



The regulatory framework in Australia for gene drive modified insect pests

OECD Conference, 5-6 October 2016

Owain Edwards Group Leader, *Environmental & Synthetic Genomics*, CSIRO Land & Water, Perth
Peter Thygesen Principal Regulatory Scientist, Office of the Gene Technology Regulator, Canberra

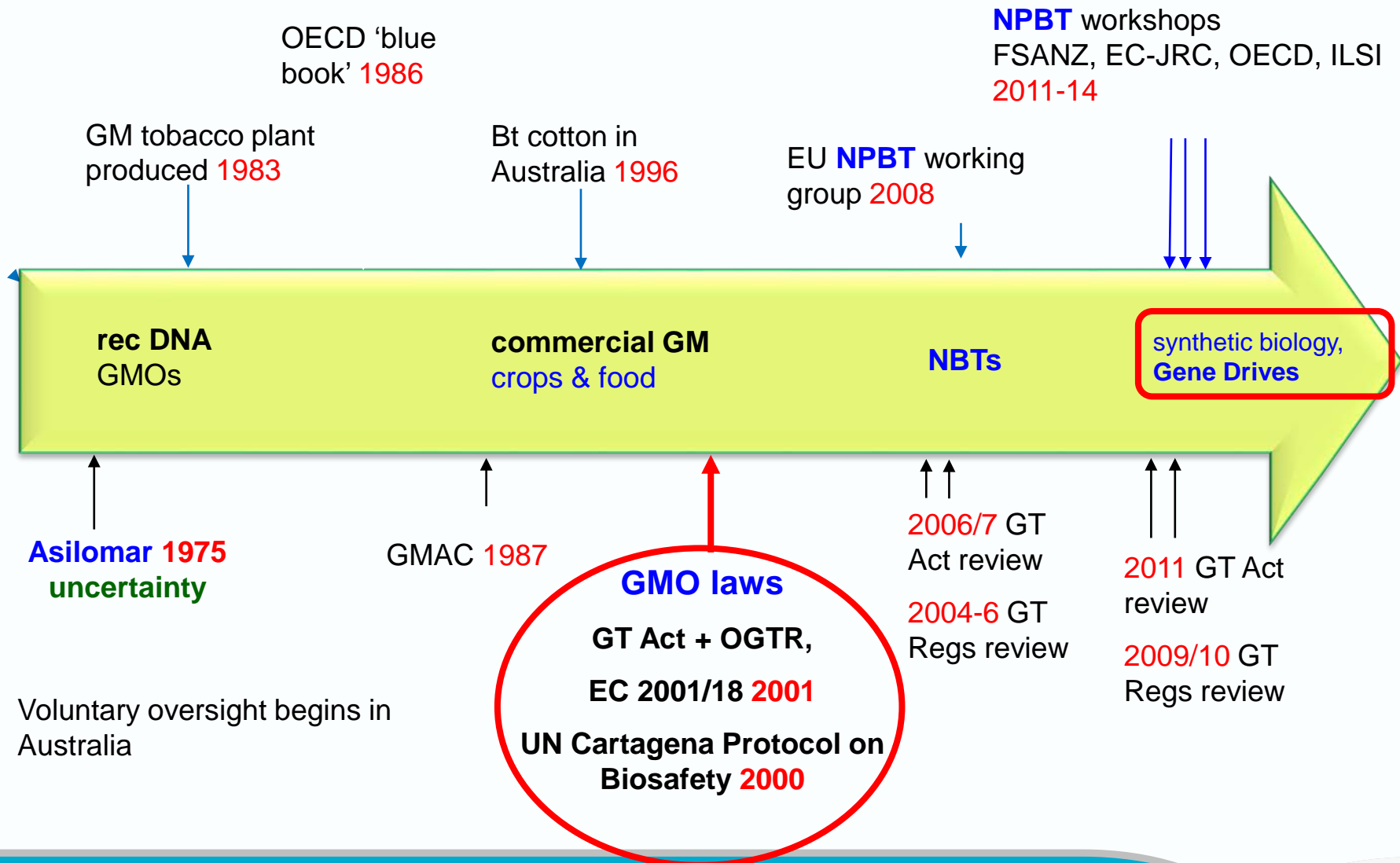
CSIRO SYNTHETIC BIOLOGY FUTURE SCIENCE PLATFORM
www.csiro.au



Overview

1. Overview of Australia's gene technology regulation
2. Formal processes for stakeholder consultation
3. Informal consultation – Regulatory Science Network

GM history



The very short story ...

