

POSSIBLE CONTAMINATION OF IMPORTED SEED WITH GENETICALLY MODIFIED MATERIAL

Summary

1. In late 2000, a seed importing company informed the Government that it suspected a shipment of sweet corn seed from the United States may have been contaminated with genetically modified (GM) sweet corn seed. The Government was concerned that this was a likely breach of the law because GM seeds have not been approved for release in New Zealand.
2. Tests could not confirm whether or not GM material was present, but showed that if there was contamination, it was at a very low level (less than 0.05%). Based on a preliminary assessment, the Government considered the risks to human health to be negligible and the risks to the environment to be very low, and took no further action in this case. However, the Government initiated some new voluntary measures for imported sweet corn seed to reduce the chance that a similar incident could happen again, recognising that it is impossible to reduce the chances to zero.

The sweet corn case

3. In November 2000, a seed importing company informed the Environmental Risk Management Authority (ERMA) that it suspected that a shipment of sweet corn seeds had been contaminated with genetically modified (GM) seeds.
4. The seeds had been grown in the United States for export as a 'GM-free' lot that used certain transport, storage and processing systems to avoid mixing with GM seeds, and were tested for GM presence before being exported. The seeds were imported to New Zealand in several consignments for supply to four companies. By the time the possible contamination came to light, some seeds had already been planted.
5. The company had arranged for the seed to be tested upon arrival in New Zealand for two of the most commonly used gene sequences in GM plants: the cauliflower mosaic virus (CaMV) 35S promoter and the nos 3' sequence from the bacterium *Agrobacterium tumefaciens*. A DNA-based test performed by Crop and Food Research Ltd indicated the presence of the nos 3' sequence but not the CaMV 35S promoter. Further testing gave mostly negative results, but a test performed by a Melbourne laboratory also detected the presence of the nos 3' sequence. In total, about 49,000 seeds were tested.
6. Based upon the positive and negative results ERMA New Zealand estimated that if there had been any contamination the level was less than 0.05%. It is not clear how contamination of the lot could have taken place, although processing, post-harvest handling and cross-pollination are possibilities. False positives can also arise if the seed sample is contaminated with the common soil bacterium *Agrobacterium tumefaciens*.
7. Officials considered and assessed the risks of the potential contamination to both the environment and human health. Since there has never been an application to release a GM crop in New Zealand, no full environmental assessment of any GM organism has been carried out. However, ERMA has processed applications for contained research and field trials involving GM corn, and had therefore assessed these risks to a certain extent. The preliminary assessment concluded that the main environmental risk posed by GM sweet corn would come from its pollen. No native plants can cross with corn so

there is unlikely to be a risk to native flora. Cross-pollination of other corn crops can occur within 200m of the site, but is very unlikely beyond this distance. Given that the possible contamination was at a very low level, any corresponding risk from GM pollen was extremely low.

8. Health risks posed by food produced from the GM sweet corn had also been assessed. Internationally only three varieties of GM sweet corn (one modified for tolerance to the herbicide glyphosate and two for protection against insect pests) are grown commercially. All three have interim approval under Standard A18 of the Australian Food Standards Code, which is incorporated into New Zealand law under the New Zealand Food Standard 1996.
9. Genetically modified foods must undergo a comprehensive safety assessment by the Australia New Zealand Food Authority (ANZFA), and be approved by the Australia New Zealand Food Standards Council before the Minister of Health can approve them for sale in New Zealand. The submissions from ANZFA and the Ministry of Health have more detail. The three available GM sweet corn varieties are already legally sold in New Zealand in processed form, and the Government considers the risk to human health to be negligible.
10. StarLink™ corn, the GM variety (not approved for human consumption) that was found in the US food supply last year, is not an issue in this case. StarLink™ is a maize (mature corn) variety rather than a sweet corn variety, and the seeds and plants look quite different. The possible contaminating seed in this case was a GM sweet corn variety, not maize.
11. Based on the preliminary assessment that the possible risks to human health were negligible and the possible environmental risks were very low, and the fact that the tests for contamination were inconclusive, the Government took no further action with regard to this particular shipment.

