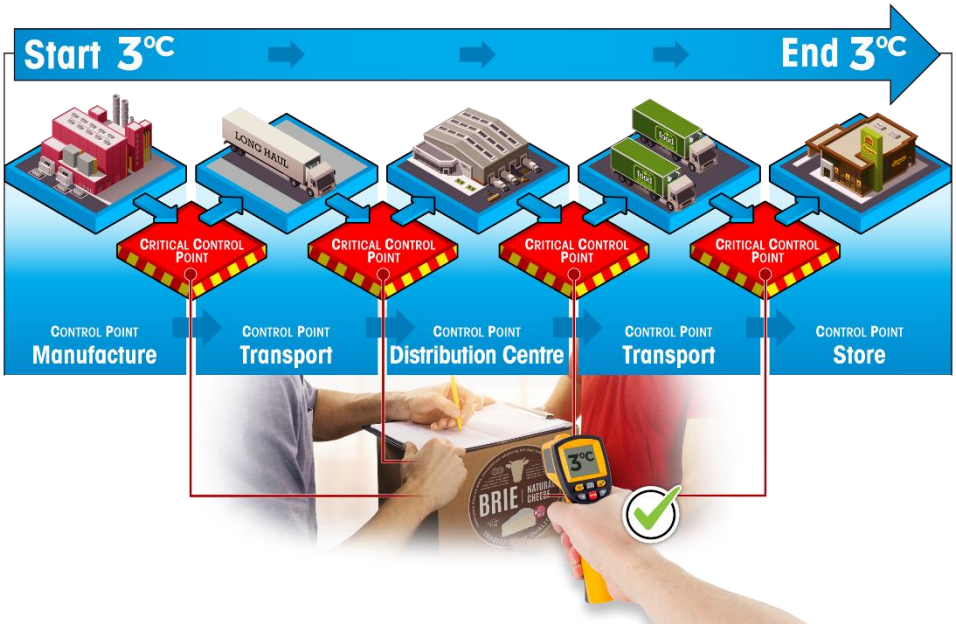
A very traditional management and control system used as the original framework for HACCP which makes use of control analysis, fault-tree schemes and multiple review systems to eliminate errors in a process. FMEA practices are commonly used in manufacturing and became prominent when adopted by NASA in rocket technology.

Current compliance in the Australian cold chain

There are very few compliant end-to-end cold chains in Australia. Long distances, commercial pressures and multiple use of 3PL providers continue to be the main reasons the majority of chains are broken. There is also a great falsehood held by a significant number of stakeholders that individual links in the chain can be observed as compliant, and therefore product validation is possible. This is an erroneous approach due to the fact that non-verification of all the links in the chain cannot provide product validation at the end.

This unfortunate situation has proliferated in recent years with the availability of electronic data coming from telematic devices in both storage and transport assets. Individual stakeholders flood their critical control points with data on the assumption this practice is sufficient for compliance by storing the data without verification and only sharing it when an issue occurs.

This contravenes the basic principles of quality management to verify steps in the cold chain as simply shown in the following diagram.



Compliant cold chains in Australia exist mostly in closed loop systems. Most popular are those operated by fast food franchise systems that recognise robust cold chain practices deliver quality and risk-free products for consumers. To achieve this, 3PL providers are kept to a minimum or required to upgrade transport and storage assets to meet continuous temperature control and monitoring requirements. The highest standards in these systems include monitoring of both air and product temperatures, and door openings, which combined achieves security and temperature verification of the product and the cold chain assets. This allows for verification at individual steps, and intervention if an issue occurs during monitoring, both of which deliver quality outcomes and loss reduction.

Pharmaceutical cold chain

Since the introduction of GAMP guidelines by the ISPE over 15 years ago, the pharmaceutical cold chain is designed to deliver a compliant cold chain with process step verification and end product validation. The most stringent systems to achieve this are those that have combined product and asset controls from manufacture to end-user delivery, and use refrigerated assets validated to ISO standards for thermal efficiency and temperature control.

An obvious example is a vaccine package with onboard cooling capacity and monitoring to ensure product temperature, which is transported or stored within an asset with refrigeration, door and temperature monitoring. This arrangement allows cold chain practitioners to use data from both points (package or asset) to verify temperature and security at individual steps and for the complete journey.

Unfortunately, it is common practice in Australian pharmaceutical delivery to use a mixture of temperature-controlled packages, thermal boxes or packages with or without temperature measurement, and hardly ever with temperature monitoring. Transport assets in Australia are usually not validated or tested for pharmaceutical transport, and transporters have no systems in place to adequately verify temperature at the CCP or delivery.

It is also common practice for transporters to absolve themselves from their own compliance duties through a responsibility shift of relying on the package temperature data, which increases the ridiculous situation of non-participation by transporters in sharing of temperature data at CCPs, or providing temperature reports at the journey end.

Conclusion and recommendation

There is significant work to be done in the broader Australian cold chain, some of which will take time to infiltrate industry practice through changes in attitude and adoption of global standards. The AFCCC and Refrigerants Australia will continue to work for the improvement of these attitudes and practices to best reflect triple bottom line principles of doing business in the modern cold chain. We recognise commercial consideration can no longer be the singular reason for change. Also, both organisations are actively involved in drafting the new Cold Food Code guidelines and training in conjunction with industry to effect this change.

We understand that the eminent issues faced in the COVID 19 vaccine challenge require earlier action. It is our view this committee could deliver a set of recommendations sufficient to improve the current vaccine product integrity and security. It is our understanding that the current self-contained nature of the vaccine roll-out program with far fewer stakeholders than the broader cold chain, could readily accept an additional overlay of requirements not already in place or enacted.

Recommendations:

1. Verification of temperature at every step must become the central requirement of the vaccine program. This must be on the ground and in the cloud. Main examples are:

    i) Verify package temperature on the ground (from visual display) whenever a CCP occurs which includes change of custody or transport and whenever the package is opened.

    ii) Verify package temperature in the cloud (from data logger) whenever a CCP occurs which includes change of custody or transport and whenever the package is opened.

    iii) Verify transport temperature on the ground at every CCP (delivery ticket from asset) which includes change of custody or transport, and delivery.

    iv) Verify transport temperature in the cloud at every CCP (delivery report from portal) which includes change of custody or transport, and delivery.

2. Transport assets must comply to ISO standards to include:

    i) thermal efficiency and performance

    ii) independent temperature monitoring capability online and offline

    iii) door monitoring capability.

3. Door monitoring is added to temperature reporting and must include:

    i) indication of door open and close events with time

    ii) ability to set rules and alerts against time and geo fence information

    iii) remote control locks (optional).

4. Establish a dedicated cold chain portal to monitor temperature data from all stakeholders. This technology is now available via open application programming interface (API) connections between different devices using encrypted data and will allow for independent and robust monitoring of temperatures, door openings and delivery times.