



Australian Government

Department of Health
Office of the Gene Technology Regulator

Jeanette Radcliffe
Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Ms Radcliffe

Submission to the Senate Standing Committee on Community Affairs

Food Standards Australia New Zealand Amendment (Forum on Food Regulation and Other Measures) Bill 2015

I understand that on 15 October 2015, the Senate referred the Food Standards Australia New Zealand Amendment (Forum on Food Regulation and Other Measures) Bill 2015 (the FSANZ Bill) to the Senate Community Affairs Legislation Committee for inquiry and report.

I am providing this submission in my capacity as the Gene Technology Regulator, from the perspective of the independent statutory office holder charged with administering the national scheme for regulating gene technology.

Regulation of Genetically Modified Organisms

The object of the gene technology regulatory scheme, as set out in the *Gene Technology Act 2000* (Cth) (GT Act) and corresponding State and Territory laws, is 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 genetically modified organisms (GMOs).

My role as Gene Technology Regulator, supported by the Office of the Gene Technology Regulator (OGTR), involves the risk assessment, risk management and monitoring of work with GMOs to ensure compliance with legislation. In granting licences for work with GMOs, I must be satisfied that any risks to human health and the environment can be managed.

The OGTR does not operate in isolation from other product regulators and works closely with those agencies to ensure regulatory coverage but prevent duplication of oversight in relation to GMOs and GM products. Under the GT Act, I am required to seek advice from Food Standards Australia New Zealand (FSANZ) on risk assessments for environmental release of GMOs (sections 50 and 52).

The requirement for the Gene Technology Regulator to seek advice from FSANZ is not affected by the FSANZ Bill.

Interaction between the Gene Technology Regulator and FSANZ

OGTR has a strong and cooperative relationship with FSANZ built on the connection between GMOs and genetically modified (GM) food. Integrated regulation in Australia is provided for by assessment and approval of commercial scale release of GM crops by the Gene Technology Regulator and corresponding assessment of GM food by FSANZ for inclusion in the Standard 1.5.2 (Food Produced Using Gene Technology) of the Australia New Zealand Food Code.

Interaction between OGTR and FSANZ is not limited to legislative requirements for request and provision of advice but includes a range of other activities. OGTR and FSANZ have a Memorandum of Understanding which recognises the importance of the relationship and exchange of advice and information between the two agencies. Senior officers of OGTR, FSANZ and other regulators engage at the strategic level as members of the Regulators' Forum (established following the 2006 review of GT Act to formalise information sharing between the OGTR and other regulatory agencies).

Oversight of GMOs and GM food to protect human health, by OGTR and FSANZ respectively, is underpinned by scientific risk analysis. Staff of both agencies liaise regularly on scientific and technical issues related to gene technology and the evaluation of the risk/safety of GMOs and GM food. OGTR and FSANZ have active and ongoing engagement in the Regulatory Science Network (RSN, established under the Regulator's Forum) which focuses on risk analysis and science for regulation. The Regulator's Forum and RSN also include representatives from a number of other Australian Government regulatory agencies.

OGTR and FSANZ will continue to maintain a strong working relationship to support the adequate and timely flow of information to inform assessments and decisions.

Proposed Amendments

The amendments proposed in the FSANZ Bill relating to the definition of "appropriate government agency" continue to capture "any other body or officer of the Commonwealth, a State, a Territory or New Zealand that FSANZ considers has a particular interest in the relevant matter". It is my understanding that the effect of the new definition will in no way remove the ability of FSANZ to seek advice from me or my office on a relevant matter.

I concur with the Explanatory Memorandum that the amendments relevant to the OGTR will improve the clarity and operation of the legislation and improve regulatory efficiency. I therefore support the amendments that update notification procedures for appropriate government agencies.

Yours sincerely

Dr Robyn Cleland
Acting Gene Technology Regulator
5 November 2015