



Australian Government

Department of Health

Office of the Gene Technology Regulator

Overview of regulation & risk analysis of GMOs





Object of *Gene Technology Act 2000* s3

To **protect** the health and safety of people,
and to **protect** the environment,
by **identifying risks** posed by,
or as a result of, gene technology
and by **managing those risks**
through **regulating** certain **dealings with GMOs**

... risk analysis





GT Act - Framework to achieve object (s4)

- (aa) provides that where there are **threats of serious or irreversible environmental damage**, a **lack of full scientific certainty*** should not be used as a reason for postponing cost-effective measures to **prevent environmental degradation**
- (a) provides an **efficient and effective system** for the **application of gene technologies**
- (b) operates **in conjunction with other C/w and State regulation** relevant to GMOs and GM products

* *lack of full scientific certainty* ↔ *uncertainty*



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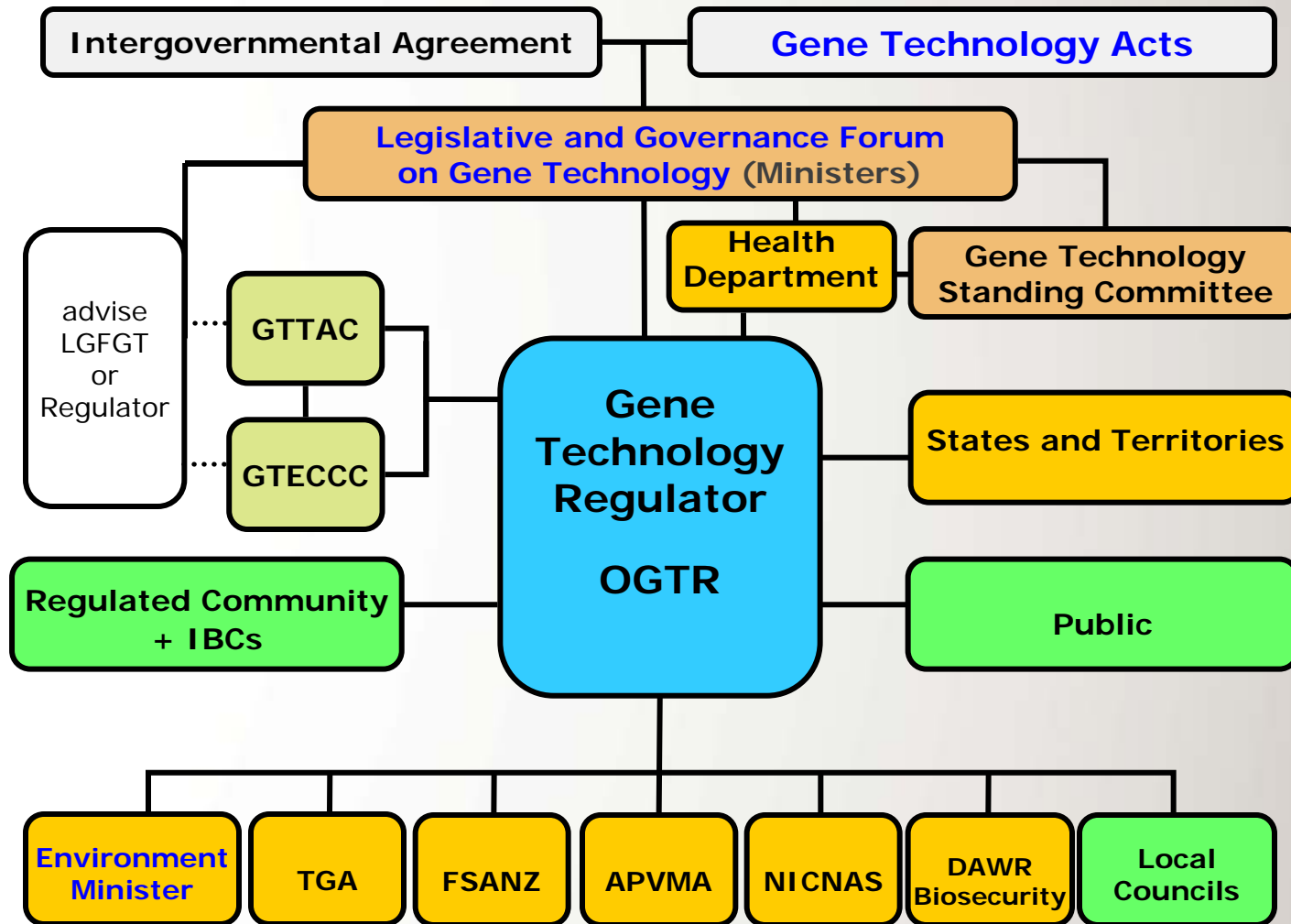
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intergovernmental Gene Technology Agreement