- Gene Technology Act 2000
- GT Regulations 2001
- Intergovernmental Gene Technology Agreement

Process based 'regulatory trigger'

Dealings with GMOs regulated

independent Gene Technology Regulator

science based, case by case, risk assessment & management

transparency and public consultation

Dealings with GMOs

- a. conduct experiments with GMO
 - b. make, develop, produce or manufacture GMO
 - c. breed the GMO
 - d. propagate the GMO
 - e. use the GMO to manufacture a thing
 - f. grow raise or culture the GMO
 - g. import the GMO
 - h. transport the GMO
 - i. dispose the GMO
- and possess, supply or use of GMO for (a) – (i)

Scope of the GT legislation

Licensing scheme – dealings with GMOs prohibited unless authorised

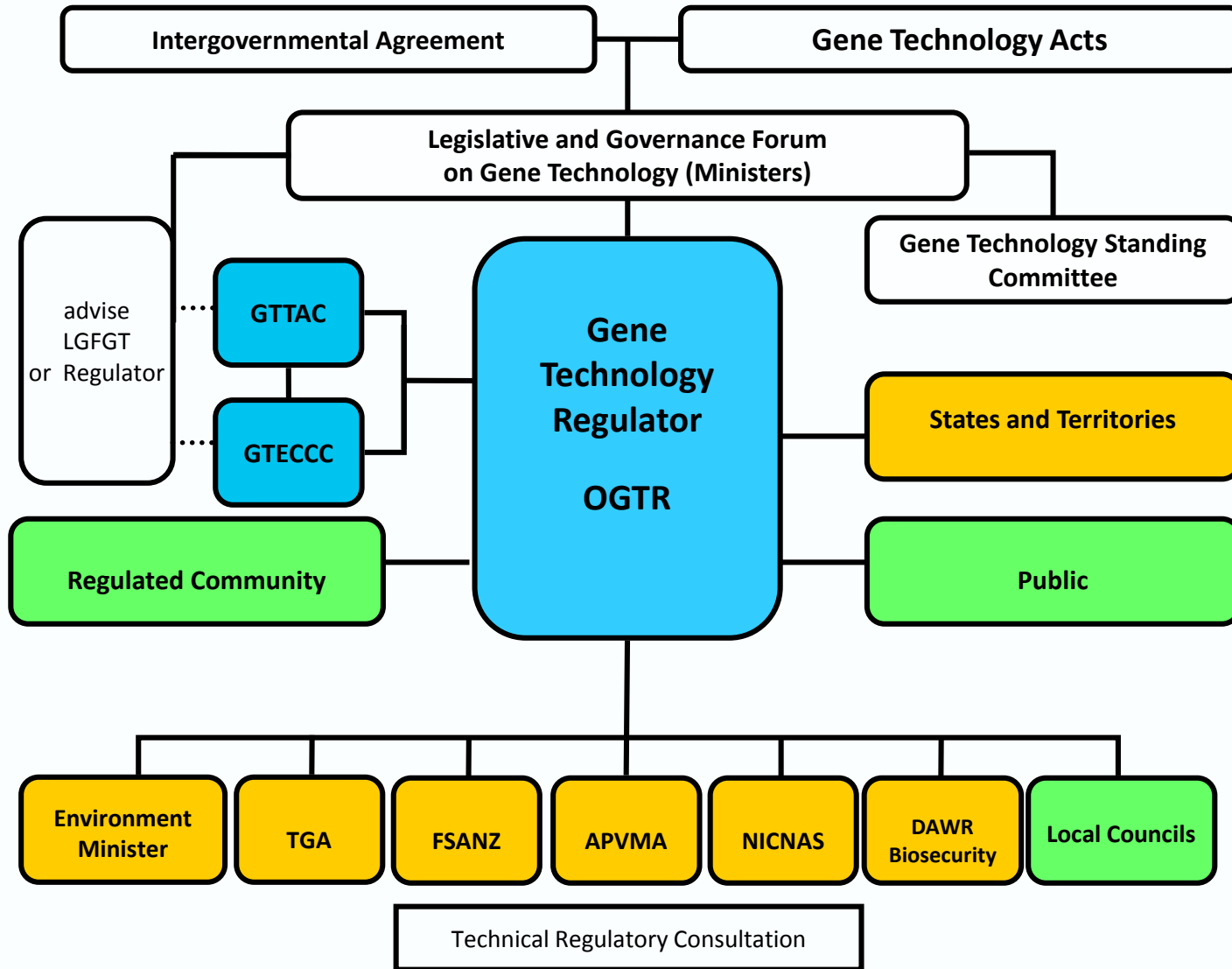
Risk assessment & risk management – **risk not benefits**

