



Australian Government

Department of Health

Office of the Gene Technology Regulator

Monitoring and Compliance





Staff Background

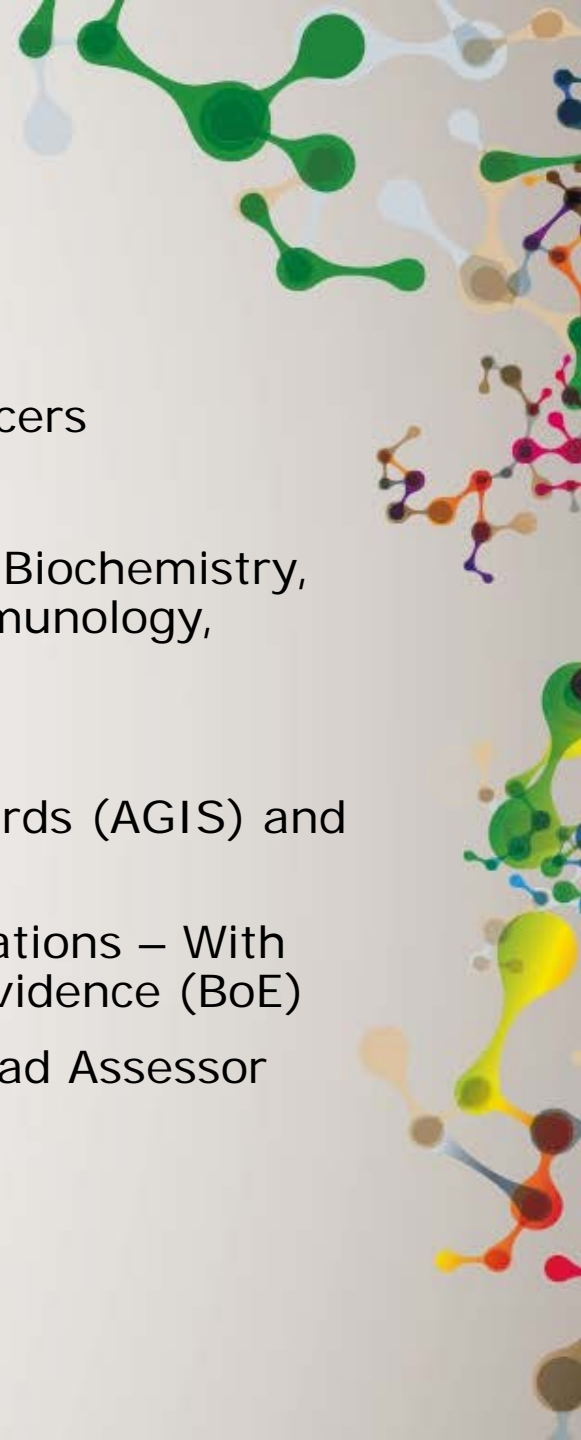
Team of 9, including 2 dedicated compliance officers

Diverse range of backgrounds

- Police, Cwlth Investigations, Plant Pathology, Biochemistry, Human Biology, Chemistry, Agribusiness, Immunology, Microbiology, Molecular Biology.

Qualifications and experience include

- Australian Government Investigations Standards (AGIS) and Attorney Generals (HOCOLEA)
- Internal Investigations and External Investigations – With various LEAs – Search Warrants / Briefs Of Evidence (BoE)
- Cert IV in Statutory Compliance and NATA Lead Assessor (ISO 17025)
- Laboratory design and construction





What we do

Undertake routine monitoring of regulated activities to assess compliance with the GT legislation

- Field (DIR) or contained licences (DNIR), certified facilities, Notifiable Low Risk Dealings
- Case assessments of self reports & allegations
- Investigations
- Cooperative Audits and Practice Reviews
- Provide input from our findings back into the evaluation process (*e.g.*) for new licences
- Manage field-release licences (DIRs)
- Review stakeholder's periodical reports, assess applications for site sign-off





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Powers available to Inspectors

Section 153 – General Monitoring Powers

Sections 154 and 155 - Search and Seizure

Emergency Powers – Section 158

Search goods – Section 164 Section 165

Warrants Section 172 and Section 173

Note: Affidavits / Warrants signed off and approved by CDPP (warrants register)



Monitoring of Field Trials (DIRs)

Inspect a minimum of 5% of current (GMO actively growing) and 5% of post-harvest sites per quarter

Monitor against the specific licence conditions for the site – *e.g.*

- Training and other records
- Location and size of the site
- Presence of gene-flow control measures
- Presence of related species and volunteers

Inspections may target specific crop practices and may be announced or unannounced





Monitoring of Contained Dealings

Undertake announced and unannounced monitoring of contained licences (DNIRs) and associated certified facilities

- Monitor against specific licence conditions – *e.g.*
 - Training and record keeping requirements
 - Transport, storage and disposal requirements
 - Work practices and approved facilities