- be based on a **scientific assessment of risks** undertaken by an independent Regulator
- regulatory burden **commensurate with risks**
- be able to be amended to **respond to the development of gene technologies**
- be characterised by **transparent decision-making** and extensive **stakeholder and community involvement**



GMO regulation – national scheme





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Scope of the GT legislation – what is covered

Licensing scheme – dealings with live & viable GMOs
prohibited unless authorised

Risk assessment & risk management – **risk not benefits**

Accreditation of organisations – *Institutional Biosafety
Committees (IBCs)*

Certification of containment facilities – PC1, PC2, PC3, PC4

Compliance – monitoring and enforcement powers

Transparency – consultation and GMO Record



Scope of the GT legislation – not covered

- ✘ **Benefits** – focus on risks to people and environment
- ✘ **Cost/Benefit** – not weighing against other technologies
- ✘ **Marketing/economic issues, coexistence** –
Policy Principle, States & Territories, industry,
- ✘ **Food labelling** – FSANZ, S&T – *consumer choice provisions*
- ✘ **Efficacy** – other regulators, industry
- ✘ **GM products** – other agencies eg *recombinant insulin*
- ✘ **herbicides, pesticides** – APVMA – *registration, use labels*
- ✘ **Intellectual Property** – IP Australia, Breeders Rights etc



Authorisations – risk based categories

Licences - GMO dealings:

- **DIR** – involving **intentional release to the environment**
- **DNIR** – **NOT** involving intentional release – **containment**
 - risk assessment (RARMP) by OGTR
- inadvertent dealings – **disposal**

Notifiable low risk dealings (NLRDs) – **containment**

- PC1, PC2 or PC3, + **IBC oversight**

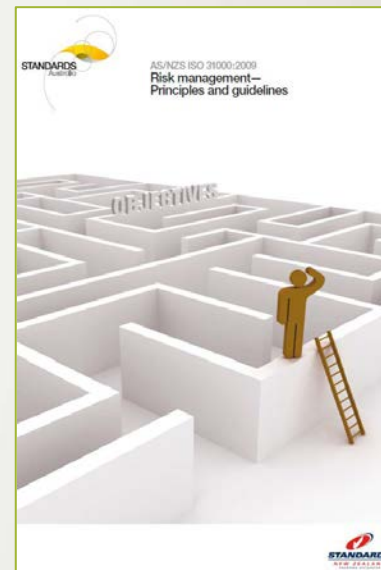
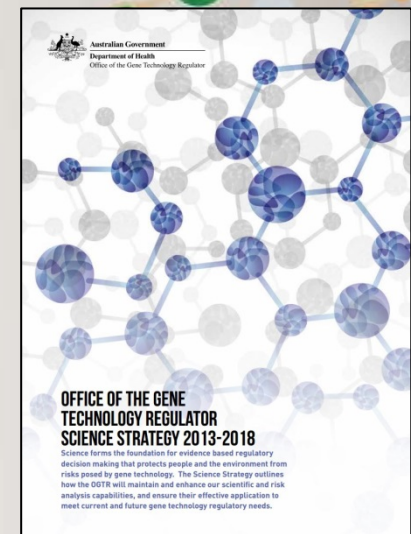
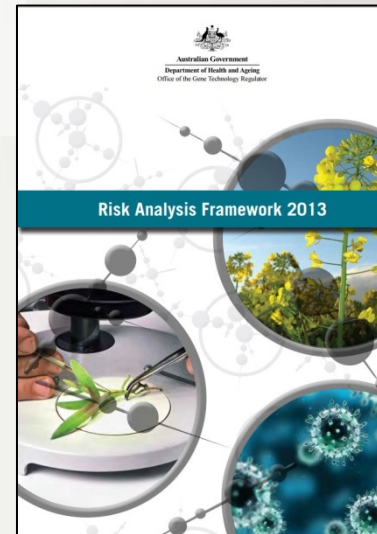
Exempt dealings – no release to environment