The legal situation

12. The Hazardous Substances and New Organisms Act 1996 (HSNO) prohibits the importation, field-testing or release of any new organism without an ERMA approval. It is an offence to knowingly, recklessly or negligently possess an unapproved new organism. This is a precautionary approach because new organisms are assumed to be unsafe until the risks have been properly assessed. The Biosecurity Act 1993 gives the Government various powers to prevent unapproved new organisms coming into the country, and to take action if they are found within New Zealand.
13. To date, no GM organisms have been approved for release, so it is illegal to import GM seeds or to grow them in New Zealand. There is also a voluntary moratorium on applications to release GM organisms while the Royal Commission on Genetic Modification is considering the strategic options open to New Zealand.
14. A GM organism that is also a food must have an additional approval from the Minister of Health before it can be marketed or sold as a food in New Zealand. New labelling regulations for GM foods, which will come into force later this year, allow for 1% unintended presence of GM material. These are consumer information provisions and are not related to the health and safety assessment – unapproved GM foods are not tolerated at any level.

15. Approval has been granted to 18 GM foods (including the three GM-corn varieties). These approvals are based either on ANZFA's safety assessments, or on approvals in other countries and lack of evidence of any health or safety risks while ANZFA conducts its own assessments.

Government action taken

16. Unapproved GM seeds continue to be prohibited and it is illegal to knowingly import GM seeds in any quantities. Importers must therefore take steps using due diligence to ensure that their shipments do not contain unapproved GM seeds. Until now there have been no specific procedures in place to test for the presence of GM material at the border. However, the Government has decided to strengthen enforcement at the border using an import health standard under the Biosecurity Act 1993. As a first step in this process, an interim protocol has been introduced for imported sweet corn seeds. To be able to enforce the law, test results confirming the presence of GM material must be rigorous enough to stand as evidence in court - the protocol has been designed to reflect this. The protocol will be voluntary until consultation with industry has taken place and the measures are formalised in an import health standard, issued under the Biosecurity Act 1993 and administered by MAF.
17. MAF will modify the import health standards (generic and specific country standards) covering the phytosanitary requirements for importing sweet corn seed, to allow sampling and testing for GM contamination. All consignments of sweet corn seed will be tested on arrival unless equivalent measures had been taken before export to ensure the seeds are GM-free. Equivalent measures must be accredited by MAF and could include assurances that the seed came from countries where no GM plants are commercially grown, or documents showing that the supplier had not handled or processed GM material. MAF will occasionally audit these equivalent measures to ensure their integrity.
18. For testing, MAF will draw samples of imported sweet corn seeds (following international guidelines) and send them to MAF accredited laboratories. Importers will pay the costs of sampling and testing. If the tests show that a consignment of seeds is contaminated, MAF will not issue a biosecurity clearance and the importer will be given the option to reship or destroy the consignment.
19. The protocol is compatible with the HSNO Act because any consignment giving a positive result for GM material will not be given biosecurity clearance. However, border measures can never provide 100% assurances. Since testing for GM material destroys the seeds, there are practical limits to how many seeds can be tested and how much testing is carried out on each consignment. MAF has developed a sampling regime for sweet corn seeds, describing how many seeds should be tested from each consignment, to give a 99% confidence that any contamination (if it is there at all) is not greater than 0.5%. It is possible, but much less likely, that the tests would detect lower levels of contamination. This means that it is still possible for a contaminated consignment to be undetected, although the chances are low. This approach is a very stringent one, and seed suppliers will need to ensure that their production and testing systems are capable of demonstrating compliance with the requirements.
20. While these measures are currently voluntary and apply only to imports of sweet corn seeds, the Government has asked officials to assess the risks from, and develop best-practice guidelines for, imports of other seeds where GM counterparts are commercially available.

21. If any unapproved GM plant were found growing in New Zealand, the Government would consider the actions that it could take under the Biosecurity Act 1993 and/or the HSNO Act 1996.