Inspect a minimum of 20% of higher-level containment facilities per year

- Monitor against the facility-specific conditions – *e.g.*
 - Training and work practices
 - Equipment and maintenance
 - Structure
 - Transport, storage and disposal
 - Record keeping



Enforcement

Legislation provides strong enforcement powers and penalties for non-compliance

- *Gene Technology Act 2000 Act* with reference to *Criminal Code Act 1995* and *Commonwealth Crimes Act 1914* – Note: *Indictable Offences*

Section	Subject	Penalty
32 - 33	Person not to deal with a GMO without a licence	2yrs / \$90,000 (5yrs / \$360,000 for aggravated offence)
34 - 35	Person must not breach conditions of a GMO licence	2yrs / \$90,000 (5yrs / \$360,000 for aggravated offence)
35A - B	Person must not breach conditions of EDD	2yrs / \$90,000 (5yrs / \$360,000 for aggravated offence)
36	Person must not breach conditions on GMO Register	\$9,000
37	Offence relating to Notifiable low risk dealings	\$9,000

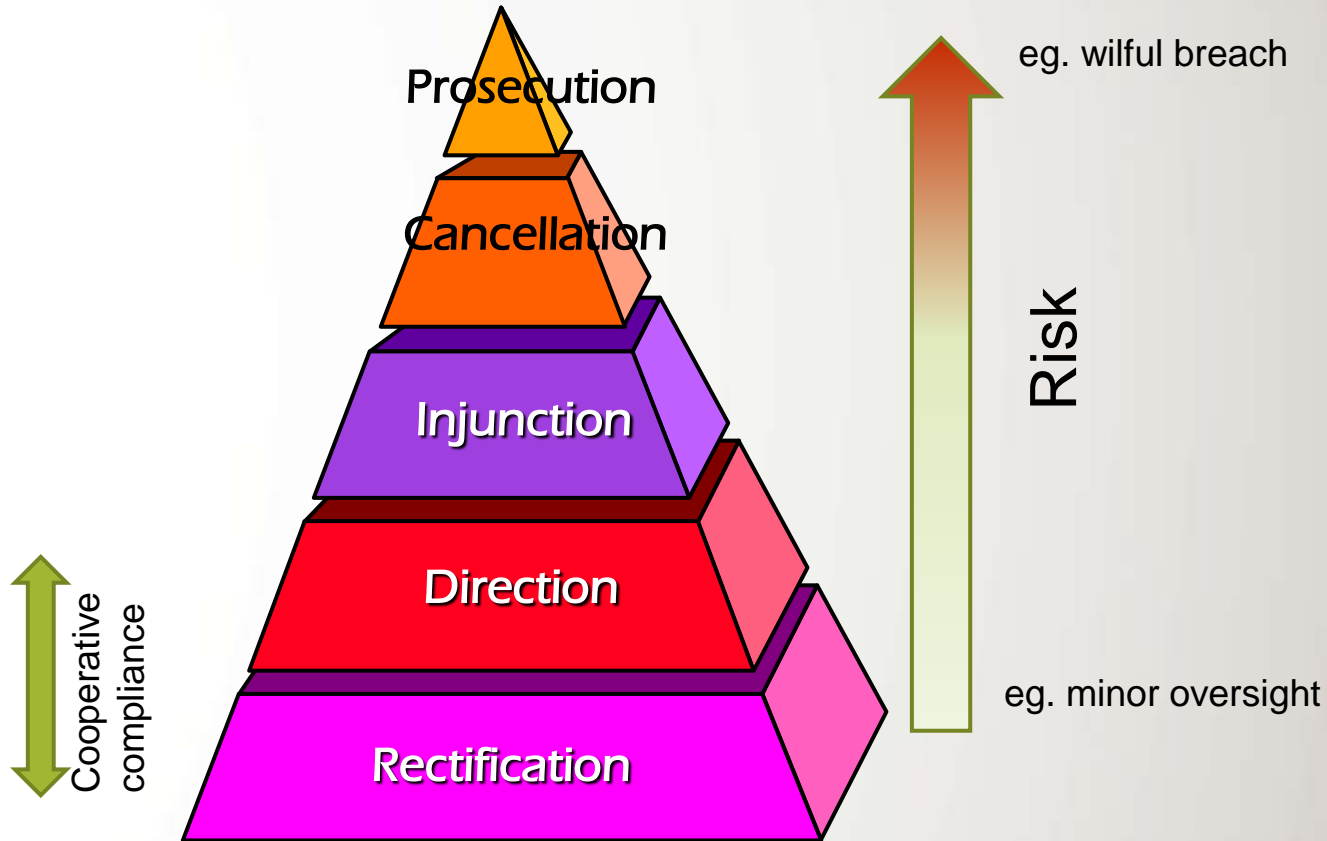


Summary of offences (continued)

Section	Summary	Penalty
146	Regulator may give directions	\$90,000 (\$360,000 for aggravated offence)
164	Power to search goods, baggage – failure to answer questions	\$5,400
187	Confidential commercial information must not be disclosed	\$21,600
188	Conduct by Directors, employees and agents	Offences Crimes Act various
192	False and misleading information	1yr or \$10,800
192A	Interference with GMOs	2yrs or \$21,600