Emergency Dealing Determination (EDD) – imminent threat



Science based GMO regulation

- Adapt / adopt existing guidance, facilitate harmonisation
- Define terms and concepts
- Qualitative, comparative assessments
- Focus on **harm** and **plausible pathways to harm**
- Distinguish **events** vs **harm**
- Regulatory science to support decision making



ISO 31000

AS/NZS HB294



Risk – definitions – 1

ISO 31000:2009

Risk: The effect of *uncertainty* on objectives

OGTR

Risk: potential for harm from an activity

Risk analysis: risk *assessment* + risk *management*
+ risk *communication*

Risk assessment:

a structured, rational approach to address uncertainty based on the *plausibility* and *strength* of *scientific/technical evidence*





Risk – definitions – 2

Risk = Likelihood x Consequence ISO, OGTR

[vs Risk = Hazard x Exposure *chemical*]

Risk matrix:

discrete descriptors for likelihood, consequence and risk



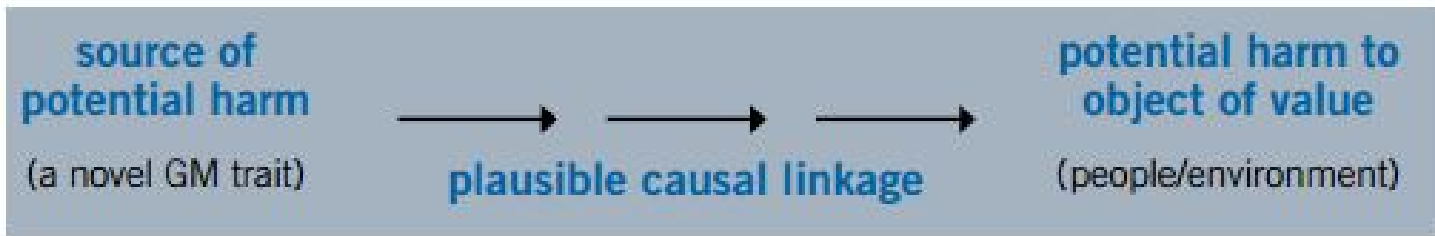
Risk in relational terms

RISK SOURCE

CAUSAL PATHWAY

RISK RECIPIENT

Figure 4.2: Components of a risk scenario



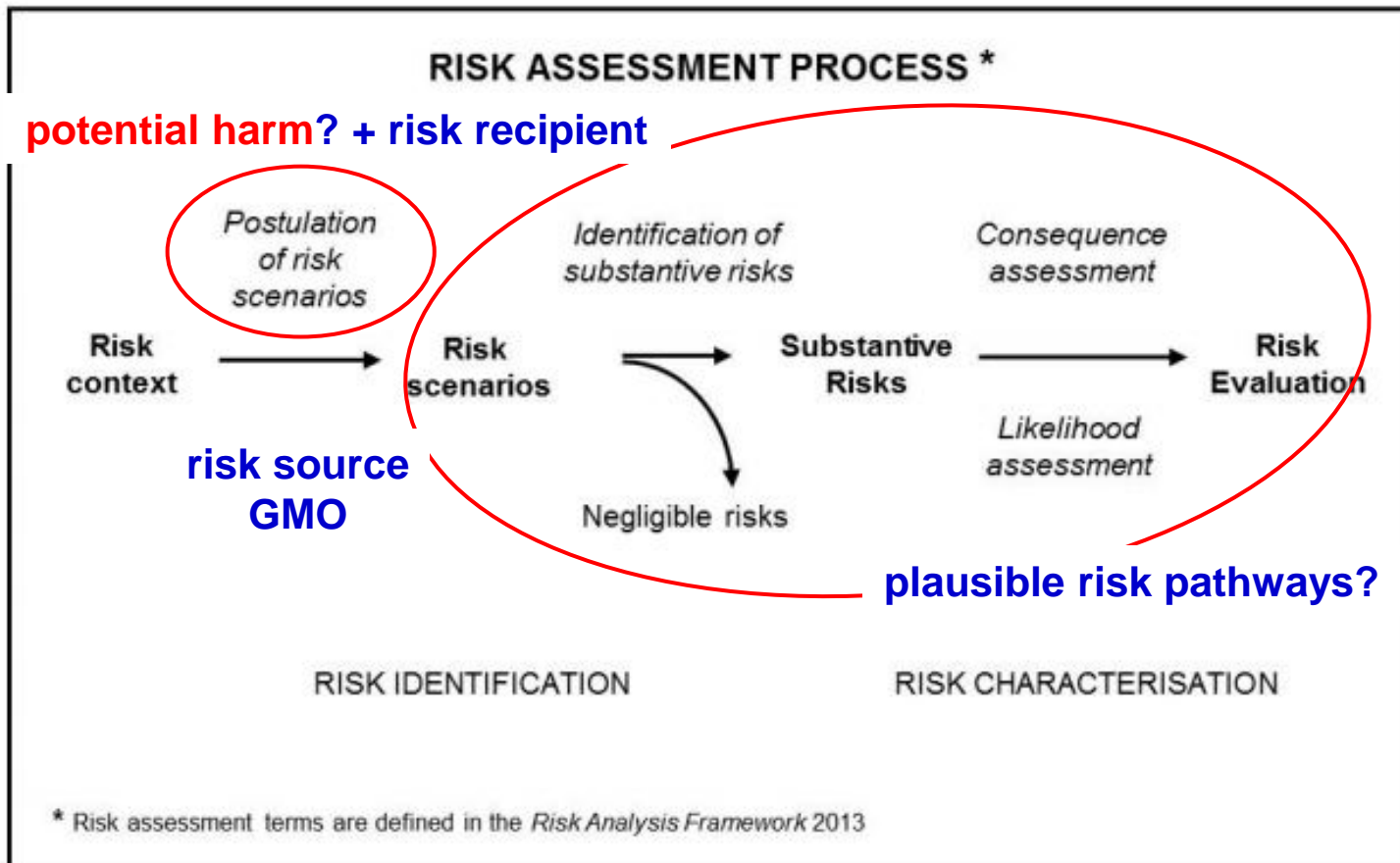
GMO

LIKELIHOOD

CONSEQUENCES



RARMPs – conceptual approach

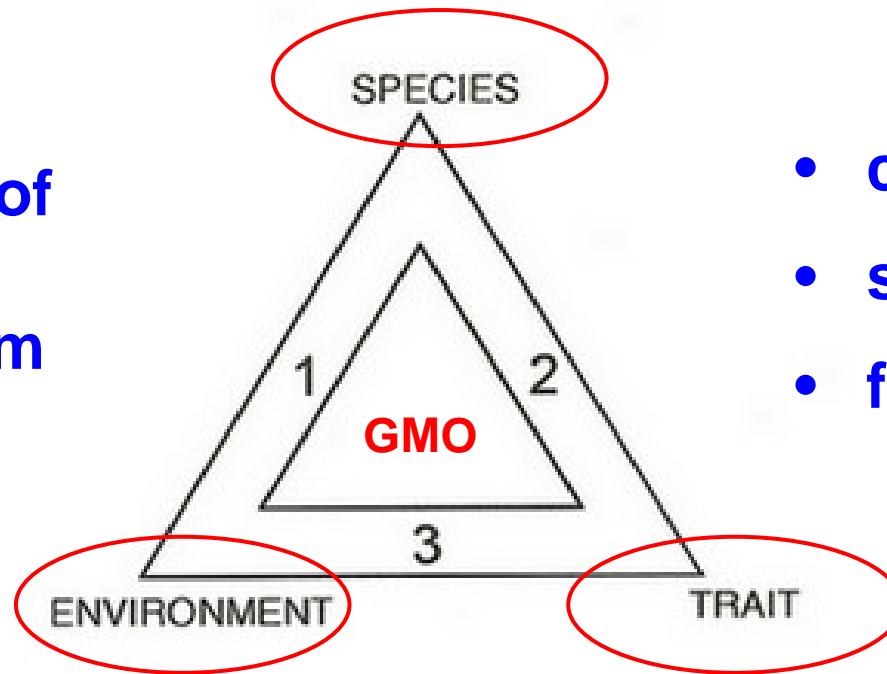


... simple Qs: how? who? what? where? when? why?



