



30 October 2024

(24-7652)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>AUSTRALIA</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Australian Government Department of Health and Aged Care Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Australian TBT Enquiry Point Department of Foreign Affairs and Trade Ph +61 2 6261 1111 tbt.enquiry@dfat.gov.au www.dfat.gov.au
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Organisms that have been modified through the use of certain gene technology (Genetically Modified Organisms - GMOs)
5. Title, number of pages and language(s) of the notified document: Public consultation on the proposed Gene Technology Amendment Bill; (163 page(s), in English), (70 page(s), in English)
6. Description of content: The National Gene Technology Scheme (the Scheme) is a collaboration between all Australian governments, supporting a nationally consistent regulatory system for gene technology in Australia. It is designed to protect the health and safety of people, and the environment, from the risks associated with gene technology. Periodic reviews of the Scheme have been undertaken since its commencement in 2001. The <i>Gene Technology Act 2000</i> , Gene Technology Regulations 2001 and corresponding state and territory legislation ensure consistent national coverage for the regulation of GMOs in Australia. The attached Exposure Draft: Gene Technology Amendment Bill and associated consultation document outline proposed changes to the regulation of GMOs following the Third Review of the Scheme (the Review). In response to the final Third Review report, a number of policy options were considered to implement the recommendations of the Review. A preferred regulatory model was identified, where dealings with GMOs would be classified into authorisation pathways according to the level of risk they pose, a model referred to as the risk-tiering framework agreed to by all Australian Governments.

<p>7. Objective and rationale, including the nature of urgent problems where applicable: While the Third Review found that, overall, the Scheme is working well, the Review outlined a number of recommendations designed to improve and strengthen the Scheme, while ensuring it is appropriately agile and supports innovation.</p> <p>In order to give effect to this the model proposed in response to the Third Review, the proposed legislation contains a mix of principles and prescriptive rules that would provide sufficient flexibility for the regulatory system to respond to scientific advances in a timely manner and support innovation, while ensuring that risks to public health and the environment are managed proportionally, and the Scheme remains fit for purpose. ; Protection of human health or safety; Protection of animal or plant life or health; Protection of the environment</p>
<p>8. Relevant documents:</p> <ul style="list-style-type: none">• Exposure Draft: Gene Technology Amendment Bill (163 pages): https://consultations.health.gov.au/best-practice-regulation/amendments-to-the-gene-technology-act-200/supporting_documents/Exposure%20Draft%20Gene%20Technology%20Amendment%20Bill%202024.pdf• Consultation document accompanying the draft Amendment Bill (70 pages): https://consultations.health.gov.au/best-practice-regulation/amendments-to-the-gene-technology-act-200/supporting_documents/Consultation%20Paper%20%20Draft%20Gene%20Technology%20Amendment%20Bill.pdf
<p>9. Proposed date of adoption: Subject to Australian Parliamentary consideration.</p> <p>Proposed date of entry into force: To be determined Subject to Australian Parliamentary consideration.</p>
<p>10. Final date for comments: 22 December 2024</p>
<p>11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>https://consultations.health.gov.au/best-practice-regulation/amendments-to-the-gene-technology-act-200/supporting_documents/Exposure%20Draft%20Gene%20Technology%20Amendment%20Bill%202024.pdf</p>