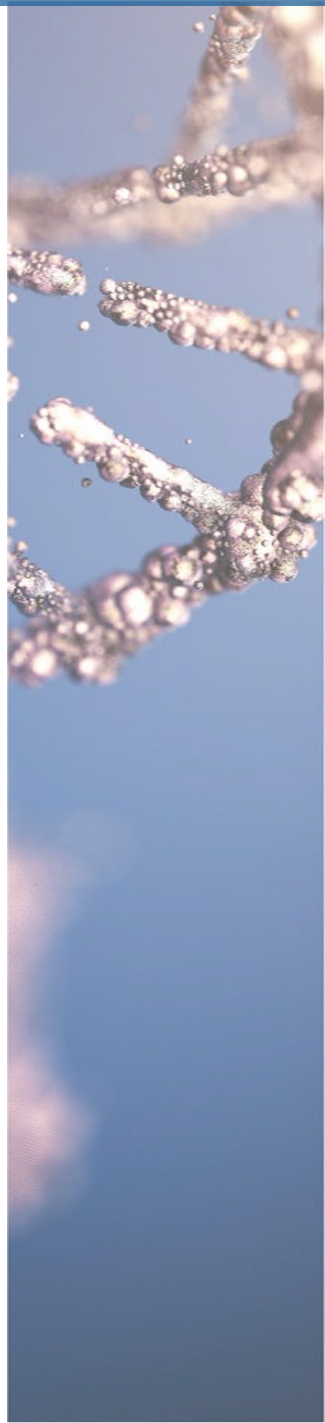
Australian Government
Department of Health, Disability and Ageing
Office of the Gene Technology Regulator

Compliance Referrals and Allegations

Phil Rohan

October 2026



M&C's Primary Functions and Activities

Licence Monitoring and Notifications

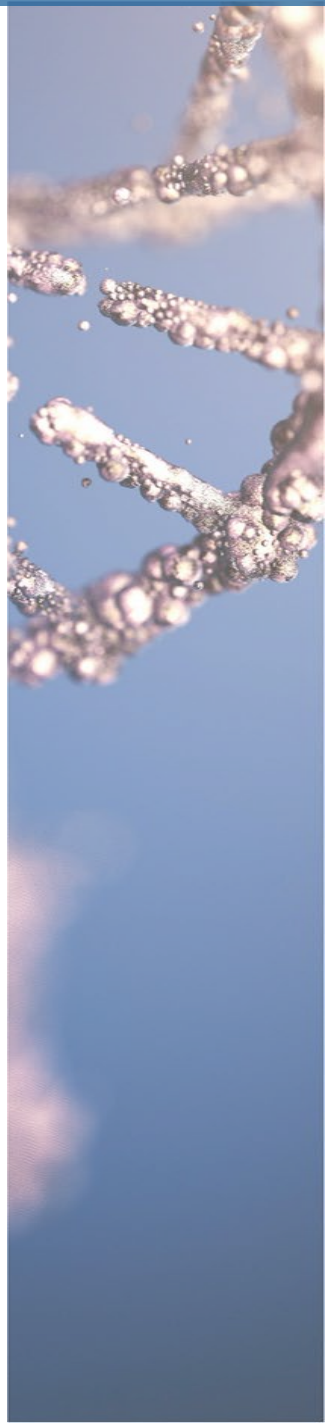
- Plant site monitoring, Commercial Licences, Annual Reports
- Compliance Management Plans for Clinical Trials

Inspections

- DIR/DNIR Licenced Dealings (e.g. Plants, Research, CTs)
- Certified Facilities (e.g. Labs, animals, high containment)