GMO assessment - OECD Guidance + Principles

- biology of parent organism




- case by case
- step by step
- familiarity

- intended use



Risk assessment – environmental releases

The Regulator **must** prepare a Risk Assessment and Risk Management Plan – RARMP

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Risk Assessment and
Risk Management Plan for

DIR 136


**Limited and controlled release of cotton genetically
modified for enhanced fibre quality**

Applicant: CSIRO

September 2015

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**The Biology of
Gossypium hirsutum L. and *Gossypium
barbadense* L. (cotton)**



Version 3.0 July 2016

This document provides an overview of baseline biological information relevant to risk assessment of genetically modified forms of the species that may be released into the Australian environment.

Version 3 has been updated to include new data on taxonomy and distribution of native Australian cotton species. Version 3 also contains new data on commercial uses of cotton, including yield, scale of cultivation and major commercial varieties used. New data has been added on toxins, water usage, weeds, pests and pathogens.

For information on the Australian Government Office of the Gene Technology Regulator visit the [OGTR website](#).



GMO risk assessment considerations

- is the parent organism a **weed / pest / pathogen** ?
- will the modification **increase weediness / pest ...** ?
- will the GMO be **toxic / harmful** – **species specificity** ?
- will the modification **confer a selective advantage** ?
- **spread in space and time**:
 - fecundity, mobility, dormancy, climatic limitations
- **gene transfer**:
 - sexual compatibility, mating system ?
 - hybridisation vs introgression ?
- can the parent / GMO **be controlled** ?





Risk management – decisions, licence conditions

The Regulator:

- **must not** issue a licence unless satisfied that risks posed by GMO dealings can be managed to protect people and environment
- **must** have regard to ... RARMP & submissions –
wrt risks to people and the environment
- may **impose licence conditions** to manage risks
- may **monitor for compliance**
- may **give directions**
- may **vary, suspend** or **cancel** licences





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Risk management – licence conditions

Licence holders **must** :

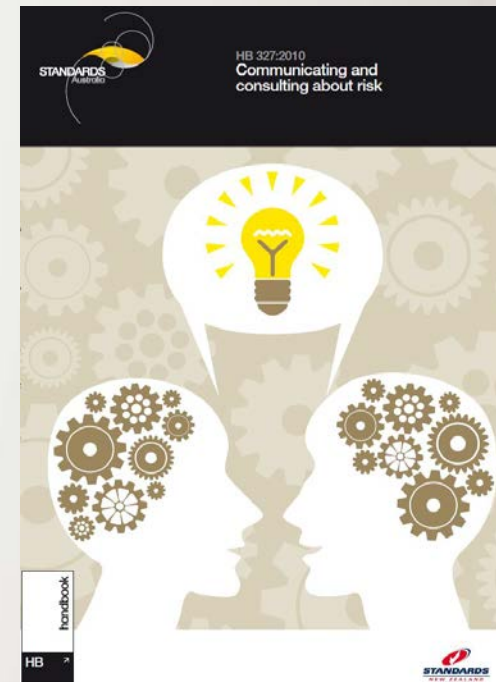
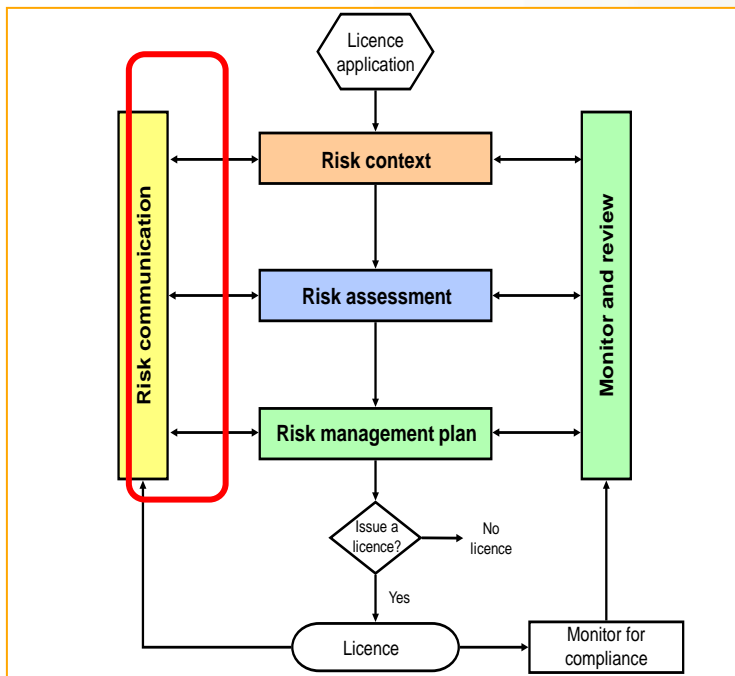
- **comply** with licence conditions
- **inform persons covered** by the licence of conditions
- allow the Regulator to **audit & monitor**
- **inform the Regulator** of **new risk information**,
unintended effects, breaches





