Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

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Notification of decision for an alternate facility under regulation 13(2)(c); and for alternate transport, storage and disposal requirements under regulation 13(3)(b) for dealings with self-amplifying mRNA (saRNA)

This notification advises the decision by the Gene Technology Regulator (the Regulator) to permit Physical Containment Level 3 (PC3) Notifiable Low Risk Dealings (NLRDs) dealings with saRNA derived from the TC-83 strain of the Venezuelan equine encephalitis virus (VEEV) at volumes of ≤25 L per vessel that meet NLRD criteria specified in Schedule 3, Part 2.1(d) of the Gene Technology Regulations 2001 (the Regulations) to be conducted in some PC2 certified facilities under the OGTR identifier FAC-022.

The decision also permits the transport, storage and disposal of these saRNA products to be conducted in accordance with the Regulator's *Guidelines for Transport Storage and Disposal of GMOs* for PC2 GMOs (OGTR identifier TSD-018).

Assessment

The following information was taken into account:

- Although the VEEV is classified as a Risk Group 3 (RG3) microorganism in Australia, the VEEV TC-83 strain is highly attenuated.
- saRNA lack genes encoding viral structural proteins. Although delivery of saRNA to cell cultures or administration to target hosts leads to the formation of a viral replication complex capable of amplifying the saRNA molecule, these molecules are unable to form infectious viral particles.
- Requirements and conditions included in the Guidelines for PC2 Laboratory, Animal, Aquatic, and Invertebrate facilities and for PC2 large-scale facilities are considered appropriate working with saRNA constructs.
- Requirements and conditions included in the Guidelines for PC2 constant temperature room are appropriate for storage of saRNA products ≤ 25 litres per vessel.
- The Guidelines for the Transport, Storage and Disposal of GMOs applicable to PC2 GMOs are appropriate for the transport, storage and disposal of saRNA products and material containing saRNA.

Decision

Pursuant to Regulations 13(2)(c) and 13(3)(b) of the Regulations, the Regulator has agreed that:

i. NLRDs involving saRNA derived from VEEV TC-83 strain at volumes of ≤25 L per vessel that meet criteria specified in Schedule 3, Part 2.1(d) of the Regulations may be undertaken in Certified PC2 facilities listed below:
   - PC2 Laboratories
   - PC2 Animal, Aquatic or Invertebrate facilities
   - PC2 Large Scale facilities

- PC2 Constant Temperature Rooms.

ii. transport, storage and disposal of saRNA at volumes of ≤25 L per vessel that meet criteria specified in Schedule 3, Part 2.1(d) of the Regulations may be conducted under the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* applicable to PC2 GMOs.

The NLRD as assessed by the Institutional Biosafety Committee (IBC) must refer to OGTR identifier FAC-022 and TSD-018.