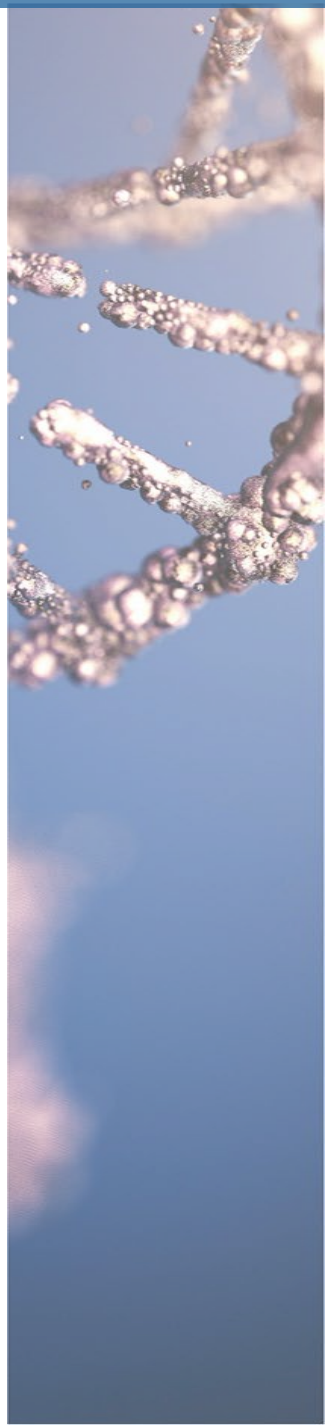
Self Reported Incidents (SRI's)

- Incidents (spills, breakages, animal related)
- Potential non-compliance with conditions



M&C Statistics – 2023-2025

	2023-24	2024-25	2025-26
Licence Monitoring Notifications:	**264**	**266**	**Being prepared** **Not yet published**
Plant monitoring Notifications:	**384**	**449**	
Self Reported Incidents (SRI's):	**108**	**98**	
Inspections (Organisations):	**(29)**	**(32)**	
• **DIR Licences**	**5**	**6**	
• **DNIR Licences**	**12**	**9**	
• **Certified Facilities**	**155**	**128**	



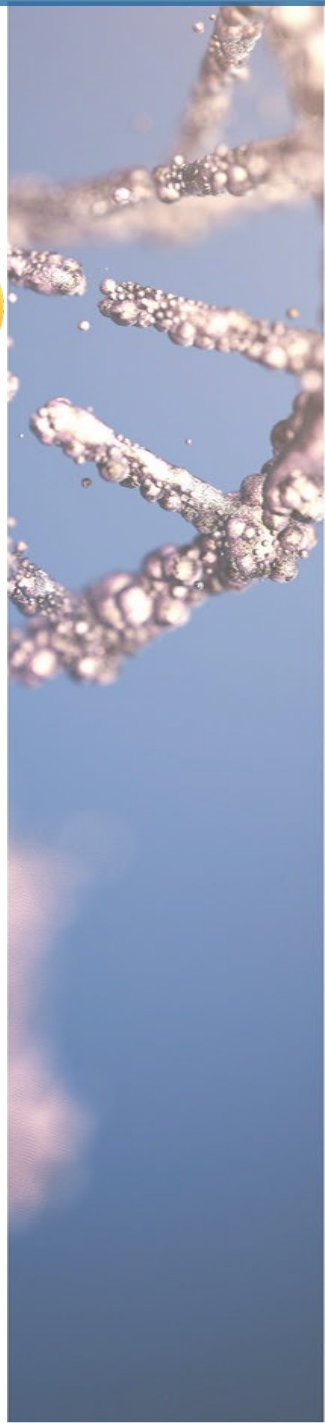
100 SRI reports/year – meaning what? 🤔

Number is of interest, but not of concern

- Required to report SRI's (Lic Conditions, Cert Guidelines)
- If in doubt, OGTR encourages entities to report incidents
- Reporting timeframes – not all are prescriptive.

Markers and trends

- Improvements in detecting Incidents
- Streamlined reporting processes = improved timeframes
- Importance for Regulator to be involved in remedy



Referrals (aka Allegations, Tip-Offs)

