



Australian Government

Department of Health

Office of the Gene Technology Regulator

ALLEGATION BY THIRD PARTIES PROTOCOL

**In accordance with the
*Gene Technology Act 2000***

April 2016

Monitoring and compliance activities are under continual improvement and will evolve as systems are assessed and validated. This document is intended as a guide only. Readers of this document should also familiarise themselves with the gene technology legislation.

Allegations Protocol

Introduction

The Office of the Gene Technology Regulator (OGTR) has been established within the Commonwealth Department of Health to provide administrative support to the Gene Technology Regulator in the performance of her functions under the *Gene Technology Act 2000* (the ACT).

The Act came into force on 21 June 2001, introduces a national scheme for the regulation of genetically modified organisms (GMOs) in Australia, in order to protect the health and safety of Australians and the Australian environment.

This protocol is to provide inquiring third parties with the appropriate information on how to report matters of non-compliance to the OGTR.

Background

Under the previous voluntary oversight arrangements for GMOs, approvals to proceed with intentional releases of GMOs into the environment were advised by the Genetic Manipulation Advisory Committee (GMAC) based on an evaluation of the biosafety aspects (being risks to the environment and / or risks to human health and safety) associated with each particular release.

As compliance with these conditions GMAC suggested was voluntary, the system relied largely on the proponents checking compliance and self-reporting any breach of GMAC recommendations and, to a lesser extent, non-compliance reports made by third parties.

In the lead up to the introduction of the *Gene Technology Bill 2000* the Interim Office of the Gene Technology Regulator (IOGTR) developed a monitoring system, however there was no legislative capacity to enforce compliance with GMAC recommendations or to enforce compliance with risk management plans. The IOGTR therefore continued to work cooperatively with organisations conducting GM field trials to secure appropriate outcomes.

The enactment of the Act on 21 June 2001 provided the legislative basis for the regulation of GMOs in Australia and provided wide reaching powers for the OGTR to monitor GMO dealings and enforce the Act.

A New Non-Compliance Protocol

This 'Allegations by Third Parties Protocol' aims to assist members of the public to report non-compliance conduct in the form of breaches against the Act to the OGTR.

What is non-compliant conduct?

GMO non-compliant conduct can be defined into four categories:

- A person is dealing with a GMO without a GMO licence and the dealing is not classified as a Notifiable Low Risk Dealing (NLRD) or an Exempt Dealing under Schedule 3 of the Gene Technology Regulations 2001;
- A GMO licence holder is not complying with their licence conditions;
- A person is not undertaking an NLRD or exempt work in accordance with the Gene Technology Regulations 2001; and
- A person's actions, when dealing with a GMO, pose a significant risk to the health and safety of people and / or the environment.

Is this a matter for the OGTR?

The OGTR is the Commonwealth agency that administers and supports the Gene Technology Regulator to administer the Act and the national scheme to regulate GMOs.

The Act prohibits persons from dealing with a GMO unless the dealing is classified as:

- An Exempt Dealing under Schedule 2 of the Gene Technology Regulations 2001;
- A Notifiable Low Risk Dealing (NLRD) – that is, a contained dealing which is known to pose minimal risk to contained facility workers dealing with the GMO, the general public or the environment;
- On the Register of GMOs; or
- Licensed by the Regulator.

How can a member of the public can report GMO non-compliant conduct?

It is important that members of the public come forward and report suspected GMO non-compliant conduct. Reports from members of the public assist the OGTR in the detection of non-compliances occurring within Australia and help identify the potential areas of risk. This enables the OGTR to recognise patterns and trends in non-compliance and to ensure its work provides the greatest benefit to the regulation of GMOs in Australia.

What information does the OGTR need?