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

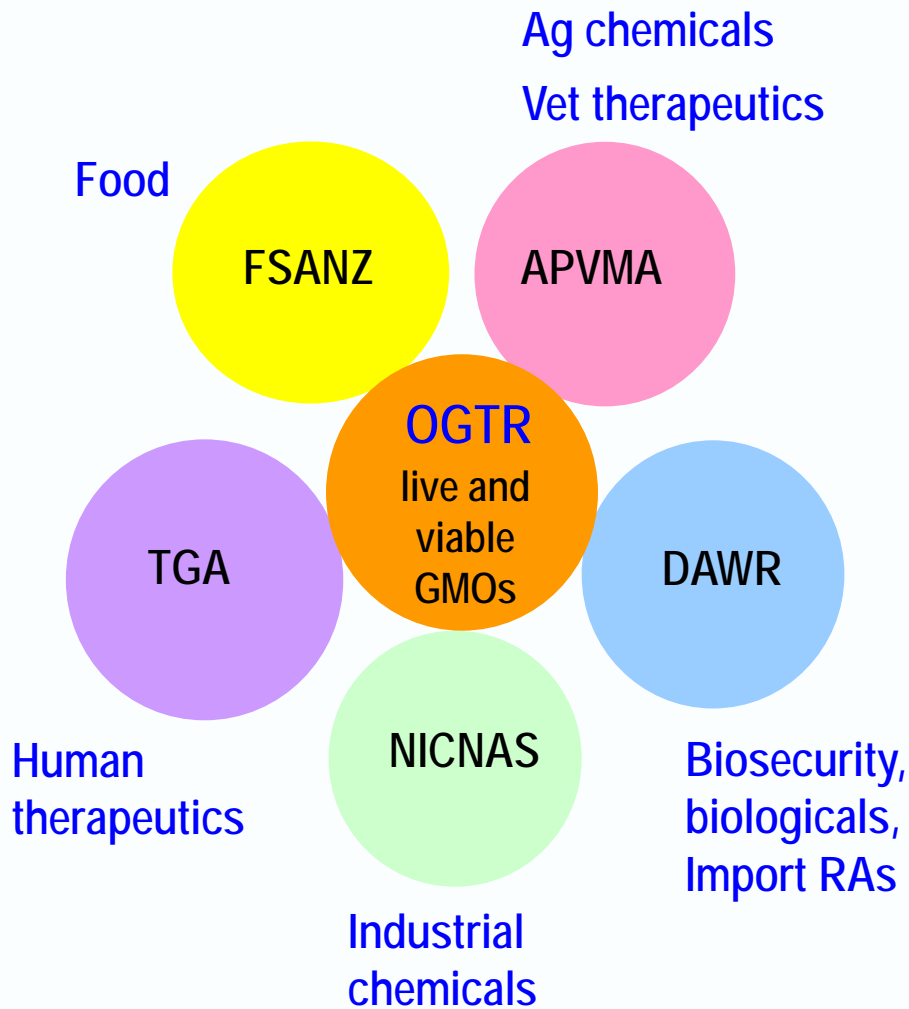
Certification of containment facilities – PC1, PC2, PC3, PC4

Monitoring and enforcement powers

GMO regulation in Australia



GMO regulation – other regulators



- Reciprocal advice
- OGTR regulates GMOs. Some intersection with other agencies
- Avoid duplication & align decision making (as far as possible).

Context - international

Regulatory trigger

process
(gene technology)

EU, Australia,
Argentina, etc.

product novelty

Canada,
New Zealand*

International context – CBD synbio AHTEG



PRESS RELEASE

Comprehensive report on synthetic biology discusses impacts on biodiversity and reviews existing regulatory regimes

Dec 2015

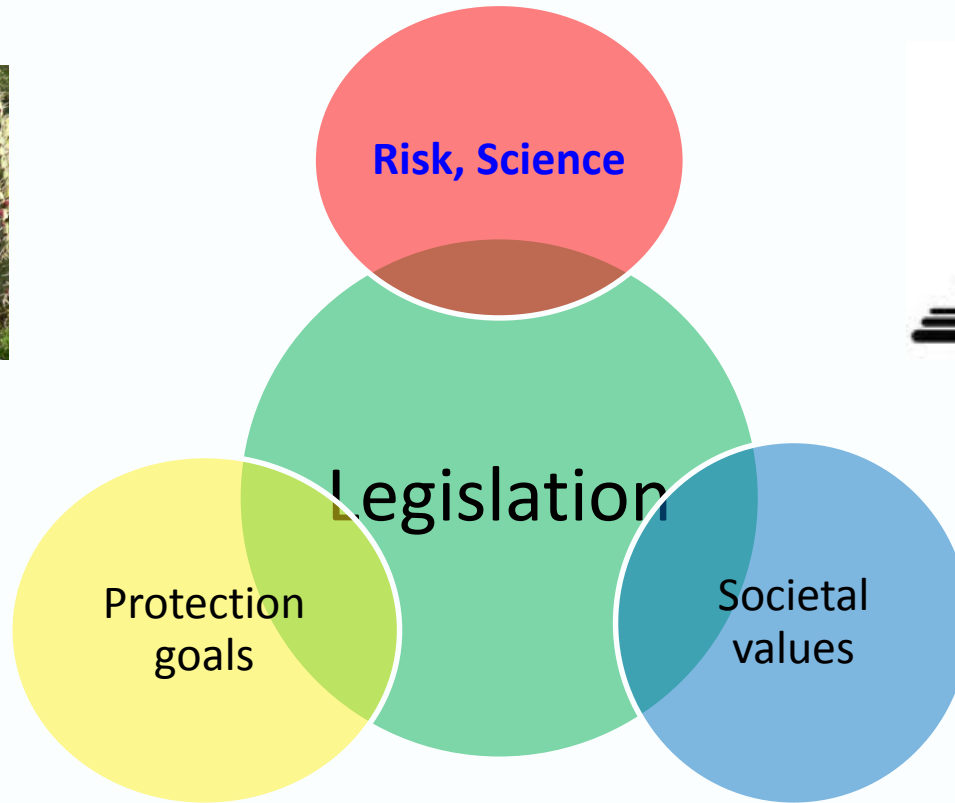
However, organisms and products of synthetic biology could also have negative impacts on the conservation and sustainable use of biodiversity, including, for example:

