ERMA New Zealand Inquiry Report INQ08001

GM Brassica Field Test GMF06001

October 2009

INQUIRY SUMMARY

1. The Report of the Royal Commission on Genetic Modification 2001 concluded that *New Zealand should keep its options open and that it would be unwise to turn our back on the potential advantages on offer, but we should proceed carefully, minimising and managing risks regarding to genetic modification*.

2. If an application is approved the onus is on the approval holder to meet and maintain the necessary systems to ensure compliance with HSNO Act controls. ERMA New Zealand and MAF also are responsible for continuing to minimise and manage any risks regarding genetic modification throughout the life of an approval.

3. The New Zealand Institute for Plant and Food Research Ltd failed to comply with two Hazardous Substances and New Organisms Act 1996 (HSNO Act) controls at the GM brassica field test (GMF06001). On two occasions, in February 2008 and December 2008 a GM brassica plant was allowed to flower. Also in December 2008 one brassica plant was found growing in a compost area. Plant and Food Research has acknowledged that it was responsible for the non-compliance with controls.

4. In response to the non-compliance, the Ministry of Agriculture and Forestry (MAF) undertook an incursion response investigation at the field test site. No significant risk to the environment was identified by MAF.

5. A compliance order was issued by MAF under the HSNO Act to Plant and Food Research, requiring a five-year programme of surveillance and soil management at the field test site to detect and remove volunteer plants which might contain GM heritable material. MAF also undertook a criminal liability investigation and decided not to prosecute, but MAF issued a formal warning to the Trial Manager of Plant and Food Research.

6. Since the incident in December 2008, Plant and Food Research have initiated a number of organisational changes to ensure compliance with HSNO Act approvals. MAF was satisfied that Plant and Food Research had taken steps to mitigate any risks and to put into place procedures to prevent further occurrences.

7. ERMA New Zealand initiated a formal inquiry (code INQ08001) under section 11(1)(e) of the HSNO Act. The inquiry examines the adequacy of ERMA New Zealand's and MAF's compliance systems in relation to the GM brassica field test; to review the controls for the GM brassica field test, and to see if there are any lessons for a similar approval held by Plant and Food Research to field test GM alliums (see Appendix 1 for Terms of Reference).

8. ERMA New Zealand seeks to incorporate lessons learnt from the operation of controls; to write more effective controls; and to respond to issues as they may occur. The inquiry has found that the controls (if complied with) are adequate to manage risk for both the GM brassica and GM alliums field tests. ERMA New Zealand considers that the MAF compliance and enforcement actions were appropriate. However we have identified some relatively minor areas for improvement in both ERMA New Zealand's and MAF's systems and have made the following recommendations.

RECOMMENDATIONS

For Approval Holder:

Recommendation 1: The approval holder should demonstrate to MAF that new techniques used in the implementing of controls placed on a field test have been scientifically validated before the control is implemented.

*For ERMA New Zealand***:**

Recommendation 2: If the GM brassica field test approval is reactivated, before the field test is re-started, a minor amendment under section 67A of the Act be undertaken by ERMA New Zealand to reword control 1.12 of the approval to specify that plant material must be chipped, shredded or mulched before composting.

Recommendation 3: If the GM brassica field test approval is reactivated, before the field test is re-started, a minor amendment under section 67A of the Act be undertaken by ERMA New Zealand to reword control 1.8 of the approval to make more clear that both GM and non GM brassica are not allowed to flower.

Recommendation 4: That for any future GM plant field test approvals, ERMA New Zealand specifies in the controls what type of plants, GM and non-GM, can and cannot flower.

Recommendation 5: ERMA New Zealand initiates discussions with representatives from Te Rūnanga o Ngāi Tahu, Plant and Food Research and MAF to discuss our interactions in relation to the GM brassica field test. The purpose of this is to identify their respective roles and responsibilities, and expectations regarding their interactions for any future field tests.

For MAF:

Recommendation 6: For future field tests, MAF should consider more frequently exercising its right to make non-notified visits to field test sites, particularly at critical periods such as when plants may bolt or flower.

Recommendation 7: That MAF should consider meeting with approval holders before the commencement of any future approved field test to determine that organisational oversight for the field test is in place.

For ERMA New Zealand and MAF:

Recommendation 8: In order to ensure controls are fully understood, workable and implemented in practice, ERMA New Zealand should be available to attend MAF inspections of field test sites, especially in the first year of operation.

GM BRASSICA FIELD TEST

TIMELINE OF EVENTS

9. In May 2007 the New Zealand Institute for Crop and Food Research Ltd (Crop and Food Research) obtained an approval to assess the agronomic performance of vegetable and kale brassicas: specifically cabbage, broccoli, cauliflower and kale, modified for resistance to caterpillar pests like cabbage white butterfly and diamondback moth (GMF06001).

