Hon Damien O'Connor

MP for West Coast-Tasman

Minister of Agriculture
Minister for Biosecurity
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Claire Bleakley
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cc: Jon Carapiet; Jon Muller
secretary@gefree.org.nz

Dear Claire

Thank you for your submission about provitamin Rice on 1 February 2018, as well as your emails on 5 and 8 February.

The forum of Trans-Tasman food Ministers, on which I sit as New Zealand's representative, has decided not to review the decision by Food Standards Australia New Zealand (FSANZ) to approve provitamin A rice. We were guided by the expert advice from scientists in Australia and independently in New Zealand, who concluded that food derived from this line of rice is as safe for human consumption as food derived from conventional rice cultivars.

I have carefully considered your concerns and they were also assessed by the Ministry for Primary Industries. The Ministry will be releasing a copy of the briefing to you shortly.

This rice is intended to provide a source of vitamin A in developing countries and cannot be sold in Australia or New Zealand under its licencing arrangements. FSANZ assessed the safety data to ensure there was no public health and safety concerns from trace amounts that could be present in imported rice. If this rice were ever to be sold here then it would have to be labelled as genetically modified.

The FSANZ assessment for a new genetically modified foods has two main elements – mandatory pre-market approval, and mandatory labelling elements. FSANZ's process for assessing the safety of genetically modified foods is based on concepts and principles developed by the World Health Organization, the Food and Agricultural Organization, and the Organisation for Economic Co-operation and Development over many years. The internationally agreed guideline for assessing the safety of food derived from genetically modified plants is the Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA plants*. The FSANZ safety assessment guidelines and data requirements align with this guideline.

The FSANZ assessment comprehensively assesses the safety of any introduced new proteins, including allergen testing. The estimate of the amount of beta-carotene was provided to demonstrate that this increase does not present a risk to consumers in Australia and New Zealand rather than to determine benefit, because the rice is not intended for sale here.

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One of your concerns was about animal feeding studies. FSANZ does not routinely require animal feeding studies for assessing the safety of new genetically modified foods. Toxicologists generally agree that such studies are difficult to perform, have low power to detect adverse effects, carry inherent risks of confounding effects, and contribute little, if anything, to assessing the safety of these foods. FSANZ can however request feeding studies if considered appropriate and will consider these studies as part of the assessment if they are provided. The Codex Guideline says:

> *Animal studies cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, often characterised by a wide variation in composition and nutritional value. Due to their bulk and effect on satiety, they can usually only be fed to animals at low multiples of the amounts that might be present in the human diet. In addition, a key factor to consider in conducting animal studies on foods is the nutritional value and balance of the diets used, in order to avoid the induction of adverse effects which are not related directly to the material itself. Detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods. Another consideration in deciding the need for animal studies is whether it is appropriate to subject experimental animals to such a study if it is unlikely to give rise to meaningful information.*

You also raise the point of FSANZ using unpublished data. It is not a requirement that the applicant supply published or independent data, as FSANZ makes an assessment of safety based on the information provided. The applicant is required to provide a comprehensive dossier of quality-assured data for each genetically modified food. This enables FSANZ to independently assess the data and decide if the food is safe. If FSANZ determines that the data are not sufficient, additional information and testing may be required, and FSANZ will ask the applicant to provide further information. Detailed information regarding the data requirements is provided on the FSANZ website, at the following link: http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx

I am confident that the framework applied under the trans-Tasman system appropriately regulates genetically modified foods. FSANZ is required to develop or review food standards with the protection of public health and safety as its first priority. This is followed by the requirement to provide adequate information to enable consumers to make informed food choices. FSANZ must also have regard to other matters, including the need for standards to be based on risk using the best available scientific evidence, and the desirability of an efficient and internationally competitive food industry. However, the most important priority is always the protection of public health and safety.

Thank you for taking the time to write to me on this important issue.

Yours sincerely

Hon Damien O'Connor
Minister for Food Safety