- The transfer of genetic material from microbes which were produced through synthetic biology and released into the environment, to other microorganisms could have unforeseeable consequences;
- The use of “gene drive” systems to spread traits aimed at suppressing populations of disease vectors (such as mosquitoes) could lead to the introduction of new diseases through the replacement of the population of the original disease vector by another vector species;
- Possible toxic and other negative effects on non-target organisms, such as soil microorganisms, beneficial insects, other animals and plants;
- Potential negative impacts to the conservation and sustainable use of biodiversity could arise from the transfer of genetic material to wild populations via vertical gene transfer and introgression.

Like other modern biotechnologies, synthetic biology raises ethical questions around the potential benefits weighed against the impacts from potential unintended consequences.

Consultation processes

Broad consultation and discussion



GMO regulation - *dramatis personae*

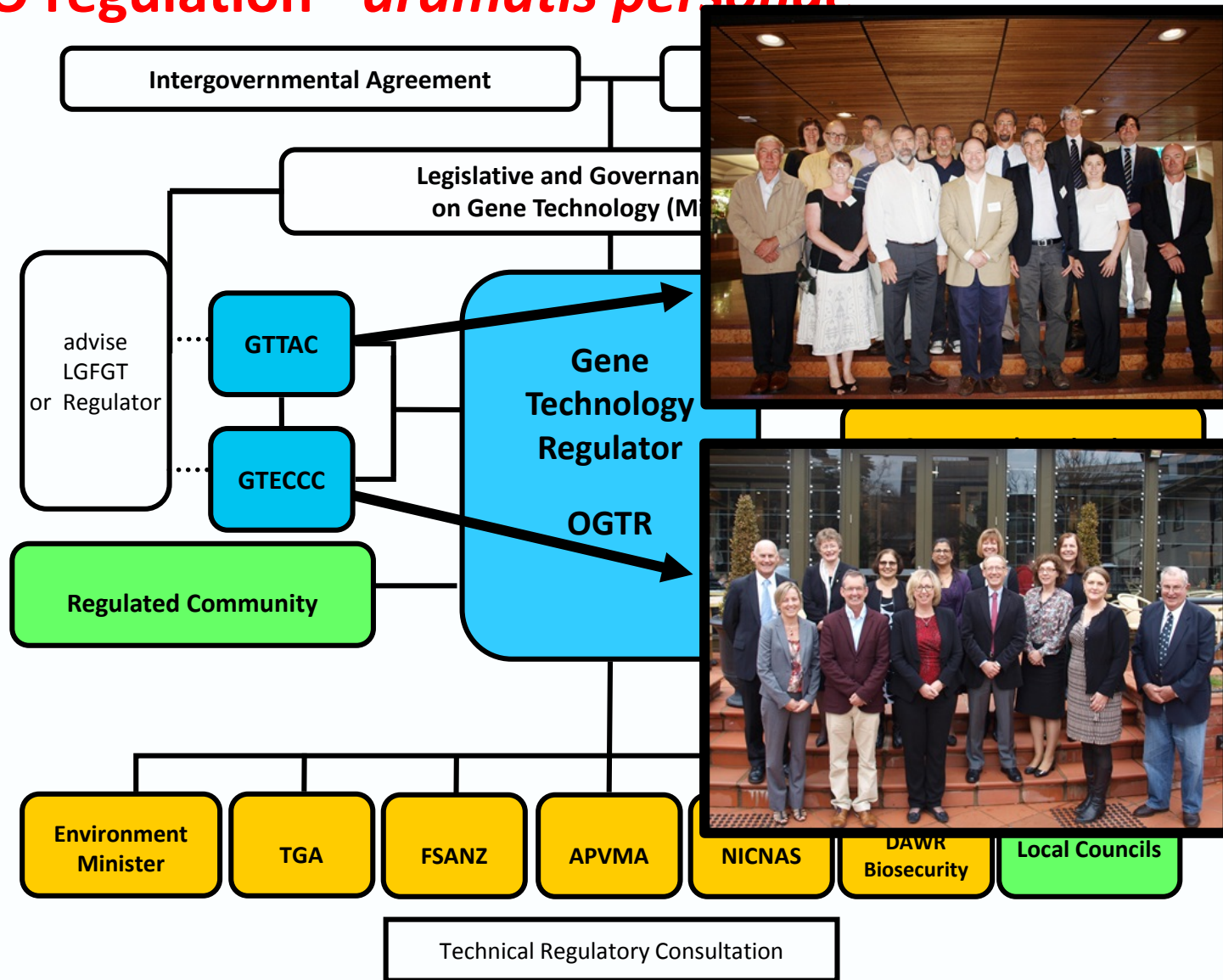
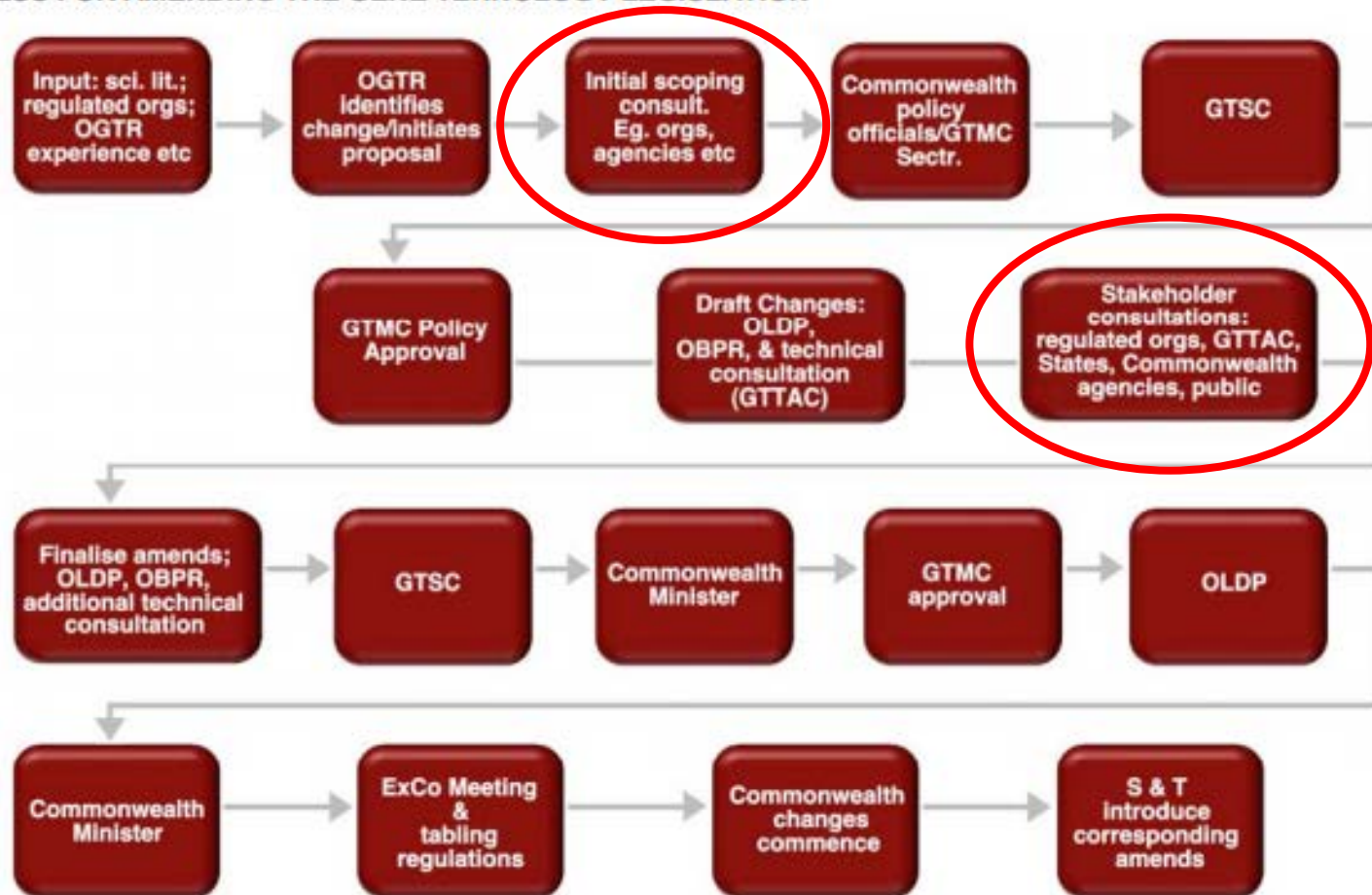


