

[REDACTED]

From: [REDACTED]
Sent: Wednesday, 19 December 2012 2:54 PM
To: [REDACTED]
Subject: RE: Request for information | New Breeding Techniques [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thank you for your email seeking information on New Zealand's regulatory approach to new plant breeding technologies. You may already be aware that **Food Standards Australia New Zealand** (FSANZ) is a bi-national government agency which develops and administers the *Australia New Zealand Food Standards Code*. All foods for sale in New Zealand and Australia are subject to the regulations in the Code, including GM foods which are regulated under Standard 1.5.2 <http://www.comlaw.gov.au/Details/F2012C00771>. Therefore our response to your queries also applies to Australia. Please note that the cultivation of GMOs is regulated separately and falls within the responsibility of the Environmental Protection Agency in New Zealand, and the Office of the Gene Technology Regulator in Australia. FSANZ does not regulate animal feed and under the Code, a GM food does not include a food derived from an animal fed on GM feed.

Q1: Has there been a decision made on the legal/regulatory status of the listed techniques with regards to GM-legislation

FSANZ is aware of the discussions taking place internationally, and is currently considering several of the technologies you have mentioned (a, b, c, e, f) in terms of whether they would be captured under our existing regulations for GM foods. Our approach has been to firstly consider each technique from a scientific perspective to better understand the nature of any food products and to determine whether these would fit under existing definitions in the GM food standard. The next step is to consider the possible impacts of these techniques from a legal perspective. At present the matters are not fully resolved, however we are holding discussions with other relevant areas of government, and of course are continuing to monitor developments overseas.

Q2: What legislation/regulation is applicable to crops/products (used for food/feed) resulting from NBTs classified as non-GM

I emphasise that we are considering each new technique separately and have not made a final determination on the regulatory status of products derived by these technologies. For some NBTs, it is not clear whether they can be conclusively regarded as non-GM, however we consider that others (for example, grafting) would be captured as a GM food.

Further consultation is needed to determine whether changes to Standard 1.5.2 would be necessary to clarify the regulatory status of the NBTs, whether we need to modify our assessment procedures for different types of technology and what additional guidance is needed for stakeholders.. There could be a reduction in the data requirements needed for assessment of some products. We are happy to provide further information on our determinations once we have finalized our views next year.

Once a determination has been made that a new breeding technology does not result in foods that fall within our definition of a GM food, there are no specific regulations/food standards that would apply to these products. However any foods derived from foods which are not considered to be GM food need to comply with all other provisions in the Food Standards Code. If lines from NBTs which were determined not to be subject to pre-approval in the Food Standard Code were to be cultivated or imported in a viable state, it would be prudent to consult with EPA (New Zealand) and OGTR (Australia) on their regulatory status regarding environmental release.

Q3: Have there been any applications for the commercial use of crops/products resulting from any of the listed NBTs

To date, FSANZ has not received any applications for commercial products derived from these new technologies. We have however received several enquiries from industry and academic researchers regarding various techniques and held discussions on their possible regulatory status.

I trust this information is helpful

Kind regards

[REDACTED]

[REDACTED]



*A safe food supply which supports the health
of people in Australia and New Zealand*

From: [REDACTED]
Sent: Wednesday, December 19, 2012 2:50 AM
To: [REDACTED]
Subject: Request for information | New Breeding Techniques
Importance: High

Dear [REDACTED]

Your contact information was provided to me by [REDACTED]. She suggested I contact you for our request for information regarding the legal status of New Breeding Techniques in New Zealand. [REDACTED] has already provided much valuable information on the regulation and legislation from a GMO perspective, but suggested that you could possibly provide valuable insights on legislation and regulation of New Breeding Techniques from a 'food' perspective.

For the Platform New Breeding Techniques (NBTs) in Brussels, a collaboration between SMEs, large international firms and research institutes, we are currently researching the legal and regulatory status of NBTs in countries outside of the EU. The ultimate objective of the Platform is to provide clarity on the legal and regulatory status of these NBTs within the EU.

The legal and regulatory status of these techniques is currently under discussion in the EU, and the risk is that the techniques will be incorrectly designated as subject to GM-legislation due to misinformation. The NBT Platform aims to create clarity in this discussion by providing clear facts and legal argumentation, in order support the European Commission and Competent Authorities in forming a substantiated opinion on NBTs, and hopefully exempt these techniques from GM-legislation.

The number of scientific studies on the subject of NBTs, among others, has led us to select New Zealand as a focus of our research efforts. A total of 13 countries will be covered by our research.

Hopefully you can help us with the following questions, or direct us to the person(s) knowledgeable on this subject:

1. Has there been a decision made on the legal/regulatory status of the techniques listed below with regards to GM-legislation? If so, what has been decided; if not, is there an indication when this decision will be made and what the possible outcome will be?
 - a. Zinc-Finger Nuclease (ZFN) 1, 2 and 3
 - b. Oligo-Directed Mutagenesis (ODM)
 - c. Cisgenesis
 - d. RNA-directed DNA Methylation (RdDM)
 - e. Grafting
 - f. Reverse Breeding
 - g. Agro-infiltration
2. What legislation/regulation is applicable to crops/products (used for food/feed) resulting from NBTs classified as;
 - a. Not regulated (that is, non-GM)?
 - b. Currently under study?
3. Have there been any applications for the commercial use of crops/products resulting from any of the NBTs mentioned above?
 - a. If so, what is their status?
 - b. In case they have been granted permission, what is the nature of these products and when are they expected to enter the market?

Thank you in advance. Since we are striving to complete the research as soon as possible, I hope to hear from you soon (preferably before the holidays, if possible). If you have any additional questions, please do not hesitate to contact me.

Kind regards,

[Redacted]

[Redacted]

[Redacted]

[Redacted]