Risk communication – the glue of risk analysis

“**continual** and **iterative process** to provide, share or obtain information and to engage in dialogue with stakeholders regarding the **analysis of risk**” *OGTR RAF 2013*





Risk communication

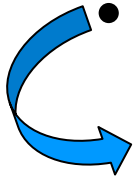
“Who says what to whom with what effect?”

for people working with GMOs:

- Regulator sets licence conditions to manage risks
- **conditions must be understood**

for the public and other stakeholders:

- Regulator provides information about the GMOs, dealings, assessment of risks and how they can be/are managed
- Provide information to the Regulator about risks





Communication – how, what, who?

Channels

- Letters
- **Emails**
- Newspapers
- Gazette
- **Website**
- Twitter

Content

- **RARMPs**
- **Licence conditions**
- Biology documents
- **Notifications**
- **Summaries + Q&As**
- Maps
- Fact Sheets
- Guidelines & Guidance
- Operational policies
- Annual Reports

Audience(s)

- Government
- GTTAC, GTECCC
- Regulated orgs
- IBCs
- Local councils
- **Public:**
 - **client register**
 - organisations
 - individuals
 - media



Transparency – GMO Record, trial locations



Filter by licence status ▼ reset

Show entries Search:

Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment

Licence No	Organisation	Title of Project	Parent Organism	Modified Trait	Issue Date	Licence Status
DIR 144	Clinical Network Services (CNS) Pty Ltd	Clinical trial of live attenuated genetically modified influenza vaccines	Influenza virus	Human therapeutic - attenuation	01 Aug 2016	Current
DIR 142	Victorian Department of Economic Development, Jobs, Transport and Resources (DEDJTR)	Limited and controlled release of wheat genetically modified for enhanced nitrogen use efficiency and water use efficiency - Victorian Department of Economic Development, Jobs, Transport and Resources (DEDJTR)	Wheat (<i>Triticum aestivum</i> L.)	Yield and Abiotic stress tolerance Selectable marker – herbicide	19 Apr 2016	Current
DIR 140	Clinical Network Services (CNS) Pty Ltd	Clinical trial of a genetically modified virus for treatment of liver cancer - Clinical Network Services (CNS) Pty Ltd	Vaccinia virus	Human therapeutic - attenuation, enhanced immune response, Reporter gene	10 Mar 2016	Current

How to use the map

- Navigate the map directly; or
- Select the 'filter trial sites' button to refine the list of licences; or
- Select a site in the list to bring it into focus on the map.

Map legend

- Current site
- Post Harvest Monitoring (PHM) site

View licence DIR 103

Licence: DIR 103

Holder: Victorian Department of Primary Industries

Site no: 1

Area: 0.256

Crop: Canola

Trait: Yield, Plant development, Selectable marker - antibiotic

Status: PHM

LGA: Southern Grampians

[Filter trial sites](#)



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Recap: risk analysis underpinning regulation

risk assessment:

identify risks, plausible pathways to harm,
likelihood & consequences, expert scientific advice

risk management:

must be satisfied risks can be managed, impose and vary licence
conditions, monitor GMO dealings, enforcement powers

risk communication:

consultation and transparency, GMO Record





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Questions ?





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