



The Hon Mark Butler MP
Parliamentary Secretary for Health

Dr Joe Smith
Gene Technology Regulator
MDP 54
PO Box 9848
CANBERRA ACT 2606

Dear Joe,

Congratulations on your recent appointment to the role of Gene Technology Regulator (the Regulator). As the Regulator, you are responsible for the regulation of genetically modified organisms (GMOs) within Australia and management of the Office of the Gene Technology Regulator (OGTR). This is an important role and I look forward to working with you to maintain the OGTR's high international profile and realising the Government's objectives.

I am pleased to provide you with my Statement of Expectations covering your role as the Regulator and setting out strategic directions for the Office of the Gene Technology Regulator (OGTR). I look forward to receiving your considered response and an indication, in a Statement of Intent, outlining how you intend to deliver on the Government's expectations.

Short and long term priorities

The Government's vision for the OGTR is that it continues to be a high performing agency that assists you 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.

Your primary concern should always be the protection of people and the environment from risks resulting from research and release into the environment of GMOs. In achieving this, you should have regard to your responsibilities as per section 30 of the *Gene Technology Act 2000* (GT Act) as well as to the Government's broader reform agenda. You should maintain a high level of awareness of the Government's health, industry and environmental policy objectives to enable the OGTR to respond fully to Government policy directions and objectives.

I also ask you to be mindful that, under the Gene Technology Agreement, the regulation of gene technology is undertaken by a nationally consistent regulatory scheme and your decisions must be consistent with policy principles issued by the Gene Technology Ministerial Council.

In exercising your responsibilities, I trust that you and the OGTR will maintain a high level of competence in the fields of science in which you operate and ensure an active awareness of new research and scientific developments.

As the regulator of dealings with GMOs, I ask you to apply a risk informed approach to regulation. The OGTR risk profile should address specific risks to the regulatory process in addition to setting risk derived regulatory goals and key performance indicators in its strategic and operational plans.

I request that you continue to perform all your functions as required by section 27 of the GT Act. I also request that you undertake regular reviews of exempt and notifiable low risk dealings, and ensure that the Gene Technology Regulations 2001 (GT Regulations) remain up to date with advances in gene technology.

In addition, I request that you continue to strengthen bilateral arrangements with other Government regulators, such as Foods Standards Australia New Zealand, the Therapeutic Goods Administration, the Australian Pesticides and Veterinary Medicines Authority, the Australian Quarantine and Inspection Service, and the National Industrial Chemicals Notification and Assessment Scheme in order to enhance coordinated decision making.

Legislative framework

The OGTR has been established within the Australian Government Department of Health and Ageing (the Department) to provide administrative support to you in the performance of your functions under the GT Act. As the Regulator, you are a statutory officer with legislative functions and obligations under the GT Act. Your functions and powers are detailed under sections 27 and 28 of the GT Act respectively.

I request that you and the OGTR operate in accordance with all relevant legislation, including the GT Act, the *Public Service Act 1999* (PS Act) and the *Financial Management and Accountability Act 1997* (FMA Act).

Role

You are responsible for implementing the national gene technology regulatory system on behalf of the Australian Government and the State and Territory Governments by administering the GT Act, the GT Regulations, and corresponding legislation in other jurisdictions.

The Department has provided the staff to the OGTR to assist you in this task. You are also responsible for leading and managing the OGTR, continually developing its procedures and practices in the light of operational experience and in response to feedback from stakeholders.

Stakeholder relationships

I note that the OGTR and the Department operate within the same broad policy platform. The Secretary of the Department plays an important role in providing me with policy advice in my oversight of portfolio agencies. To ensure that the Secretary and the Department can undertake this advisory role, I ask that you inform the Secretary (or the Department) of relevant issues and information affecting the portfolio. I would like the OGTR and the Department to foster a close working relationship based on the principles of open communication, no surprises and information sharing, in accordance with the ministerially endorsed Relationship and Appointment protocols. In having regard to the interests of the Government, I ask that you provide me and the Department with appropriate notice of key issues, reports and events that may impact on Government operations or policies.

Your effectiveness depends on sound relationships with stakeholders. These stakeholders must have confidence that you will administer the legislation and regulations competently, reasonably and objectively.

Accordingly, I request that you seek advice from the Gene Technology Technical Advisory Committee and Gene Technology Ethics and Community Consultative Committee, and consult with stakeholders, including individuals and organisations dealing with GMOs, relevant Australian, State and Territory Government bodies, professional and interest groups, and the community.

Compliance activities

I request that you exercise prudence in your financial management of the OGTR Special Account and in doing so that you comply with the requirements of the FMA Act. As the Secretary of the Department is ultimately accountable for the Special Account, I ask that you adhere to the financial management policies of the Department.

Under the FMA Act, the Secretary is required to manage the affairs of the agency in a way that promotes the efficient, effective and ethical use of resources. I ask that you support the Secretary in this regard. Under the FMA Regulations, all officials are required to do this in a manner that is not inconsistent with the policies of the Commonwealth (for example, Commonwealth Procurement Guidelines).

Any breaches of the FMA Act, FMA Regulations, FMA Delegations, FMA Orders or financial management and other policies need to be reported in OGTR's input to the Department of Health and Ageing's annual certificate of compliance.

As required by section 136 of the GT Act, I request that you continue to report through me to the Australian Parliament both annually, on your operations, and quarterly, on matters including:

- GMO licences issued during the quarter;
- any breaches of conditions of a GMO licence that have come to your attention during the quarter; and
- auditing and monitoring of dealings with GMOs under the GT Act by you, as the Regulator, or by an inspector, during the quarter.

Copies of the Annual Report should be provided to the States and Territories. I also ask that you provide progress reports on your operations to meetings of the Gene Technology Ministerial Council and provide input to the Annual Report of the Department of Health and Ageing, including financial and performance information.

The agency as an employer

I note that staff at the OGTR are employed by the Department of Health and Ageing under the PS Act. I request that the OGTR comply with the provisions outlined in the Department's Collective Agreement. The OGTR should set a high level of human resource standards consistent with the Department's human resource policies and assist in ensuring that the Government's workplace policies are effectively implemented.

I ask that OGTR employees continue to model Australian Public Service (APS) standards and values. I look to you to lead the OGTR in a way that ensures that it is seen as a good place to work, family friendly and inclusive of our diverse community. I ask you to encourage employees of the OGTR to uphold in their work the values embodied in the APS Code of Conduct and the APS Values.

Conclusion

As outlined above, the purpose of this Statement is to share with you my expectations of the Regulator role and the operations of the OGTR. This Statement of Expectations is not a

Ministerial Direction, conferral of function or a delegation of power under any Act.

I look forward to working with you in the future and receiving your Statement of Intent addressing how it is proposed these expectations will be met.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Mark Butler', written in a cursive style.

MARK BUTLER

10 AUG 2009