Ref: CTO 2020 054 [VS]
Biological Products: Media comprised of restricted components that are to be used for human diagnostic use, within human medical laboratories (including for *in vitro* human research purposes) hospitals

CTO direction as to equivalent measures in relation to media comprised of restricted components where that media is to be used in human medical hospitals for distribution by Thermo Fisher Scientific New Zealand Ltd

Replaces CTO direction(s) on 01 January 2021: CTO 2020 036 [VS]

Pursuant to section 27(1)(d)(iii) of the Biosecurity Act 1993 I, Lucy Johnston, Manager Animal Imports, Ministry for Primary Industries (under delegated authority), give the following directions for media comprised of restricted components where that media is to be used in human medical hospitals for distribution by Thermo Fisher Scientific New Zealand Ltd in relation to the *Import Health Standard for Biological Products (BIOPRODIC.ALL)*:

Clause 25 of BIOPRODIC.ALL states:

Biological products (including samples) that are assessed by MPI to be risk goods may be eligible for a biosecurity authority to move to an MPI approved transitional facility provided they meet all conditions on the permit to import. See Guidance Document on requirements for processed and unprocessed risk goods.

The following products contain biological products of animal origin that are risk goods under BIOPRODIC.ALL:

Product name	Catalogue number
AmnioMAX C100 SUP	12556015, 12556023
AmnioMAX-II Complete	11269016
MarrowMAX Bone Marrow Medium	12260001, 12260014
PB Max Karyotyping Medium	12557021, 12557013

The hospitals and their associated human medical laboratories where the listed products will be used are not approved to 154.02.17.

Since the end use is for use in a human diagnostic/medical laboratory, it is unlikely that the media or any product derived from that particular media will come into contact with an animal. MPI considers that the products listed above do not need to be used in a transitional facility approved to the MPI *Transitional Facilities for Biological Products* standard (154.02.17) if on sold to one of the following hospitals for human diagnostic use or for use in their associated [human] medical laboratories only:

- Capital and Coast District Health Board (CCDHB)

Biosecurity New Zealand
Animal and Plant Health Directorate
Pastoral House, 25 The Terrace
PO Box 2526, Wellington 6140, New Zealand
Telephone: 0800 00 83 33
www.mpi.govt.nz

Ref: CTO 2020 054 [VS]
Biological Products: Media comprised of restricted components that are to be used in [human] medical hospitals

- Auckland District Health Board (ADHB)
- Canterbury District Health Board (CDHB)
- Waikato District Health Board
- Wellington Hospital

To note: The assessment on the products above is based on the information provided by Thermo Fisher Scientific New Zealand Ltd to MPI. This CTOd must be reviewed if BIOPRODIC.ALL is replaced by another import health standard or the product composition of any of the below listed media changes (including the origin of the ingredients of biological products of animal origin).These hospitals and their associated human medical laboratories where the listed products are required are not approved to 154.02.17.

The reason for this direction is that the biosecurity risks associated with this commodity have been assessed and are managed effectively.

This direction takes effect from 01 January 2021 and continues in effect until amended or revoked.