Dr Bradley Armstrong PSM
Deputy Commissioner, Australian Border Force
Chair, National Committee on Trade Facilitation (NCTF)

IMPORTATION OF HYGIENE AND MEDICAL GOODS

Dear Bradley,

As discussed at the National Committee on Trade Facilitation (NCTF) on Thursday 25 June 2020, Freight & Trade Alliance (FTA) gave a commitment to supply extra views on measures to facilitate the importation of hygiene and medical goods.

We trust that the following information is of assistance.

SUMMARY OF RECOMMENDATIONS

1. More guidance as to the scope of the Item 57 bylaw should be documented by Federal Government agencies to overcome industry concerns that the interpretation may have changed by the time of a future audit.

2. Introduce administrative measures including
   (1) a dedicated email address for regulated goods queries;
   (2) methodology to ensure that PPE and similar goods are not held at the ports pending clearance;
   (3) post entry audits should be undertaken alleviating the need for goods to be held at the border, especially given TGA available staffing and response times for reviews; and
   (4) Sec.71E movement permissions should be approved.

3. The measures should be extended to 31 December 2020.

CONTACT

Susan Danks
Head of Customs and Regulatory Compliance, Freight & Trade Alliance (FTA)

0407 128 378
sdanks@FTAlliance.com.au

THE BYLAW

Item 57 of the 4th Schedule requires BOTH that the goods are medical or hygiene products AND that those goods are capable of use in combating the disease. Bylaw 2019608 hangs off Item 57 so those are the preconditions to its use.

Bylaw 2019608 to Item 57 – Goods to be used in response to the COVID-19 pandemic

1. *This by-law may be cited as Customs By-law No. 2019608.*
2. *This by-law shall be deemed to have taken effect on 1 February 2020.*
3. *For the purposes of Item 57 of Schedule 4 to the Customs Tariff Act 1995 (the Customs Tariff), the following **medical or hygiene** products are prescribed:*
   - *(a) any of the following equipment that, when worn, is capable of limiting the transmission of organisms to humans:*
     - *(i) face masks;*
     - *(ii) gloves;*
     - *(iii) clothes or gowns;*
     - *(iv) goggles, glasses, eye visors or face shields;*
   - *(b) disinfectant preparations classified to heading 3808 in Schedule 3 to the Customs Tariff, excluding hand sanitisers;*
   - *(c) soaps;*
   - *(d) COVID-19 test kits, reagents and viral transport media.*

Products such as masks limit the transmission of "organisms" to humans. FTA advice to members was to be very cautious of making claims in regard to face masks, gloves, clothes or gowns and goggles, glasses, eye visors or face shields without having written confirmation from the importer that they are able to do that. FTA understands that dust masks, as an example, do not work to substantially limit the transmission of organisms to humans, while noting that no degree of "limit" has been specified.

Soap is a difficult one given we are being told to wash our hands to kill the virus and any soap may therefore be covered by the bylaw if it does that..

The Australian Border Force (ABF) issued ACN 2020/20 and refers to such goods as being used to "treat, diagnose or prevent" the disease, which may be sufficient for soap.

- **Recommendation: More guidance as to the scope of the Item 57 bylaw should be documented by Federal Government agencies to overcome industry concerns that the interpretation may have changed by the time of a future audit.**

HOW EFFECTIVE HAS THE MEASURE BEEN IN FACILITATING THE IMPORTATION OF THE HYGIENE AND MEDICAL GOODS?

All importers and service providers in Australia are subject to financial and other stresses during this time. FTA intent in this communication is to assist importers and customs brokers in ensuring that only those goods clearly subject to Therapeutic Goods Administration (TGA) registration and controls are detained.

The measure may have been effective in allowing for a large influx of medical and hygiene goods to be imported without payment of duty to help bolster the shortage of Personal Protective Equipment (PPE) stockpiled or for immediate dispatch and use by those in need. This measure allowed for duty free status without the need of a Certificate of Origin (where applicable, given that a significant percentage of PPE is manufactured in China and other preference countries).

HAVE YOU ENCOUNTERED ANY ADMINISTRATIVE ISSUES IN MAKING A CLAIM FOR CONCESSIONAL TREATMENT?

