

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2016 - 2017, 19 October 2016

Ref No: SQ16-000584

OUTCOME: 5 - Regulation, Safety and Protection

Topic: OGTR Processes

Type of Question: Written Question on Notice

Senator: Rice, Janet

Question:

Does the OGTR have the power to require applicants to conduct and submit additional research data where knowledge gaps exist?

- a) If yes, has this ever been done?
- b) If yes, please identify the applicant and application
- c) To what extent does the OGTR rely on the data set submitted with each new application as opposed to wider sources of evidence?
- d) Are all relevant scientific papers and datasets considered during assessment or are some/many/all excluded? On what criteria does the OGTR include or exclude papers or datasets?

Answer:

Yes. Applicants must provide the information specified by the Gene Technology Regulator, in accordance with the *Gene Technology Act 2000*. The Regulator can require applicants to submit further information if there are information gaps. If the required information does not already exist, then further research and experimentation may be required. The application process is stopped until the required information has been submitted.

- a) Yes. The Regulator often requires applicants to provide further information.
- b) Yes. Where applications that have been stopped because further information is required, the applications and applicants are listed in the quarterly reports issued by the Regulator. These are available on the OGTR website.
- c) Scientific staff of the OGTR use information in the public domain from searching the scientific literature as well as information supplied by applicants.
- d) Scientific staff of the OGTR apply a “weight-of-evidence” approach when considering the body of existing knowledge for each application as outlined in the Regulator’s *Risk Analysis Framework 2013*. This document is available on the OGTR website.