Figure 5.1

PROCESS FOR AMENDING THE GENE TECHNOLOGY LEGISLATION



OGTR Technical Review of GT regulations

FOCUS: Provide clarity about whether organisms developed using a range of new technologies are subject to regulation as GMOs and ensure that new technologies are regulated in a manner commensurate with the risks they pose

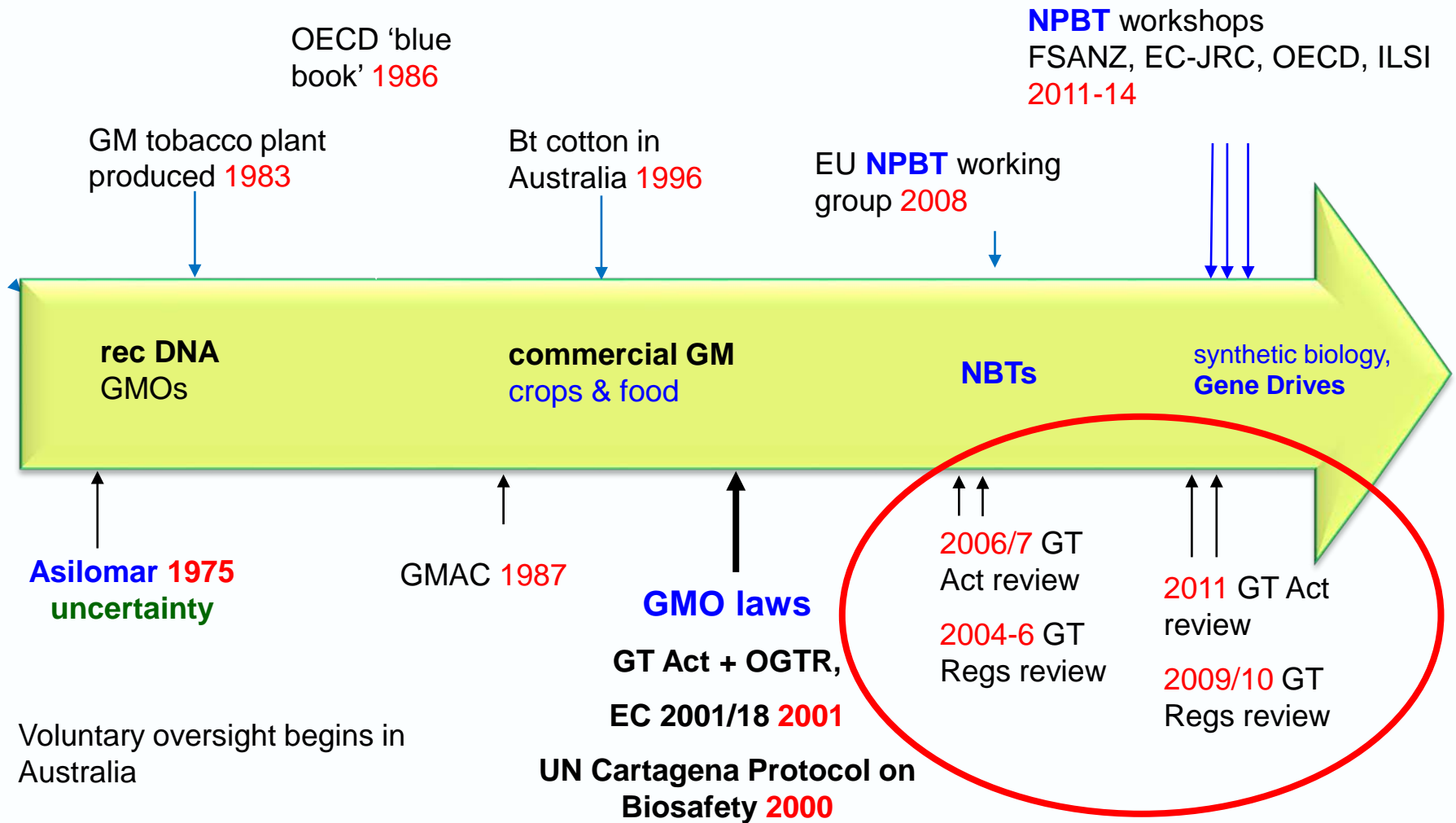
CONTEXT: Since the last technical review, several technologies have developed rapidly, in particular site-directed nuclease and oligo-directed mutagenesis

PROGRESS: Public consultation on an Options Paper (Oct-Nov 2016), including questions on gene drives

For details <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/regs-process-1>

NEXT STEPS: Draft proposals for amendments, Consultation on proposed amendments, Agreement of State/federal governments.

