



Ref: CTO 2015 089 [1]

Virus: Genetically Modified Live-Attenuated Vaccinia Virus: Pexa-Vec

### CTO direction to biosecurity inspectors for the clearance of Pexa-Vec

Pursuant to section 27(1)(d)(iii) of the Biosecurity Act 1993 I, Marnie Thomas, Manager Animal Imports, Ministry for Primary Industries (under delegated authority), give the following directions for genetically modified live-attenuated vaccinia virus (Pexa-Vec) to be given clearance in accordance with the following measures, different from those in the applicable import health standard for microorganisms (MICROIC.ALL):

Clause 6.4 of MICROIC.ALL states:

- 6.4 *Microorganisms that are **new organisms** may be given **biosecurity direction** provided the following requirements are met:*
- 6.4.1 *The product is accompanied by a copy of the permit to import, listing the HSNO Act approval number,*
  - 6.4.2 *All the conditions on the permit to import are met,*
  - 6.4.3 *All the relevant controls and purpose of the HSNO Act approval are met, and*
  - 6.4.4 *The containment facility listed on the permit to import is approved at the time of import to the MAF and ERMA New Zealand Standard: Facilities for Microorganisms and Cell Cultures 2007a and any subsequent amendments to that standard. This standard is available from the MAFBNZ website <http://www.biosecurity.govt.nz/regs/trans/stds>*

Under section 28B of the Biosecurity Act 1993, biosecurity clearance for goods that are or contain a new organism can be given if those organisms are approved under section 38I of the HSNO Act 1996. Pexa-Vec is approved for clearance under HSNO approval code GMR100003 under this section.

Pexa-Vec does not need a biosecurity direction to a containment facility (as per clause 6.4.4 of the IHS) and can be imported with no post-entry conditions. However, such importations are subject to the controls set by the EPA in the decision document relating to HSNO approval code GMR100003 ([http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/APP202601\\_APP202601\\_Decision.pdf](http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/APP202601_APP202601_Decision.pdf)).

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

This direction takes effect from the date of signing and continues in effect until amended or revoked.