MARKET ACCESS ADVICE

Reference Number: MAA1703
Date of Issue: 20/01/2017
Date of Effect: Immediate

China: Re-establishment of conditions for trade in bovine blood and blood products

Attention	**Industries**	Export Establishments Industry bodies – Serum industry, AMIC, MLA Licensed exporters
	Department of Agriculture and Water Resources	Central and Regional Offices ATMs and FOMs OPVs and Meat inspection staff
Affected Markets		**China**
Further Information		Name: Emily Orchard-Mills Email: emily.orchard-mills@agriculture.gov.au Phone: 02 6272 2370 Name: Steven Martin Email: steven.martin@agriculture.gov.au Phone: 02 6272 5910 **OR** Please contact exports@agriculture.gov.au if you have any queries.

This Market Access Advice is further to MAA1460 and MAA1570.

On 14 November 2016, agreement to a protocol specifying trade conditions for **finished bovine blood and blood products** for export to China was reached between the Australian Government Department of Agriculture and Water Resources and The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ).

Before trade can commence, export certification arrangements must be agreed with AQSIQ. Industry will be advised as soon as this occurs.

Please note, **trade in semi-finished bovine blood and blood products remains suspended** pending further negotiations with AQSIQ.

The purpose of this Market Access Advice is to outline the conditions of the protocol.

Definition of finished bovine blood products

Finished bovine blood products are defined as blood products derived from bovine blood that have undergone sufficient treatment to ensure sterility and purified proteins, which are not required to be sterile.

Establishment listing

Establishments processing finished bovine blood products for export to China are required to be listed (approved) by the department and registered by AQSIQ. To achieve these approvals, establishments must have undergone on-site audits by both AQSIQ and the department to verify compliance with

Chinese Government requirements. This includes requirements for an ISO9001 quality management system, good manufacturing practice, and product segregation, identification, tracking and recall. If an exporter is interested in obtaining approvals to export finished bovine blood and blood products they should contact npgexports@agriculture.gov.au.

Sourcing

Only blood products derived from cattle of Australian or New Zealand origin is eligible for export.

Blood must be sourced from cattle that do not have clinical evidence of bovine viral diarrhoea virus or bovine leukaemia virus and, for slaughtered cattle that have passed official ante-mortem and post-mortem inspection. Australian origin blood must come from cattle that come from the bluetongue virus (BTV) free zone in Australia.

The department requires that all blood processors have in place an auditable, documented system to demonstrate compliance with China's sourcing requirements.

If you require further information on these requirements, please contact npgexports@agriculture.gov.au.

Testing Procedures

To be eligible for export, all product must have undergone the following testing:

Testing Item	Testing Method
Sterility test (including bacteria and fungi) *Excluding 'purified proteins'	Culture method
Bluetongue virus	Virus isolation **and/or** RT-PCR
Bovine viral diarrhoea virus	Virus isolation **and/or** RT-PCR
Bovine leukaemia virus	Virus isolation **and/or** RT-PCR
Mycoplasma	Culture method
Pathogen that has cytopathic effect	Observation of cytopathic effect after cell culture and dyeing
Pathogen that causes haemadsorption	Haemadsorption test after cell culture

For all testing procedures, a 'not detected' result must be obtained. In the case of testing using RT-PCR, product which has produced a positive result is only eligible for export if this test is followed by a negative result by virus isolation.

The cell lines used in testing for pathogen that has cytopathic effect and pathogen that causes haemadsorption must be listed on the export certificate.

Testing of products against these requirements must take place in a National Association of Testing Authorities accredited laboratory or an equivalent international laboratory approved by the Australian Government. Compliance with this requirement will be assessed during initial and subsequent on-site audits by the department.

If the product has been irradiated, documentation to support this processing must be provided.

The Manual of Importing Country Requirements (MICoR) has been updated to reflect the above advice.

The information provided above is current at the time of writing and is intended for use as guidance only and should not be taken as definitive or exhaustive. The Commonwealth endeavours to keep information current and accurate, however, it may be subject to change without notice. Exporters are encouraged to

verify these details with their importers prior to undertaking production/exports. The Commonwealth will not accept liability for any loss resulting from reliance on information contained in this notice.