

28 January 2021

The Honourable Guy Barnett MP  
Minister for Primary Industries and Water  
Parliament House  
HOBART TAS 7000

Submitted via email: [sdn1regulations@dpiw.tas.gov.au](mailto:sdn1regulations@dpiw.tas.gov.au)

Dear Mr Barnett,

Thank you for the opportunity to provide feedback on the *Draft Biosecurity (SDN-1 Modified Organism) Regulations 2020*. The University of Tasmania strongly supports the implementation of a modern biosecurity regulatory framework and commends the Department of Primary Industries, Parks, Water and the Environment for the recent assent of the *Biosecurity Act 2019*. The University welcomes the introduction of subordinate regulations under the new Act and the Department's proactive engagement with stakeholders.

The University acknowledges the complications for Tasmanian businesses arising from the decision by the Commonwealth Gene Technology Regulator to update the definition of genetically modified organisms (GMOs) to exclude organisms modified by the SDN-1 technique. In line with the University's Strategic Plan 2019-2024, which highlights the priority of becoming a place-based institution and working in partnership with governments toward Tasmania becoming more prosperous, equitable and sustainable, we are supportive of the proposed regulations to assist and enable Tasmanian businesses to occupy a distinctive niche in the competitive global marketplace.

As one of three Tasmanian organisations currently approved by the Office of the Gene Technology Regulator (OGTR) to conduct dealings with GMOs, and one which conducts research using SDN techniques, the proposed regulations will directly affect the University's operations. The University acknowledges the emphasis placed on maintaining the competitiveness of Tasmania's research institutions as noted in the accompanying fact sheet, and welcomes the opportunity to assist the Department in ensuring processes for enforcing the regulations are administratively light to achieve our shared objective. The University's Institutional Biosafety Committee, which is responsible for ensuring all gene technology activities at the University are conducted lawfully, is in a position to draw on their significant expertise and offer sound advice as this is a fundamental operational activity within their remit. The University cordially welcomes further engagement with the Department to further discuss or trial the proposed registration process for SDN-1 dealings and co-design iterations, if required, to ensure it does not create an undue administrative burden.

The University's overarching position is in support of the Department's proposed changes and we wish to note the following observations on specific aspects of the draft regulations:

- Information in the accompanying fact sheet notes that dealings with SDN-1 organisms will be limited to Physical Containment (PC) facilities. The University queries whether this is limited to PC facilities certified by the OGTR, or those which meet the criteria for a PC facility as determined by *Australian Standard 2243.3 Safety in Laboratories – Microbiological Safety and Containment*. Furthermore, a specific containment level is not noted in the fact sheet. The University recommends that the PC1

containment level is appropriate, unless the organism in question is of a risk group which necessitates a higher containment level.

- Details are not provided pertaining to audit of the facilities used for containment of SDN-1 organisms. The University recommends deferring to existing institutional arrangements for facility compliance management rather than implementing an additional layer of facility auditing to ensure PC compliance.
- The University notes that the *Biosecurity Act 2019* includes a provision in Section 79(2)(d) for payment of a prescribed fee for obtaining a registration, and queries whether a prescribed fee will be charged by the Department for obtaining a registration under the proposed regulations. Furthermore, Section 79(3) notes that a separate application may be required for each regulated dealing that the applicant wishes to engage in. Enforcing either of these Sections would contravene the objective of implementing an administratively light registration process. As research by the University directly supports the state, the University proposes an overarching institutional registration with no fee, acknowledging the requirement for a fee for commercial activities.

As the only University in Tasmania, we have a responsibility, along with our partners at all levels of government and the community, to realise opportunities that allow us to utilise our expertise and capability to provide sustainable advantage for Tasmania. The University is in full support of the implementation of a modern biosecurity regulatory framework for protecting the state's interests, and values the opportunity to further engage with the Department regarding the draft regulations. The University looks forward to continuing its successful partnership with the Department in the future.

As always, please do not hesitate to contact me should there be anything with which I can assist or if there is anything you wish to discuss.

Yours sincerely,



**Professor Anthony Koutoulis**  
Deputy Vice-Chancellor (Research)