10. On 1 December 2008 HortResearch and Crop and Food Research merged to form the New Zealand Institute for Plant and Food Research Limited (Plant and Food Research).

11. MAF visited the Plant and Food Research GM brassica field test site on the afternoon of Monday 22 December 2008 following a complaint to MAF from the Soil and Health Association that GM brassica were flowering at the site. MAF noted that GM brassica within the field test site were not flowering, but that some buffer row brassica plants were flowering. A single brassica plant was observed growing in the compost area.

12. The GM brassica on site were GM kale which had regenerated after harvesting. The plants had been cut off above ground level. GM cauliflower, broccoli and cabbage plants had already been harvested with plants pulled from the ground and disposed of according to the approval controls.

13. On 23 December 2008 Plant and Food Research was shown photographs that the Soil and Health Association alleged showed flowers on a GM kale plant at the trial site. Plant and Food Research's Trial Manager also viewed the photographs and determined they were inconclusive.

14. As the photographs were inconclusive, Plant and Food Research management instructed the Trial Manager to re-inspect plant waste removed from the trial (during routine monitoring of the field test site) on the morning of 22 December 2008. This inspection confirmed that a single flower had developed on a stem which had been removed by the Trial Manager. MAF was informed by Plant and Food Research immediately.

15. On Wednesday 24 December 2008 *The Press* (Christchurch) ran an article on the GM brassica field test which included photos of an alleged GM flowering brassica plant. The photos had been taken by the Soil and Health Association at the field test site on Sunday 21 December 2008.

16. MAF visited on Wednesday 24 December 2008 where the Inspector took a photo of the stem that had been removed from the plant which was stored in a containment facility (see photo below), and reviewed the log of visits to the field test site.

17. The relevant controls in the approval are:

i) *Brassica oleracea plants shall be prevented from producing open flowers in the field test site. Plants identified as initiating bolting must either be immediately moved back into a containment structure or killed* (1.8).

ii) *All living brassica vegetative material the subject of this approval and not retained for research material shall be killed by composting, autoclaving or another scientifically validated method* (1.12).

18. MAF concluded that controls 1.8 and 1.12 of the approval had not been complied with, because a GM brassica plant had flowered and a brassica plant was growing out of the compost area.

19. On Wednesday 24 December Plant and Food Research removed all GM kale plants showing re-growth. Plants were removed from the field test site for autoclaving whilst brassica leaves were left to decompose on site.

20. MAF issued a retrospective Critical Situation Report (CSR) to Plant and Food Research on 13 January 2009 for non-compliance with the above controls and required Plant and Food Research to undertake the following corrective actions (see Appendix 2) :

i) All brassica GM field material to be removed and killed either by composting or autoclaving as per HSNO Act approval GMF06001 control 1.12 by 14 January 2009.

ii) An internal review of procedures in relation to HSNO Act approval controls to prevent this or similar non-conformances in the future by 26 January 2009.

21. On 13 January 2009 Plant and Food Research dug up and removed any remaining brassica root balls and all remaining non GM material from the buffer rows. The material was autoclaved, buried or composted. The site was ploughed the next day.

22. ERMA New Zealand registered the event as an incident on 15 January 2009 and recommended that an inquiry be conducted into the incident.

23. MAF received a draft report from Plant and Food Research on 26 January 2009, outlining Plant and Food Research's internal review of procedures in relation to HSNO Act approval controls to prevent this or similar non-conformances in the future (see Appendix 3).

24. On 5 February 2009, Plant and Food Research delivered its final internal review report to MAF. Also on that day, the Plant and Food Research review team advised MAF that its inspection of historical photos taken of the GM field test indicated that GM brassica may have flowered in February 2008.

25. On 11 February 2009 Plant and Food Research notified ERMA New Zealand that they had discontinued any further research under the GM brassica approval and suspended commencement of a separate field test of GM alliums (GMF06002).

26. In February 2009 MAF conducted an incursion response investigation. MAF concluded that it was unlikely that GM material had escaped the trial site, and there was a low risk that cross-pollination with non GM brassicas may have occurred at the trial site, and a very low risk that seed may have set at the site during 2008.

27. On 5 March 2009, MAF issued a Compliance Order (see Appendix 4), under section 104 of the Hazardous Substances and New Organisms Act, requiring Plant and Food Research to undertake action deemed necessary to avoid, remedy, or mitigate any actual or likely adverse effects on people or the environment resulting from the breach of controls. The Compliance Order required a five-year programme of surveillance and soil management confined to the trial site to detect and remove volunteer plants which might contain GM heritable material, and which could later be a source of escape of GM heritable material.