Broader issues

22. This incident highlights the difficulty of reliably detecting very low levels of GM material since, as with all other quarantined material, 100% detection is impossible. There are two sources of difficulty, one lies in the limitations and sensitivity of analytical techniques to detect and quantify gene sequences, the other in the probability that a sample chosen for testing will contain some of the contaminating seeds.
23. While several analytical tests for GM material are available, they all have some limitations and can give inconsistent results including both false positives and false negatives. They also rely on knowing that certain gene sequences are present in order to be able to detect them. Consequently it would not be possible to detect GM material that was completely unknown. Several New Zealand laboratories are capable of performing the tests, but none offer full commercial services.
24. Even if more sensitive and reliable tests were developed, the statistical and practical limits of sampling would still make it difficult to verify low contamination levels. Testing destroys the seeds so it is not practical to test an entire consignment and thus give absolute assurance that it is totally free of GM seeds. Any sampling and testing regime has to recognise that a certain level of contamination may not be detected.
25. New Zealand imports seed from several countries including the United States and the European Union. Many of these seeds are for growing crops, but there is also a substantial business in growing seeds for export and as part of the cycle of developing and bulking new cultivars of staple crops. New Zealand currently imports several types of seeds that have GM counterparts overseas – maize, sweet corn, canola (for seed), tomatoes and squash – all of which carry a risk of contamination with GM seeds. The Government considered that banning all imports of these seeds was not a practical option since it would be likely to have serious negative impacts on industry as well as significant international trade implications.
26. It is also clear that other ‘GM-free’ countries face the same issues as New Zealand, so that there is a risk (although small) that their seeds are also contaminated with GM material. A preliminary analysis shows that New Zealand businesses would incur significant costs if they had to change suppliers to obtain seeds only from countries that do not grow GM varieties.
27. Possible contamination of seeds is not a new issue – the seed industry maintains a high level of purity by avoiding cross-pollination or accidental mixing with other seeds, although it is never possible to guarantee 100% purity. What is new is that GM seeds are involved, and contamination of this kind is particularly difficult to detect without laboratory testing. The potential for unintentionally importing GM seeds is likely to increase as new GM crops are developed and more GM crops are planted around the world. In some countries, there are no requirements to separate GM and non-GM products. There are no international standards yet for assuring non-GM trade, though the Biosafety Protocol, which New Zealand has already signed, proposes labelling and notification for international shipments of GM seeds.
28. Several international forums are grappling with this issue and some countries have proposed their own measures, but there is no international consensus on testing

processes or standards. For example, the European Union is considering a proposal for an import protocol that prohibits seed shipments contaminated with unapproved GM material but allows between 0.3% and 0.5% contamination with approved GM material.

29. New Zealand's response to the seed contamination issue will also need to take into account the provisions of the World Trade Organisation (WTO) Agreements, in particular the Agreement on Technical Barriers to Trade (TBT) and the Agreement for the Application of Sanitary and Phytosanitary Measures (SPS). The TBT applies to technical regulations and the SPS applies to regulations aimed at protecting human, animal or plant life or health. In broad terms, the Agreements aim to ensure that regulatory measures are objective, transparent and non-discriminatory, and do not constitute disguised restrictions on trade. Further detail on these Agreements is contained in the submission of the Ministry of Foreign Affairs and Trade to the Royal Commission.
30. It would be desirable to liaise closely with Australia on responses to this issue, given the increasing integration of our two economies, including joint food standards. There is a possibility of further regulatory harmonisation in other related areas. While preferable, identical responses may not be necessary as the mutual recognition principle in the Trans-Tasman Mutual Recognition Arrangement (TTMRA), which allows goods legally sold in one country to be sold in the other, may not apply in this case. The border controls proposed for dealing with this issue probably fall within the exemptions contained in the TTMRA for laws prohibiting or restricting imports and quarantine measures. This would ensure that seed entering one country could not access the other under the terms of the TTMRA but will instead have to comply with that country's border requirements.

Further information

The following officials can clarify or discuss any of the issues raised in this report:

- Mr Richard Ivess (MAF) Director, Plants Biosecurity. Contact for information on border controls and biosecurity issues.
Tel: 04 474 4127 Email: ivessr@maf.govt.nz
- Dr Donald Hannah (ERMA), Manager, Science and Analysis. Contact regarding the sweet corn case, interim protocol, and testing regimes.
Tel: 04 496 4839 Email: donald.hannah@ermanz.govt.nz
- Dr Steve Vaughan (MfE), Manager, Hazardous Substances and New Organisms. Contact for information on the HSNO Act.
Tel: 04 917 7404 Email: steve.vaughan@mfe.govt.nz