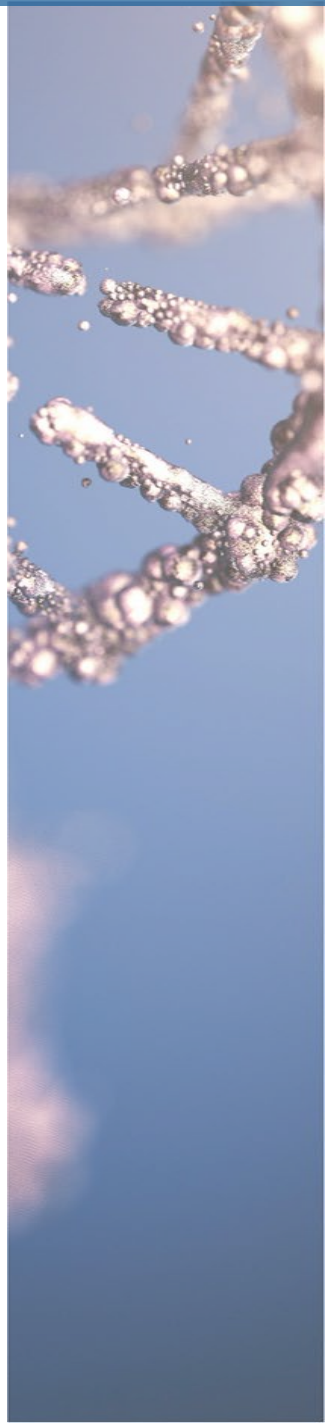
Difference between SRI's vs Referrals

Anonymous referrals (person *may* be known to OGTR – or not)

- M&C avoids identifying the complainant externally
  - May *not* overtly investigate if that might identify anonymous complainant

Information to include in a referral

- All relevant matters: 'Who, what, where, when, why, how' – but we'll take what we can get
  - If insufficient information is received, may be unable to progress enquiries
  - If contact details for a complainant are known, we may seek clarification
  - No expectation for complainant to conduct own investigation