TGA registration and goods listed on the ARTG

When consignments are routed "red line" on lodgement, the Entry message as returned by 'third party' software stipulated only to send document to a 'Redline' email, no mention was made of Regulated Goods which may have increased delays in the document assessment/processing.

Brokers importing goods for the national stockpile advise that when Regulated Goods were sent the documents, including relevant IDM & TGA Registration Certificate, the goods were released quite quickly ONCE they had received advice/approval from TGA. This process caused a delay in obtaining a 'clear' status of the affected shipments of anywhere from 3-5 days from time of lodgement and document submission. Having a copy of the TGA Certificate for the commodity in question did hasten the processing of the shipment, this appeared to be a requirement for obtaining a release, but ABF assessing officers did not ask for certification initially.

Once a profile is attached to an Importer's ABN/CCID and that they are a TGA Sponsor, then FTA understands that the 'Redline Hold' on every shipment is lifted as the entries no longer required assessment by Redline/Regulated goods. FTA understand this may not happen where the importer is not the Sponsor but is a distributor of that sponsor.

FTA suggest a centralised 'Redline Processing email' and 'Regulated Goods email' would expedite the process from a national perspective. It has worked for Dept of Agriculture, so it should be applied to ABF as well as this would streamline the process rather than differentiating between Redline NSW/QLD/VIC/SA emails and personnel.

Counterfeit goods and those not meeting TGA requirements

The regulator's (ABF and TGA) apparent concern with allowing such a large influx of these goods was the risk of counterfeit goods or goods that did not meet the TGA requirements. As a consequence, many consignments, whether or not claiming the bylaw, were held at the border for significant periods while the consignment was referred to TGA, for assessment.

It should be noted that a high proportion of detained goods do not require TGA registration as they are for industrial or similar use and/or require registration by NICNAS as a cosmetic such as some hand sanitisers. Such goods are often already duty free under ChAFTA or similar FTAs and did not claim the bylaw. Other goods, such as hand sanitisers to the WHO formulation and falling within the coverage of Therapeutic Goods (Excluded Goods - Hand Sanitisers) Determination 2020, also did not require TGA registration.

While we have been advised that counterfeit goods are a concern, suspect counterfeit goods should only be detained by ABF where the holder of the trademark is registered with ABF. Are there any such registrations?

Was any allowance made for the Chinese governments pre-export examinations of PPE to ensure compliance with their own registration requirements?

In relation to goods of a type that may have required TGA registration and the sponsors to be registered:

1. TGA advise that they provided training to ABF in TGA import requirements for goods that may require registration of sponsors and inclusion on the ARTG.
2. FTA are not able to run a report in the ICS to determine how many consignments of, for example, face masks were imported during, say, May 2020.
3. Did ABF use the training provided by TGA to assess any consignments given the significant volume of referrals to TGA?
4. TGA advise that in May they received a significant volume of referrals from ABF. They had neither the staff to process this many referrals nor the understanding of the critical nature of time frames in import consignments and the significant storage and other costs that accrue.
5. While FTA have discussed with TGA the importance of providing IDM our feedback from brokers is that IDM and NICNAS / TGA registrations were provided to redline upon lodgement or shortly thereafter. Any broker queried by FTA was also able to provide photos of the relevant goods so that any claims made on the labelling could be reviewed. This is not to claim 100% compliance. It is to put on record that some of the most significant storage amounts were for consignments for which sufficient IDM was provided.
6. Significant storage costs were incurred by many importers as a consequence of the delayed assessments by TGA. The largest referred to FTA was in excess of $20,000, but we have other examples of storage in excess of $5,000.
7. ABF refused s.71E permission to move held goods from the wharf and as a direct consequence of this, the storage costs were far higher than might otherwise have been incurred.
8. FTA are not disputing the need for some consignments to be investigated, we are alerting the regulator to the costs being incurred in an already difficult business environment, and that there are options available such as post entry audits so as not to disadvantage genuine importers whilst investigations proceed. It is FTA understanding that goods requiring listing on the ARTG as a medical device are not prohibited from being imported, but they cannot be supplied without the listing. This term is defined by TGA as:
   Includes supply:
   - *(a) by way of sale, exchange, gift, lease, loan, hire or hire purchase; and*
   - *(b) whether free of charge or otherwise, by way of sample or advertisement; and*
   - *(c) whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons; and*
   - *(d) by way of administration to, or application in the treatment of, a person.*
   - (e) *In relation to a medicine, means the overall arrangements for the meeting of consumer demand*.