History of formal reviews



Formal review process

Sub. No	Organisation or Individual
1	Ian Turnbull, Melbourne, VIC
2	Anne Goddard, Maroubra, NSW
3	Dr. L.S. Manning, Research Centre, Royal Perth Hospital IBC, WA
4	Hon Bryan Green MP, Deputy Premier Tasmania
5	Paula Fitzgerald, Agrifood Awareness Australia Limited, Kingston ACT
6	Sally Wylie, Consumers for GM Free Food, Margaret River, WA
7	Guy Izzett
8	Bruce Piper, Council of Grain Grower Organisations Ltd (COGGO), Como, WA
9	Bridgett Leggett and Anne Barr, WA
10	Elizabeth Beggs, Laboratory and Biosafety Committee, Deakin University, Burwood, VIC
11	Graham Wearne, Woodanilling, WA
12	Tracy Skipplings, Margaret River, WA
13	Kim Hack, National Association for Sustainable Agriculture Australia WA Inc (NASAA WA Inc), Margaret River, WA
14	Anne Goddard, Maroubra, NSW
15	Dr. Monica Leggett
16	Mary Gardner, Byron Bay, NSW
17	Matt Linnegar, National Farmers' Federation, Kingston, ACT
18	Dr. Mark Sweetingham and Dr. Rosalie McCauley, Government of Western Australia, Department of Agriculture and Food, WA
19	Dr Helen Leonard, Queensland Institute of Medical Research, QLD
20	Heather Baldock, Producers Forum, Kimba, SA
21	Kim Hack and Penny Massop, York, WA
22	Dr Anna Lavelle, Ausbiotech, Malvern, VIC
23	Alan Hales, Research Services University of Newcastle, Callaghan, NSW
24	Matthew Cossey, Crop Life Australia, Canberra ACT
25	Nina Murray, AgForce, QLD
26	Dr Joe Smith, Office of the Gene Technology Regulator (OGTR), Department of Health and Ageing, Canberra, ACT
27	Peter Olson, Goonengerry, NSW
28	Professor John Rasko, Associate Professor Bing Yu and Dr Gabrielle O'Sullivan, Royal Prince Alfred Hospital Institutional Biosafety Committee, Camperdown, NSW
29	Michael Leader, Monsanto, St Kilda Central, VIC

Sub. No	Organisation or Individual
30	Robin Condon, Dairy Industry, Southbank, VIC
31	David Harris, Nuseed, Laverton VIC
32	Phil Aitken, WA
33	Alan Hill, The Western Australian Farmers Federation (Inc.) (WAFarmers), East Perth, WA
34	Sherry Thomas, Organic & Biodynamic Meats WA Co-operative Ltd, WA
35	James Holden, Pioneer Hi-Bred Australia, Toowoomba, QLD
36	Janet Thompson, Western Graingrowers, Pastoralists and Graziers Association of WA (Inc), Belmont WA
37	Bill Fuller, Australian Seed Federation, Manuka, ACT
38	Dr Nina McCormick, Bayer CropScience Pty Ltd, East Hawthorn, VIC
39	Confidential
40	Trixie Whitmore, Sydney, NSW
41	Beatrix Ludwig, Bondi, NSW
42	Mark Walter, Slater & Gordon Lawyers on behalf of The Safe Food Institute, Melbourne, VIC
43	Elizabeth Hamilton, Sydney, NSW
44	Shirley Collins, Shenton Park, WA
45	Dr Zoltan Lukacs, Grains Research and Development Corporation (GDRC), Kingston, ACT
46	Bob Phelps, Gene Ethics on behalf of the GM-Free Australia Alliance, Carlton VIC
47	Department of Innovation, Industry, Science and Research, Canberra, ACT
48	Department of Agriculture, Fisheries and Forestry, Canberra ACT

The

Review

Final report

August 2011
Report to the

CSIRO S





Australian Government
Department of Innovation
Industry, Science and Research

2011 Review of the Gene Technology Act (2000)

Public Submission

**By the Department of Innovation, Industry, Science
and Research**

And

**The Commonwealth Scientific and Industrial Research
Organisation**

Informal consultation



Australian Government
Department of Health
Office of the Gene Technology Regulator



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

CSIRO-RSN Symposium on the Use of Gene Drive Technology in Controlling Pests and Diseases

June 29th 2016, Discovery Centre, Black Mountain, Canberra



Australian Government
Department of Health
Office of the Gene Technology Regulator