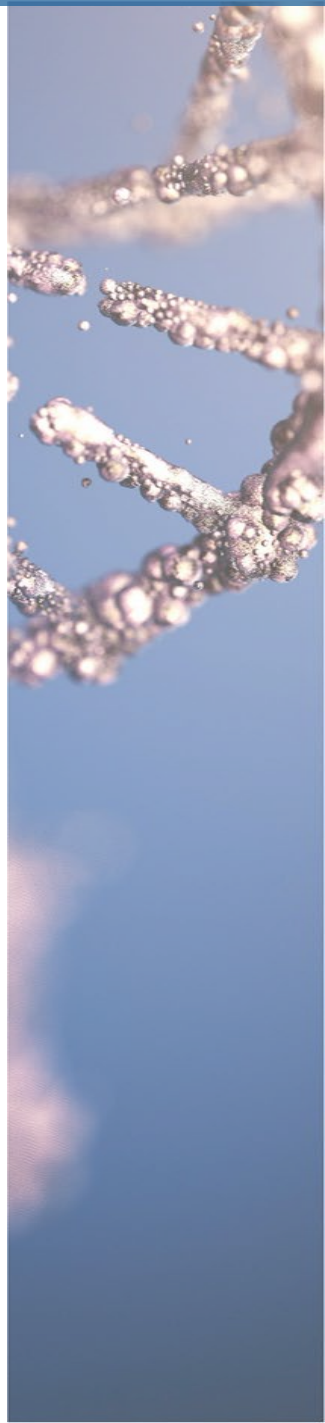
Referrals – Next steps

Verification of referral

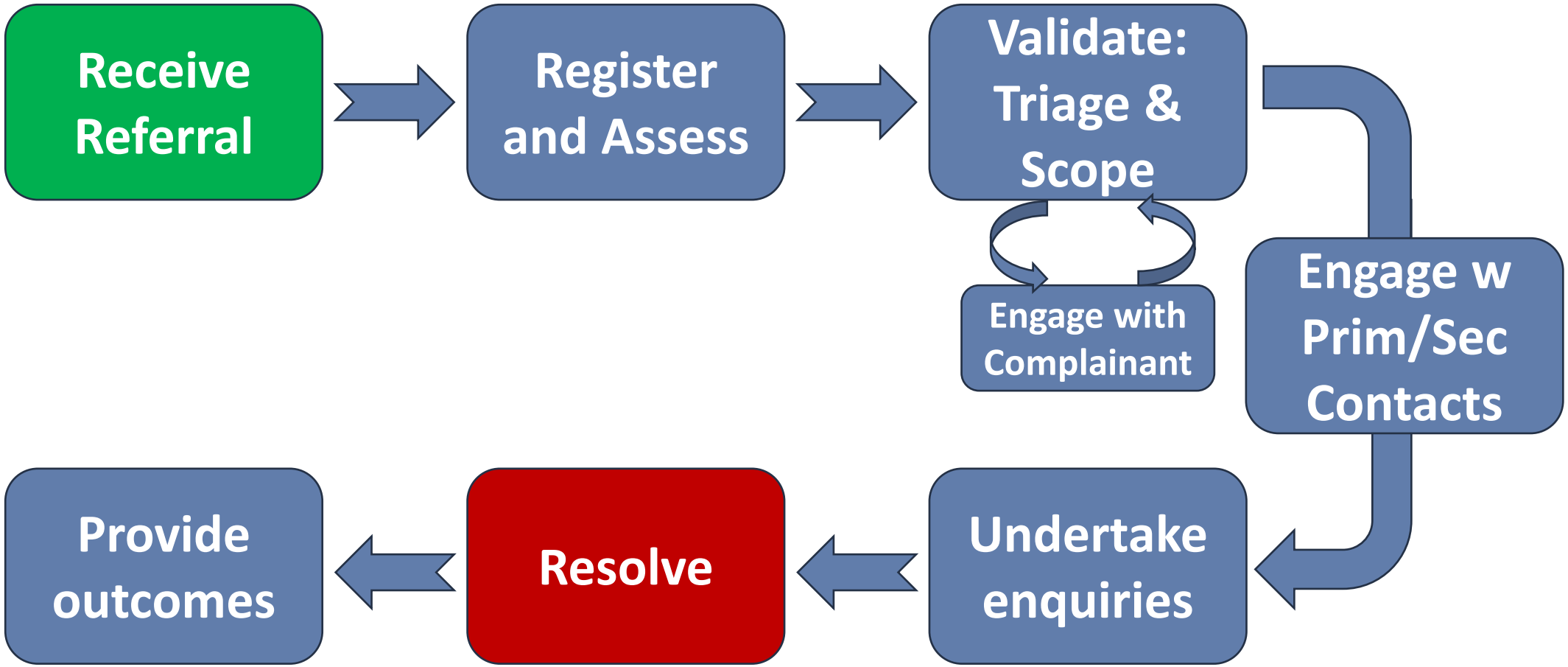
- Assess if referral is in/out of OGTR remit
- No assumptions made that the referral is wholly accurate
- Identify and manage vexatious referrals

Plan follow up steps – approaches are highly variable

- Engage with Primary/Secondary Contact where appropriate
- May undertake visit/inspection
- Actions proportional to the issue



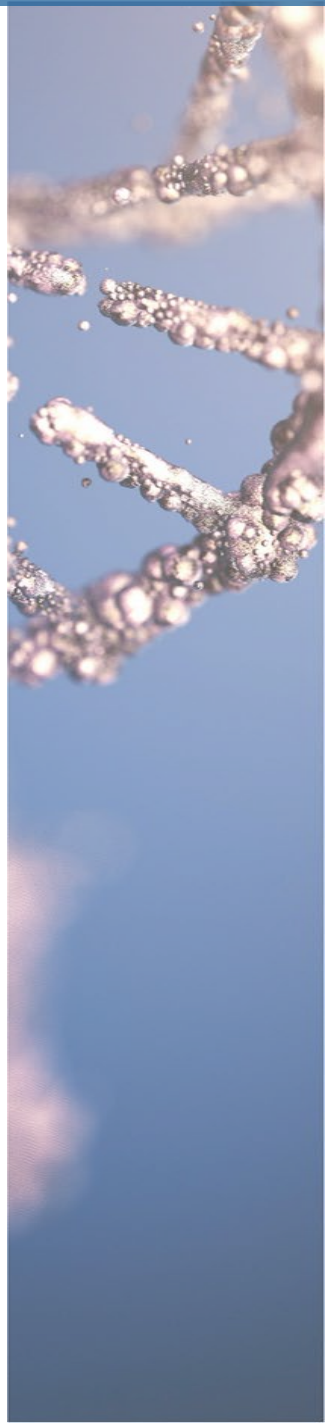
Referral flowchart



Compliance Frameworks and Standards

Monitoring & Compliance Protocols

- Allegation by Third Parties Protocol (2019)
- OGTR M&C Compliance Framework (2018)
- Compliance and Enforcement Policy (2016)



