COMPLIANCE, MONITORING & ENFORCEMENT

The Gene Technology Regulator (the Regulator) has powers to enforce compliance with the legislation. To provide a suite of modern regulatory tools, it is proposed that some standard regulatory powers will be adopted.

Review recommendation being addressed:

Recommendation 12: To ensure the Scheme's current monitoring and enforcement activities remain adequate:

- a) regular reviews of these activities are undertaken;
- b) regulatory requirements for working with gene technologies are widely communicated and known;

and

c) the scope and associated risks of 'DIY biology' activity continue to be monitored.

Alignment with the Regulatory Powers (Standard Provisions) Act 2014

Many Commonwealth regulators adopt standard provisions from the Regulatory Powers Act. To ensure compliance powers in the National Gene Technology Scheme are consistent and up to date, some provisions from the Regulatory Powers Act have been included in the Gene Technology Amendment Bill 2024 (the draft Bill), including to replace current inspection and enforcement powers.

Monitoring & Investigation powers

The monitoring and investigation powers are mostly unchanged, but are updated to reflect new authorisation pathways.

Additional monitoring and investigation powers

Powers that are not in the Regulatory Powers Act will be retained from the Gene Technology Act. These specifically apply to gene technology regulation. In addition, there will be a new power enabling the Regulator to require information and documentation to be produced if it is relevant to the Regulator's functions and regulation of GMOs.









Definitions

The Bill introduces some new terminology. Instead of 'inspectors' there would be 'authorised inspectors' and 'authorised compliance officers'.

Some changes would be made to provisions from the Regulatory Powers Act to make sure they apply appropriately to the Gene Technology Act.

Definitions of 'thing' and 'equipment' would be broadened to cover all 'things' authorised inspectors might need to deal with to conduct their duty.



Enforcement powers

Currently, the Regulator can issue directions in limited circumstances and can seek injunctions against people whose activities would be an offence against the Act. Further enforcement powers are needed to balance proposed changes to authorisation pathways, which will reduce up-front regulatory oversight of some GMO dealings.

The Bill proposes to expand the range of situations in which the Regulator can issue directions. The Bill would also adopt further enforcement powers from the Regulatory Powers Act. This would enable authorised inspectors to issue infringement notices for contravention of civil penalty provisions and enable the Regulator to use enforceable undertakings.



Emergency powers

The draft Bill proposes to change the threshold for exercising emergency powers from an 'imminent risk of death, serious illness, serious injury or serious damage to the environment' to 'a significant risk to human health and safety or to the environment'. This would increase consistency of when these powers can be applied and ensure it maintains the objectives of the Scheme.

Want more detail?

You can review the proposed changes to compliance, monitoring and enforcement in the draft Gene Technology Amendment Bill.

The policy rationale for these changes has been outlined in the Consultation Paper: Draft Gene Technology Amendment Bill.

Contact us for more information on this consultation:

gene.technology.implementation@health.gov.au

