



Australian Government

**Department of Health,
Disability and Ageing**

Deputy Secretary

Ms Joanna Abhayaratna
Executive Director
Office of Impact Analysis
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: Helpdesk-OIA@pmc.gov.au

Dear Ms Abhayaratna

Certification of Sunset Instrument

I am writing to the Office of Impact Analysis (OIA) regarding the *Biosecurity (Human Health) Regulations 2016* (the Regulation), which, as per the *Legislation Act 2003*, is scheduled to sunset on 1 October 2026. Pending Ministerial approval, it is intended that the Regulation be remade with one key amendment affecting the operational application of existing biosecurity requirements, along with several minor and technical updates. These amendments will ensure continuity of the human biosecurity measures that support the *Biosecurity Act 2015* and to keep the Regulation contemporary and effective.

The Department of Health, Disability and Ageing (the department) certifies that the *Biosecurity (Human Health) Regulations 2016* are operating effectively and efficiently, and therefore an Impact Analysis is not required for the remake of this legislation.

The assessment that the Regulation is operating effectively and efficiently has been informed by a consultation process which involved The Department of Agriculture, Fisheries and Forestry (DAFF) and relevant technical experts within the Australian Centre for Disease Control. This consultation was undertaken between November 2025 and January 2026 as part of the department's review of the Regulation. DAFF concurs with the department's approach to remake the Regulation.

I also note that the regulatory burden to people, businesses, and community organisations has been quantified using the Australian Government's Regulatory Burden Measurement framework. These are provided below.

Table 1: Average annual regulatory costs (from business as usual)

Change in costs (\$ million)	Business	Community organisations	People	Total change in costs
Total, by sector	\$0	\$0	\$0	\$0

Table 1 confirms that there is no change to the regulatory burden estimate. The Regulation is being remade with amendments that do not impact the regulatory burden, and accordingly the estimated costings remain unchanged.

I acknowledge that the OIA will publish this letter for transparency purposes.

If you have any queries about this advice, please contact the Border Health Section on humanbiosecurity@health.gov.au

Yours sincerely



Penny Shakespeare
Deputy Secretary
Health Resourcing Group

26 March 2026