

Rural and Regional Affairs and Transport  
Answers to Questions on Notice  
**Agriculture, Fisheries and Forestry Portfolio**

**Hearing:** Supplementary Budget Estimates

**Question No:** SQ23-000200

**Outcome:** Outcome 2

**Division/Agency:** Biosecurity Animal Division

**Topic:** Safety mRNA Vaccines

**Question Date:** 28 February 2023

**Question Type:** Written

**Senator Roberts asked:**

What Australian safety testing is being conducted, or is intended to be conducted, to ascertain the safety of mRNA vaccines? Please clearly identify Australian activity -vs- imported activity, which constitutes taking someone else's word for it.

**Answer:**

Vaccines for human use in Australia are approved by the Therapeutic Goods Administration (TGA), part of the Department of Health and Aged Care, after a careful evaluation process. Questions regarding safety testing of mRNA vaccines for human use should be referred to the TGA or the Australian Government Department of Health and Aged Care.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) have not registered, or approved under permit, any mRNA veterinary vaccines in Australia.

Meat & Livestock Australia (MLA) is coordinating a project to develop mRNA vaccines for livestock, including for lumpy skin disease (LSD). MLA has advised that the LSD vaccine will undergo preliminary safety and efficacy testing in Canada.

Should the vaccine be shown to be safe and effective, the product would need to be assessed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in order to register the product as safe for use in Australia.

The APVMA takes a systematic, scientific, evidence-based approach to decision-making and must be satisfied that all proposed agricultural and veterinary chemicals meet the statutory criteria for safety (including the risks of residues in food), efficacy and trade prior to registration or approval under permit. Detailed information about the APVMA's statutory criteria for chemical product approval and registration can be accessed at: <https://apvma.gov.au/node/628>.

Additional safety requirements may be imposed by the Office of the Gene Technology Regulator depending on the nature of the vaccine.

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**Hearing:** Supplementary Budget Estimates  
**Question No:** SQ23-000128  
**Outcome:** Outcome 2  
**Division/Agency:** Biosecurity Animal Division  
**Topic:** mRNA Vaccine Use  
**Hansard Page:** 123  
**Question Date:** 14 February 2023  
**Question Type:** Spoken

**Senator Roberts asked:**

Senator ROBERTS: Thank you for being here today. Many constituents of ours have been contacting my office regarding mRNA vaccines in cattle. It was my understanding that, if we actually used a lumpy-skin or foot and-mouth disease vaccine, we would then be considered to have that disease, which would be economically ruinous. I have heard that as mRNA vaccines don't include those diseases then they can be used. Can you update the committee on the facts around these issues, please?

Mr Metcalfe: If I could perhaps assist, I think these are really matters for the department, not for the APVMA. Those officials have now left, so we'll take that on notice and reply to you.

**Answer:**

There are no foot-and-mouth disease (FMD) and lumpy skin disease (LSD) mRNA vaccines that are commercially available internationally, however some are in the early stages of research and development.

Unlike conventional live or inactivated vaccines, the production of mRNA vaccines does not require the culture of the viral agent.

However, the use of mRNA vaccines for FMD or LSD before an incursion would affect Australia's status for these diseases, and therefore export market access for livestock products. Australia is officially recognised by the World Organisation for Animal Health (WOAH) as "FMD free without vaccination". Use of any type of FMD vaccine before an incursion would reduce this status to "FMD free with vaccination" which would affect our access to premium markets.

The WOAH Terrestrial Animal Health Code outlines the international standards for LSD, which does not allow for vaccination to be used in LSD free countries.