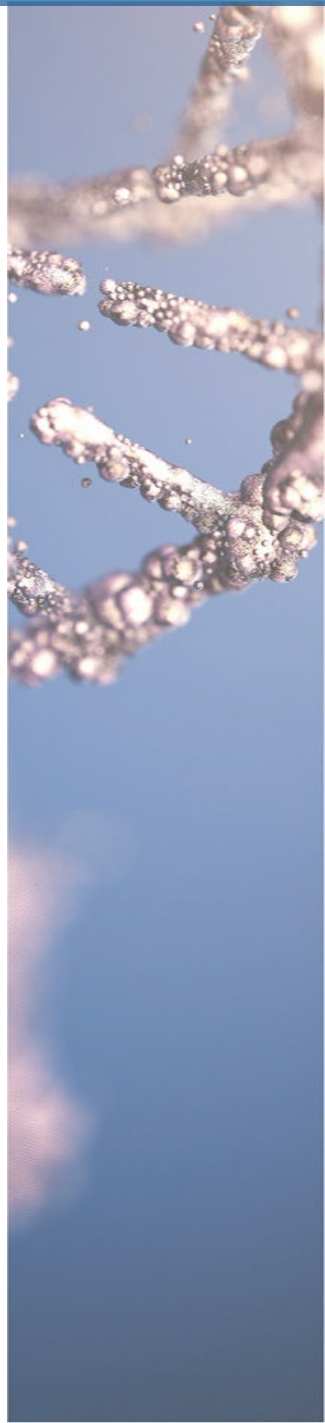
Outcomes and Powers

Enforcement outcomes and powers (*Gene Technology Act 2001)*

- Current monitoring and investigative powers – early 2000's
- Inspections with consent (Licences: Power to enter without)
- 'Co-operative compliance' – promote voluntary compliance

General regulatory stance:

- Outcomes proportional to incident
- Address non-compliance
- Deter future non-compliance



Example - GloFish importation



GloFish are GMOs that generally have organs or tissues that fluoresce. Known to be used in research (eg to understand how skeletons and organs develop); or imported recreationally (pets)

GloFish cannot be imported or kept without an OGTR licence.

- Quarantined, referral from Cth Dept (Home Affairs/DAFF)
- Engage with and educate importer/ retailer
- Negotiate voluntary euthanising fish, and disposal
- Not released to importer, no non-compliance
    - If no recklessness or negligence (consider intent, prev incidents)





Example – Inadvertent Dealings (ID)

Possession of a GMO without realising or intending to. An Inadvertent Dealings licence may be required, to authorise all further GMO dealings, including destruction/disposal.

Low Level Presence of imported material – soybean, petunias, lucerne – often believed non-GM when obtained.

- Referral received from Cth Dept (DAFF)
- Engage with entity/importer, applies for ID Licence
- OGTR monitors return and disposal of stock.
- Compliance based on adherence to ID Licence.



Example – Dealings without authorisation

Dealings with GM material without/not in line with authorisation.

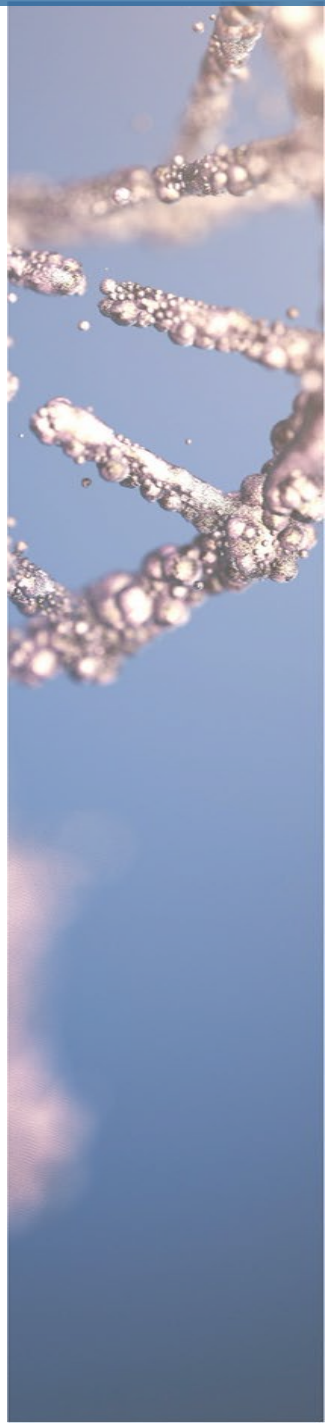
- Referral received (SRI, 3rd party (allegation))
- Validate and clarify details, triage and scope referral
- Engage with P/S Contact, Visit/Inspect, Identify actions taken
- Compile chronology, consider governance, intent
- Provide report to delegate, and make findings regarding compliance (GT Act/Regs/Guidelines)
- Outcomes: Compliance actions, BPRs may apply.