   This reinforces the opportunity of post entry audits and s.71E movement permissions rather than border holds.

9. In providing feedback to FTA, many brokers have commented that ABF officers have tried to assist and that the delays appear to be with TGA assessment, so this is not a criticism of ABF officers or indeed of TGA. As you know, TGA registration is not a matter that has commonly been checked at the border prior to the pandemic and it was always unlikely their officers would be familiar with the requirements and timeliness required in dealing with international consignments.

Examples

1. TGA registered face masks

FTA have examples provided by industry of delays in clearance of TGA registered masks that are not addressed to govt and for the national stockpile.

Is there a reason that masks routed redline and producing evidence of TGA registration on redline lodgement were still subject to these delays?

Example: Air cargo surgical grade masks with TGA permit, arrived into Melbourne 18th May, declaration lodged 18th May and not released until 4th June 5:49pm. Client incurred $2700.00 storage through the terminal, after paying a huge airfreight rate. That was about the same amount as duty would have been payable at 5%. The broker contacted ABF numerous times asking for help with the border hold. All the documents were in order, so I presume this was to either check the masks themselves or to verify the TGA permit. The broker got this cleared once he alerted their ABF Trusted Trader contact

2. Dust masks

The presentation and claims made regarding face masks and gowns determine if these goods are regulated by the TGA under the Therapeutic Goods Act 1989 (the Act). Face masks that are non-sterile and designed as safety or protective apparel for use in the home or for recreational or occupational use are excluded from regulation by the TGA under the Therapeutic Goods Act (The Act). Please see the Therapeutic Goods (Declared Goods) Order 2019. https://www.legislation.gov.au/Details/F2019C00884

This means that non-sterile PPE including masks, gowns and gloves that do not make any therapeutic claims are regulated as general consumer items and do not need to be included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied. FTA suggest that they should not therefore be subjected to border holds and could either be cleared by the redline team when documents and such evidence is lodged or the profile and CPQ could be amended.

Example: AEGHGHW6H paid in excess of $500 per day storage. The broker did not claim the bylaw and the description is as non-medical goods. ChAFTA was claimed with certificates. The email chain attached and provided to ABF included a picture showing the goods labelled as industrial masks.

Example: An airfreight shipment held for 7 days that had been cleared on export by Chinese customs but held here – the broker advises he does not believe goods were inspected and FTA eventually managed to get them some support thru Alice Stanley from the COVID group but should not have needed to do that.

Example: The FID had not claimed the bylaw, used a description of “NON-MEDICAL FACE MASKS - NON-WOVEN FABRIC" and claimed ChAFTA. All required & requested information was provided 10+days before ETA.

Timeline:

20/05

- Entry Lodged, 6307.90.40 as “non-medical face masks - non-woven fabric”
- Docs submitted to Redline Email

21/05

- IDM Requested by Officer
- IDM Supplied

30/05

- Vessel arrival

01/06

- Email to Redline requesting Status Advice / Confirming ETA

02/06

- FCX Unpacked – Cargo Available
- Received Redline Officer email response – Docs forwarded to TGA for Assessment – Quality Assessment
- Replied to Email asking for an expected Time Frame for TGA Processing & If there is a mechanism for recovering storage fees incurred because of extended ABF/TGA Delay in clearing goods?

03/06

- Received Redline Officer response “I have requested an update from TGA.”

05/06

- LCL Depot Storage Fees Start
- Email to Redline Officer requesting TGA Update & to advise storage fees have started.

12/06

- 14:54 ATD (too late to get it out)

More than $$400 per day storage / M3 for 9m3 was incurred.

It was explained to FTA that the hold was because the supplier had “medical” in their name. That was not, however, the name of the supplier on the mask and should not have influenced the extent of this hold.

If this consignment was a border hold, the question as to the extensive delay before x-ray is still relevant.

FTA have other examples of delays but used these in emails with officers on behalf of members and provided photos of such masks. The labelling on both clearly indicated they were for industrial use. The labelling was neither unclear nor questionable and the intended purpose for import was not ambiguous.

FTA understand there can be reasons for delays, but we also suggest that ABF and TGA have a responsibility to process the shipment/documents/information, in a timely manner, that does not impact the consignee in a negative way such as through detention and storage fees.