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

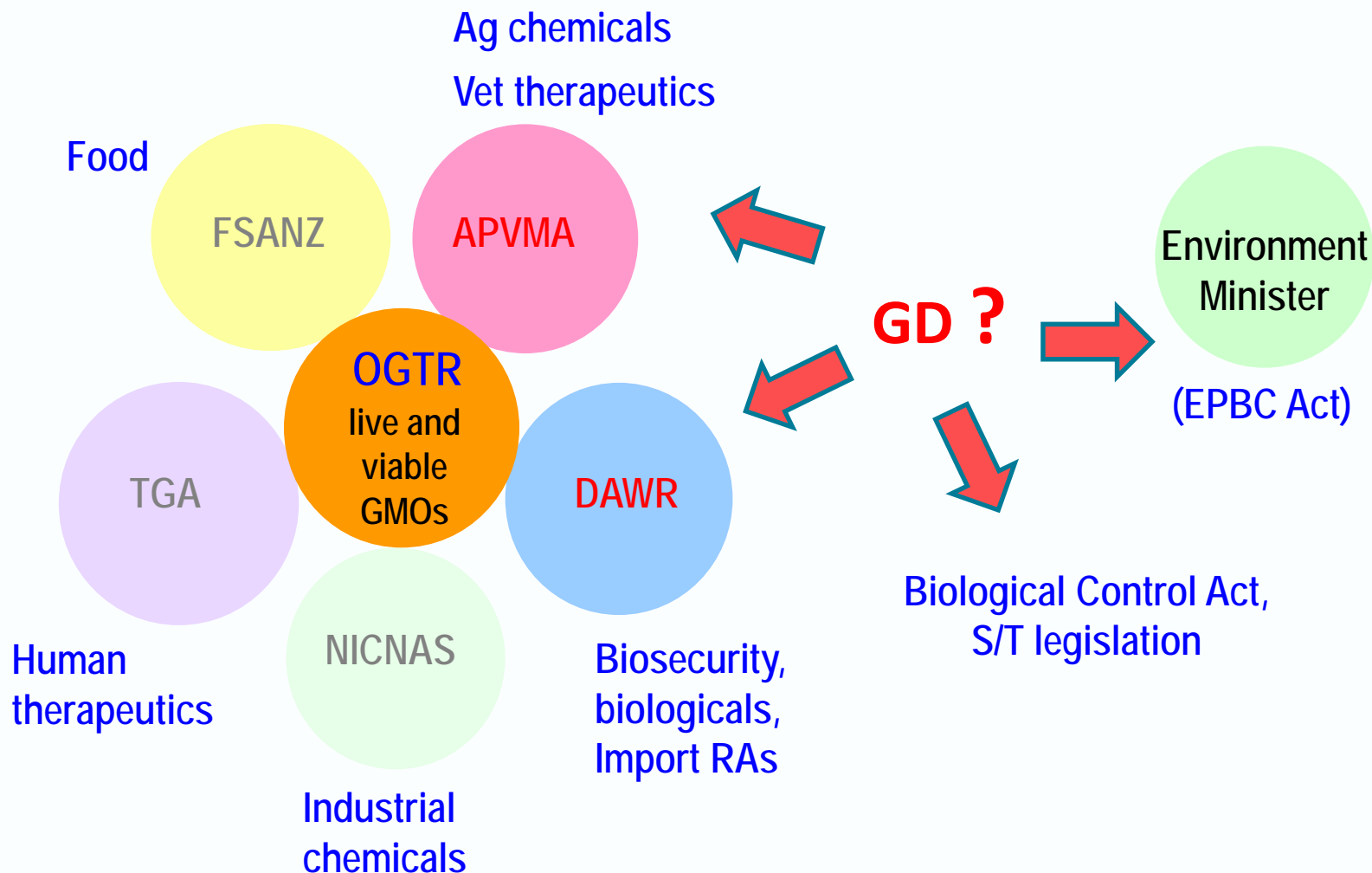
CSIRO-RSN Roundtable

June 30th 2016, Boardroom, Discovery Centre, Black Mountain, Canberra

Outcomes of Symposium and Roundtable

- Currently no gene drive specific regulation for contained research, same minimum requirements as any other GMOs
 - Proposal that additional specific containment measures might be warranted for gene drive organisms
- Current regulations for GMO contained work require institutional biosafety committees (IBCs) to consider if facility is at appropriate containment level.
- Communication from OGTRs to IBCs on considerations for gene drive work suggested in the interim

Gene drive regulation – other regulators ?



Summary

- Australia has a process-based regulatory framework for gene technologies
- Science-based oversight by the Office of the Gene Technology Regulator (OGTR), with the cooperation of other regulatory agencies
- Regulations subjected to periodic review, including broad consultation
- The Regulatory Science Network offers additional opportunities for stakeholder consultation



Thank you

BIOSECURITY FLAGSHIP
www.csiro.au