When reporting suspected GMO non-compliant conduct to the OGTR it is important to provide as much detail as possible. However, it is not necessary to gather evidence or to prove GMO non-compliant conduct has occurred. The OGTR does not want you to conduct your own private investigation as you would risk breaking a range of Australian laws by doing so. Your good intentions may destroy the integrity of a future OGTR investigation, and even worse, the evidence may become inadmissible in a court of law because the continuity of evidence could not be clearly established. Ultimately this may result in a failed prosecution.

Reporting GMO non-compliant conduct to the OGTR

You can [report online](#) or e-mail, post, fax your report of possible non-compliant conduct of GMO dealings to the OGTR. We also have a Free-call Gene Technology Regulator Hotline 1800 181 030 for making inquiries about non-compliance. Our postal address is:

Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
CANBERRA ACT, 2601

Our e-mail address is available on our [website](#).

Our fax number is 02 6271 4202

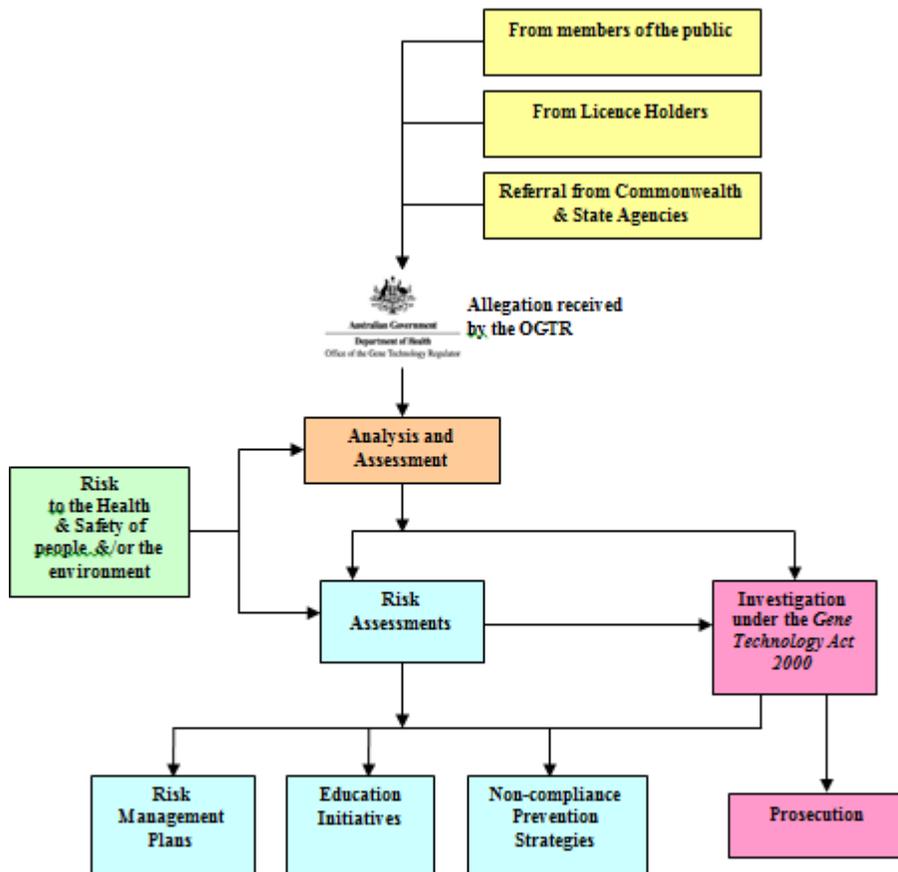
Any information concerning alleged non-compliant conduct of GMO dealings provided to the OGTR will be treated in the strictest confidence.

Information Checklist

Use the following checklist to help you prepare the information the OGTR will need to assess your allegation of GMO non-compliant conduct.

