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Jon Muller
Secretary
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Dear Jon Muller

Thank you for taking the time to meet with me on 4 June 2013, and for your letter of 11 June 2013, to which you attach a new study focusing on genetically modified (GM) animal feed.

At our meeting, I undertook to respond to you on a number of questions and issues. I have set out my response to each of these below.

1. What are the processes Food Standards Australia New Zealand (FSANZ) uses to consider the need to review or update approved GM foods in light of new studies?

FSANZ frequently monitors the scientific literature and other information relating to the development and safety of GM foods. From time to time, studies may be published (either in the peer-reviewed scientific literature or elsewhere), which purport to show adverse effects from GM foods, or which are claimed by others to be evidence of adverse effects. Some of these studies may relate to specific GM foods that FSANZ has already assessed and approved. When new studies are published which question the safety of already approved foods, FSANZ undertakes a review of the new information to see if the previous safety assessment should be revised. The outcome of this review, including whether any further action by FSANZ will be undertaken, is published on the FSANZ website. FSANZ also maintains a list of studies that are frequently cited as evidence of adverse effects from GM foods. The FSANZ response to each study is provided. The list of studies can be accessed via this link:
http://www.foodstandards.gov.au/consumer/gmfood/adverse/Pages/default.aspx

2. The relevance of animal feeding studies to GM food assessments

Animal feeding studies can provide additional information for GM food assessments, but they do not provide conclusive results about the safety of foods due to the range of confounding factors inherent in the design of feeding studies of whole foods.

Regulatory risk assessors do not require animal studies other than for acute (short term) toxicity because the effects of unnatural nutrition on the test animal cannot be avoided, and because any toxic effect from the GM food would be unlikely to be seen in such animal testing. Some applicants for approvals for GM foods do conduct repeat dose studies of up to 90-days in rodents, and if submitted, regulators will assess those studies even though they are not required. The tests can only give an indication of potential toxicity, and internationally regulators usually discourage this type of study in the interests of limiting animal testing.

FSANZ convened an expert panel in 2007 to specifically consider the question of whether animal feeding studies are necessary to determine the safety of GM foods, and the conclusions from the expert panel can be found in the following link to the FSANZ website:
http://www.foodstandards.gov.au/consumer/gmfood/Pages/roleofanimalfeedings3717.aspx

3. How is scientific evidence evaluated for risk management decision making?

Scientific research and evidence is used to characterise hazards, with risk determined by evidence of the potential impact of a hazard and the likelihood of it occurring. This process is called 'risk assessment'. Expert risk assessment is used to determine if there are risks that need to be managed by regulatory or other means. Risk management is a separate step to risk assessment, in which options for managing risks are considered in terms of how well they mitigate the risk, along with their practicality and cost. Risk managers then make a decision as to which risk management option to follow. Risk management decisions are informed by broader policy frameworks. In relation to GM foods, the policy framework was considered by the Royal Commission on Genetic Modification in 2001. The Royal Commission's major conclusion was that 'New Zealand should keep its options open. It would be unwise to turn our back on the potential advantages on offer, but we should proceed carefully, minimising and managing risks'. In this respect, the Royal Commission considered that the FSANZ GM food assessment processes and the existing GM food labelling requirements were appropriate. Since that time, FSANZ has been continually monitoring research on GM food safety, and its processes have remained consistent with World Health Organization guidelines and other regulatory agencies worldwide.

4. What are the legal options available to GE Free New Zealand if the Regulations Review Committee does not recommend disallowance of the food standard that recognises in New Zealand FSANZ's approval of A1073 food derived from soy DAS-44406-6?

Government decision making is subject to the powers set out in legislation passed by Parliament. If any person considers that the Government has exceeded its powers in making a decision, the decision making process can be subject to judicial review by the High Court.

You may wish to seek legal advice about your options in relation to contesting the decision making process in relation to the approval for sale in New Zealand of food derived from soybean DAS-44406-6.

5. Why there are no diagnostic tools for illnesses caused by GM foods?

Debate about the safety of genetically modified foods hinges on the biological credibility of the claims that GM foods present greater risk to consumers than non-GM foods. Every time we eat any food of plant or animal origin (that is any fruit, vegetables, meat or offal), we are eating foreign genetic material and foreign proteins where present, and so we are already constantly exposed to potential hazards from these sources. Exposure to novel proteins and DNA is no different. However, because humans may not have been exposed to these proteins or DNA through food before, it is important that they are subject to scientific risk assessment. The basis of this assessment is comparison to the nearest conventional variety. This comparison means that the measure of safety for a GM food is whether its risk profile is comparable to a food that has been traditionally consumed by humans.

There are risks associated with the consumption of any food. For instance, it is possible to consume too much, too little, to be allergic to a food, or to not be able to digest a food (e.g. lactose in some populations). Because human nutrition, metabolism and physiology are complex, there is still much ongoing work to determine physiological and metabolic indicators for diet across different population groups, and down to the individual level. What GM food assessment currently tells us is that the risks associated with consuming an approved GM variety are no different to the risks of consuming a conventional variety. It is difficult to conceive of diagnostic tools that would provide useful information on a particular food containing a GM product and an illness.

In a subsequent email to my office of 6 June 2013, you asked for access to the human safety studies on soybean DAS-44406-6. The data used for FSANZ's assessment of this soybean (including the information provided by the applicant) is publicly available on the FSANZ website at http://www.foodstandards.gov.au/code/applications/Pages/a1073.aspx. Literature referred to by FSANZ that is not directly available on the FSANZ website, but is publicly available, may be associated with copyright restrictions.

You also asked for a response to the question, 'how can you tell the public that [approved GM] foods are safe when there is a complete absence of evidence of the effects on ingestion of the whole soybean/GE plant'?

As outlined above, because humans, and, to a lesser extent, animals, require considerable variety in their diets, it is very difficult, if not impossible, to design feeding studies that can control for confounding factors. You will appreciate that if a diet is restricted to a single food, or small number of foods, then that will have a significant impact on physiology and metabolism. Therefore, rather than focusing on the whole food, GM food assessments seek to determine the toxicology (including dose response) of any novel protein, DNA or compounds in the genetically modified variety that are different to those in the closest conventional comparator. Dose response to specific compounds is tested in animal models. Exposure to compounds in food, whether naturally occurring, the result of genetic modification, or from addition to food (for example added vitamins and minerals) also needs to be understood in relation to a varied diet. FSANZ's approach to dietary exposure assessment is to estimate very high potential exposure whereby it is assumed that the food (and therefore compounds within the food) would be consumed at the

highest possible credible level of consumption. This means that FSANZ's risk assessments are highly conservative. If, after this conservative assessment, toxicological and dietary exposure data indicate a low risk, then it is possible to have confidence that a GM food is as safe as comparable conventional foods.

Thank you for the set of studies you provided me at our meeting, and subsequently in your letter of 11 June 2013. I have sought advice from officials at MPI on the relevance of the studies to GM food assessments. MPI has advised that in its view the studies do not indicate a need to reassess approved GM foods, or to change the assessment procedures used by FSANZ. I have confidence in MPI's advice on this matter.

Yours sincerely

Hon Nikki Kaye
Minister for Food Safety