Compliance Philosophy





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Other compliance mechanisms

Suspension (accreditation, licence, certification)

Cancellation (accreditation, licence, certification)

Directions (licence)

Injunctions (Court)





Audits and reviews

Proactive Compliance

- Engagement with stake holders to ensure good governance (S188)

Auditing Organisations and Institutional Biosafety Committees (IBC)

- Assist IBCs as an organisations expert panel and encourage 'buy in' within their wider organisational areas (ERM / Internal Audit / University Senate)

Encourage dialogue and discussion to achieve compliance

Audit/review themes include:

- Authorised activities, facilities and equipment, governance and shared services





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Investigations

Reactive – Alleged Non-compliance

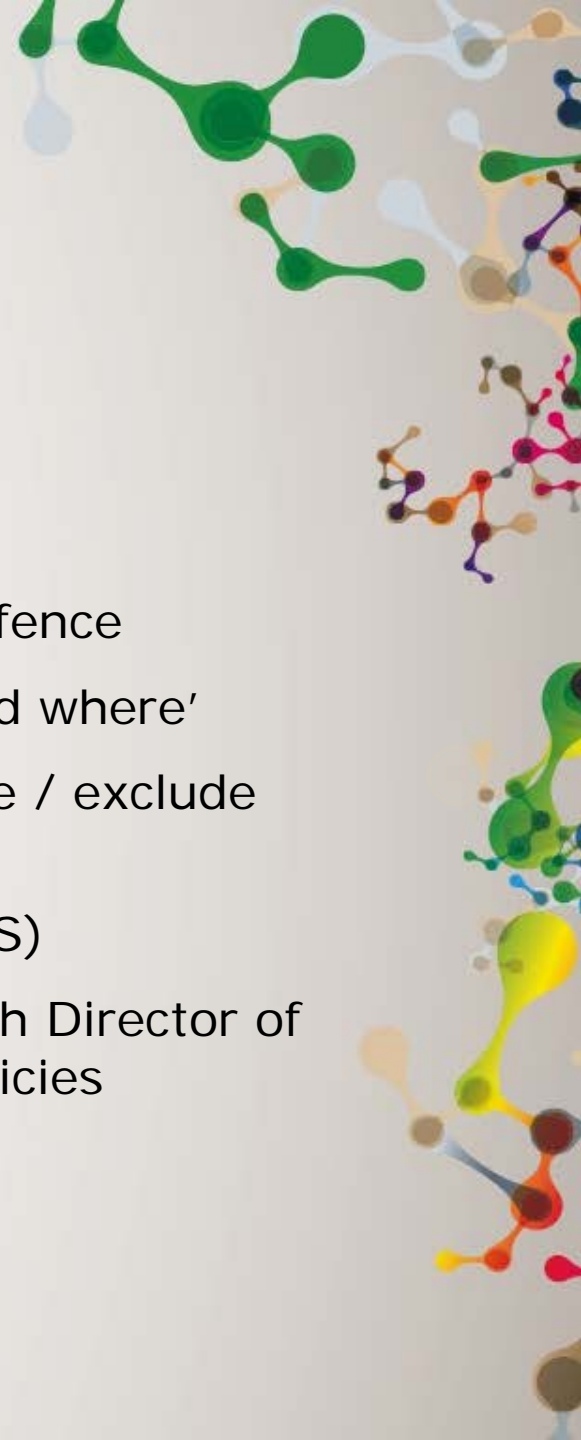
Requires admissible evidence of an alleged offence

Avenues of inquiry 'who, what, when, how and where'

Proofs and Facts in issue (open mind – include / exclude also for disclosure in Brief of Evidence)

Elements of the offence must be proven (AGIS)

Follows Attorney General's and Commonwealth Director of Public Prosecutions (CDPP) guidelines and policies





Other interactions

Some of the groups that we interact with in order to ensure compliance and prevent non-compliance issues arising in future:

- Do It Yourself (DIY) researchers (*e.g.* Biohackers)
- AQIS DoA – Compliance Section and Live Animal Imports Section
 - Glowfish, GM seeds, Biologicals etc
- Department of Environment and EPAs - State / Territories / Commonwealth
- Information and dissemination of OGTR requirements from Suppliers
 - Waste providers, Hepa filters, Biosafety Cabinets, Backflow





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Reporting of Monitoring and Compliance Activities

Routine Monitoring and Compliance activity is reported quarterly on the OGTR website. Includes details of field and contained licences monitored and the number of certified facilities inspected.

Finalised Monitoring and Compliance findings are published in OGTRs Annual Report to Parliament.





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In Summary

The *Gene Technology Act 2000* and *Gene Technology Regulations 2001* have strong enforcement powers

Engagement with stakeholders in promoting compliance is paramount;

Investigations are conducted in accordance with relevant broader government policies, procedures and legislation





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