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Queensland Institute of Medical Research

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2011 REVIEW OF THE GENE TECHNOLOGY ACT

QIMR submission on the independent review of the Gene Technology Act 2000 by the Gene Technology Ministerial Council

Public perception versus scientific endeavour

While scientists accept the public perception that GMOs may be dangerous if released into the environment, the public need to also made aware of their role as part of biological research and be shown that in appropriately made facilities there is little change of any negative impacts of the work.

Much of this work is contained and classified as low risk both to persons and the environment.

The regulatory burden

The Gene Technology Act impacts on research because it imposes a regulatory burden which is greater than many overseas competitor countries. Within Australia other regulatory authorities also impact. The main ones being the Workplace Health and Safety Legislations, soon to be harmonized and the AQIS Regulations for certified facilities. For organisations dealing with contained facilities the inconsistencies between OGTR and AQIS certification requirements causes problems of compliance and harmonization of these regulatory bodies would be highly beneficial to research.

Time costs

There is a cost in time commitment although at present there is no charge for a licence or a certification under the Act.

For organisations conducting dealings with GMOs, scientists must obtain an approval for low level dealings through their Institutional Safety Committee (IBC) if the work is deemed a low risk dealing or a licence through the OGTR if it is a high risk dealing. Writing such applications takes time and for licenced dealings this can be quite a detailed time consuming application.

For an IBC to work, a number of scientists from the breadth of research fields of the organisation must sit on the committee reading and assessing applications put forward by their fellow scientists. In larger organisations this can be a commitment of 2-3 days a month , 10-11 months a year. All time which is taken away from their research effort. This is often a larger time commitment than sitting on an NHMRC grant review panel which only happens once a year.

While scientists accept there needs to be control over high risk dealings, the speed at which approvals occur is limiting. For a high risk dealing still to be conducted in a laboratory setting, the application must go to the IBC and then to OGTR for final approval. These applications take 6 months in practice (90 working days) for an approval, as does any amendment (change in experimental procedure , new animal/bacterial species). For dealings involving release these time frames are much longer.

This is a delay in research and slows Australian productivity relative to other parts of the world in which Australian Scientists compete to be the first to publish and to obtain external grant funding.

Costs of facilities

An organisation must also certify its facilities at either PC1, PC2 or PC3 for general organisations (few none government organisations will have PC4 facilities). This means that on an annual basis the members of the IBC or their delegates must undertake check list audits to ensure the facilities meet the certification guidelines set out by OGTR.

If guidelines change there can be increased non budgeted costs on an organisation to upgrade its facilities or in some cases build new facilities in order to comply with new requirements if the research work is to continue.

The OGTR inspectors also check PC3 facilities once each 3 years as their certification is renewed and usually one other time within the 3 year certification period. At these times the facilities must be shut down and work cease while the inspection takes place (some mid- term audits can be undertaken without access, but not re-certification ones). As facilities have to be decontaminated prior to inspection this can be a week of down time when the facility is unavailable and no research can be conducted.

Evidence based regulatory changes

Each time the Act or Regulations are reviewed there appears to be a tightening of the requirements. For instance , this year there has been a change in the transport/storage and disposal requirements for GMOs, requiring more stringent paperwork and containment for transport.

There is little or no evidence given to suggest such a tightening is required. Those who act within the Regulatory framework imposed by the OGTR Act, do so in a highly compliant manner and there a few if any accidents of contained dealings. Those organisations who choose not to comply are not impacted by any regulatory changes unless identified by the authorities where penalties can then be imposed. However the OGTR accept there have been no prosecutions for low risk dealing breaches.

There needs to be an acknowledgement that contained dealings that are low risk are unlikely to escape from a PC2 facility either by infecting the personnel working there or by accidently release to the environment. The regulatory impact for these dealings is severe given the risk they pose.

Impact statements

As part of any review of the Act or Regulations there should be an impact statement of what it costs to the Research community and thus to Australia and what would be the cost (perceived risk and its impact) if no change occurred.

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On behalf of QIMR

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