FTA seek guidance on what ABF considers a reasonable period for such goods to be held by ABF/TGA where such goods are clearly labelled and make no claims of therapeutic use.

FTA seek guidance on how such goods should be marked so as the labelling is not seen as "unclear or questionable" when no therapeutic uses are claimed or implied by that marking.

FTA suggest that further training should be provided to officers so that goods not subject to TGA controls are more readily identified and released given the significant financial costs being incurred by importers as a direct consequence of these delays.

FTA has been advised by Toll, the company with the contract for the NSW government stockpile, that they are not having major delays as the goods they are importing require TGA registration and they have copies of that registration. The delays and holds appear to be for those goods not controlled by TGA. May we respectfully submit that more of these audits should be undertaken post entry and goods should not be held at the border, especially given TGA available staffing and response times.

3. Hand sanitiser

Hand sanitisers can be either hand washes for use with water or hand rubs for use without water, and most are regulated as either a cosmetic by ACCC/NICNAS or a therapeutic good by TGA depending upon how they are used, what they contain and what they claim to do.

Two consignments of hand sanitiser detained at the port were registered with NICNAS and a copy of that registration was provided to ABF when the red line documents were lodged. Sanitisers registered with NICNAS are not medical grade, are not controlled by TGA and do not require listing on the ARTG.

These products were not marked as therapeutic goods. (photos were provided.) Evidence of NICNAS registration was provided on redline lodgement. The formula on the back label of the photo matched the WHO formulation. Products with one of two specific formulations provided by the WHO were excluded from the TGA regulations during the COVID-19 pandemic on 28 March 2020, as long as they only contain specified ingredients in particular quantities in the final formulation, and comply with certain manufacturing practices, and advertisement and labelling conditions. Provided that the exact formulation and other requirements are followed, this formulation is permitted for use in both healthcare facilities and consumer use.

The broker advised that they believe the importer had met all the requirements, that the ABF had been helpful, and that the delay appeared to be with the TGA assessment. This feedback is common in these matters.

If the hold was a border hold because of intelligence received, however, it is respectfully submitted that x-rays and/or other examinations should have been undertaken as a priority. Criminal elements would be alerted by these delays.

Two consignments:

Storage #1: $5250 (Fremantle)

Storage #2: in excess of $20,000 (Melbourne) (leniency by port received)

Entry lodged 20 May. Delivery advised to FTA for Thurs 17/6 by TGA, but not released by ABF until 22/6.

- **Recommendation: Introduce administrative measures including (1) a dedicated email address for regulated goods queries; (2) methodology to ensure that PPE and similar goods are not be held at the ports pending clearance; (3) post entry audits should be undertaken alleviating the need for goods to be held at the border, especially given TGA available staffing and response times for reviews; and (4) Sec.71E movement permissions should be approved.**

SHOULD THE MEASURE BE EXTENDED BEYOND JULY? IF YES, FOR WHAT PERIOD AND IN WHAT FORM? IF NOT, WHY NOT?

FTA have received correspondence from brokers, including those with contracts for the national stockpile/ the NSW Health contract, confirming that they have seafreight consignments not due until July, which is outside the proposed operating date.

Based on the current situation of the Pandemic, from media reports, we believe that the measures should be extended probably to at least the end of September 2019 in their current capacity, as this would allow for coverage during Australia's Flu season and cover for the potential of a second wave.

After September, it could be limited to only essential consumables from approved importers (similar to Cheese Quota Scheme perhaps) are eligible to utilise this By-Law, with applicable TGA approval. Items such as:

- Disposable Face masks;
- Gloves;
- COVID-19 test kits & reagents;

If appropriate, the measure could be concluded at end of the December 2020 as the threat of the pandemic and a 'second wave' should have sufficiently diminished by this time.

- **Recommendation: The measures should be extended to 31 December 2020.**

IF THE MEASURE IS TO BE EXTENDED, IS THE CURRENT PRODUCT SCOPE FIT FOR PURPOSE? IF NOT, HOW SHOULD THE PRODUCT SCOPE BE AMENDED?

Should the measure be extended then its current scope would fit the purpose but only to a set period. After that FTA suggest that, after review, the measure could be wound down as the market/national stockpile should be sufficiently stocked for any subsequent 'spike' in cases.