1. Your name, your preferred title, your home address and your telephone numbers (work and home) so the OGTR can contact you if necessary;
2. The name of the licence holder and / or persons you believe are being non-compliant. Are any private citizens, organisations or companies involved? If so, please also include their names and contact details, if known, and any other information you believe may be relevant;
3. A summary of the matter you are reporting. Please include names, dates, times, locations and any other information you believe may be relevant;
4. If it is not apparent from your summary, please indicate how you became aware of the matter you are reporting;
5. Are there other people who know about this matter and who could assist the OGTR. If so, please include their names and contact details and indicate whether they are aware that you have provided their details to the OGTR;
6. Please indicate whether you have reported this matter to any other agencies. It will help if you include the names of any other agencies you have contacted about this matter, when you contacted them and their responses;
7. Do you have or know of any documents, records or other information that may be relevant? Please include any information on any documents or records that you believe may assist the OGTR. Note that you do not need to provide these documents to the OGTR. They will be requested if needed; and
8. If the OGTR pursues the matter or decides to refer it to another agency, it may be necessary to identify you as the source of this information. Do you consent to your name and contact details being disclosed to another agency?.

How the OGTR treats information it receives



Analysis and assessment of information

What will the OGTR do with the information you provide? All information is analysed to help the OGTR understand the nature and scope of actual and potential GMO non-compliant conduct. Your information may assist with other matters of current or future interest to the OGTR. It may ultimately result in an OGTR investigation, a GMO non-compliant conduct prevention project, an education program or a combination of any of these approaches. All information is considered in light of other relevant details on the same people, licence holder or similar types of conduct.

Broadly, the OGTR considers whether information about a possible GMO non-compliance conduct relates to the licence agreements by the licensee concerned, or whether it indicates a weakness in the way a licence holder works. The OGTR also considers how serious the alleged GMO non-compliant conduct is in relation to its potential to endanger the health and safety of people and/or the environment. If necessary, remedial action will be initiated to mitigate any immediate risks.

Will you be involved if an investigation is conducted?

Your information may not necessarily result in an investigation. If it does you should be aware that investigators will contact you if it is necessary to obtain further details or to clarify points. If necessary, investigators may request a witness statement from you for the purposes of:

- Recording the evidence that a witness is capable of giving at a court hearing;
- To help determine whether one or more offences have been committed and what action, if any, should be taken;
- Forming part of a brief to the Commonwealth Director of Public Prosecutions;
- To assist the prosecutor in court by forming the basis of examination in chief;
- As a reference point for the witness at a later date, either before or during court proceedings; and
- In some circumstances, tendering in court (for example where it may be tendered instead of the witness giving evidence, or if the witness gives inconsistent evidence).

A witness statement may be taken from you if you are able to give evidence relevant to the offence in question. Statements are not only taken in order to prove an offence, but are also considered where they show that a person is not guilty of an offence.

Will you find out what happens to the information you provide?

You should not expect to be informed directly of the results of any action the OGTR may take on a matter you raise. The OGTR will confirm the receipt of your information in writing, however, you should not expect any further correspondence. The information may be kept for assistance with other matters, or used in a GMO non-compliance conduct prevention or education strategy. Your information may also be the subject of inquiries conducted by the OGTR with the GMO license holder concerned or we may refer the matter to another agency to deal with.

Will anyone else know you contacted the OGTR?

The OGTR ensures that all information received, as well as its source, is treated confidentially. However, in some cases it is not possible to pursue a matter or refer it to another agency without identifying the person who reported the issue. For this reason you will be asked to indicate whether you consent to your identity being disclosed to another agency when you provide information to the OGTR.

Remaining anonymous

Does the OGTR need to know your identity? It is important that people provide their name, address and telephone number so that they can be contacted if further details are needed.

The OGTR may also decide to conduct inquiries into a matter raised or referred by another agency, including the organisation involved in the alleged GMO non compliance conduct. If it is not known who provided the information, the ability to deal with the matter can be limited as there is no way of knowing whether raising the matter with another agency will identify a person against their wishes.

You can provide information anonymously; however, this means that you cannot be contacted to obtain further details if necessary. This may limit the OGTR's ability to deal with the allegation.