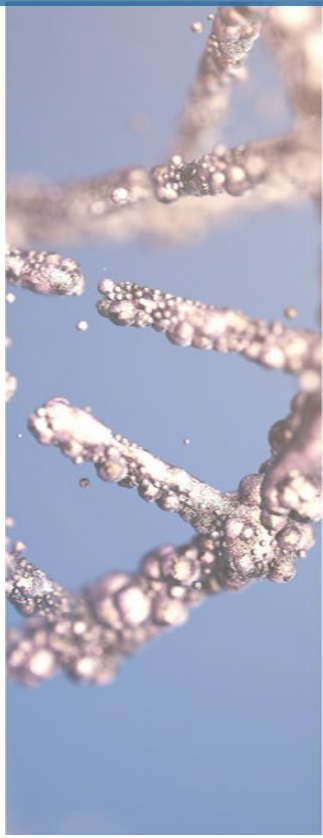


Key messages

What should you leave this Forum knowing?

- Anyone with information relating to a potential non-compliance is encouraged to refer allegations and incidents
- M&C considers and investigates referrals discreetly, proportionately, and with an open-mind
- Regulatory stance likely to remain consistent despite changes
- Powers will continue to be applied appropriately



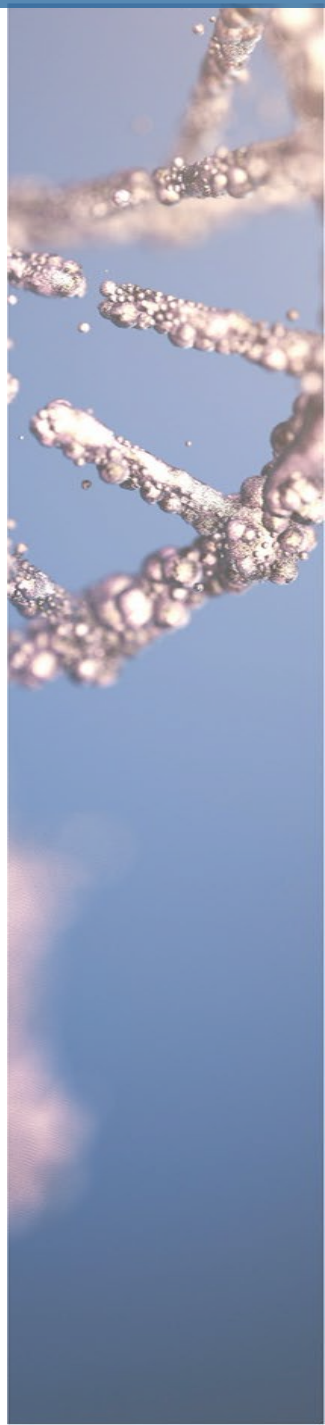


Contacting Monitoring and Compliance

Contacting the Monitoring and Compliance Section

- Email: OGTR.M&C@health.gov.au
- Online referral: https://www.ogtr.gov.au/about-ogtr/contact-and-subscribe/report-non-compliance-or-unintended-presence-gmos
- Hotline: 1800 181 030
- Mailing address: GPO Box 9848 CANBERRA ACT, 2601
    - Please don’t post GMOs to us!

Questions



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

Contact Us

1800 181 030

ogtr@health.gov.au

www.ogtr.gov.au