28. A special committee of the Environmental Risk Management Authority (the Authority) was set up on 5 March 2009, comprising Dr. Manuka Henare (chair), Richard Woods, Dr. Valerie Orchard, Dr. Shaun Ogilvie, Helen Atkins and Dr. Deborah Read. The committee agreed that an internal inquiry be conducted into the breach of controls of the GM brassica approval GMF06001 under Section 11(1)(e) of the HSNO Act 1996. The purpose was to review the breach of controls at the GM brassica field test site, and in light of the review inquiry to see if there are any lessons for other field tests.

29. Following the completion of the MAF incursion response investigation the MAF Enforcement Directorate undertook a criminal liability investigation which was completed in July 2009.

30. The MAF Enforcement Directorate found that whilst an offence was disclosed against section 109(1)(e)(i) of the HSNO Act 1996 the offence may be considered more of a compliance breach than criminal offending meriting a prosecution.

31. Accordingly a formal warning was given to the Field Trial Manager. No action against Plant and Food Research was considered appropriate in the circumstances by MAF.

ASSESSMENT OF INCIDENT

HSNO Act Controls

32. For field test applications, draft controls are sent to the applicant. The purpose of this is to ascertain how feasible the controls are and to ensure that they can be complied with. Crop and Food Research did not have any comments on the (above) two proposed controls for the GM brassica trial.

33. ERMA New Zealand sends the draft controls to MAF for comment. Throughout the application process, MAF and ERMA New Zealand liaised on the writing, workability and enforceability of the field test controls.

34. After the application was approved, and prior to the commencement of the field test, MAF, ERMA New Zealand, Crop and Food Research staff, and members of Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga met to discuss the controls to ensure everyone had a common understanding of the control requirements.

35. Control requirements were not met by Plant and Food Research. Plant and Food Research took responsibility for the non-compliance. Nevertheless ERMA New Zealand should consider the adequacy of the controls to determine whether they could be improved.

36. The questions asked by ERMA New Zealand when reviewing the adequacy of the GM brassica approval controls in this inquiry are as follows**:**

    i) Are the controls sufficiently clear that a reasonable person with no prior knowledge of the project would be able to understand them?;

    ii) If the controls had been met would the GM brassica have flowered and/or a brassica plant grown in the compost area?; and,

    iii) Notwithstanding points i) and ii) can the controls be made clearer?

Flowering of brassica

37. One of the key aspects of the field test was that the GM brassicas were not allowed to flower. To prevent this occurring control 1.8 was set:

    Brassica oleracea plants shall be prevented from producing open flowers in the field test site. Plants identified as initiating bolting must either be immediately moved back into a containment structure or killed.

38. ERMA New Zealand considers that:

    i) the control is sufficiently clear;

    ii) if the control had been met GM brassica would not have flowered;

    iii) the control wording could not be made clearer.

39. To ensure that GM brassicas do not flower staff involved in performing the monitoring need to be supervised by the organisation. The assurance was provided based on the Trial Manager's previous experience and the technical expertise of Crop and Food Research staff. ERMA New Zealand was assured that the flowering requirement was able to be met. Crop and Food Research stated to ERMA New Zealand in their application that:

> *Appendix 3 describes and illustrates in more detail the sequence of events clearly visible prior to any flowers opening in broccoli, cabbage, cauliflower and forage kale. This visually clear sequence of events and the use of trained staff to monitor the plants every 3-4 days will ensure that plants are removed from the field as they bolt, well before any flower would open.*

40. At the Hearing, the Authority heard from submitters about the practicalities of identifying flowering in brassicas. After consideration of ERMA New Zealand staff advice (Evaluation and Review report) to the decision-making committee, reading submissions, and hearing what was presented at the Hearing, the Authority set the following control (6.3) for monitoring of the site to detect the onset of bolting or early flowering:

> *During the period when GM brassicas are present in the field test site, the site shall be monitored to detect the onset of bolting or early flower opening using a scientifically validated method and staff appropriately trained in that method. Monitoring intervals shall be appropriate to the developmental stages of the brassicas to detect the onset of bolting or early flower opening. Any plants detected as initiating bolting or with early flower opening will be contained as set out in control 1.8.*

41. Based on the Crop and Food Research application ERMA New Zealand was assured that the monitoring requirement could be met. ERMA New Zealand considers that;

    i the control is sufficiently clear;

    ii) if the control had been met GM brassica would not have flowered;

    iii) the control wording could not be made clearer.

42. Crop and Food Research documented the proposed methods to detect the onset of flowering and bolting in the facility containment manual.

43. A MAF inspection on 30 January 2008 found that Crop and Food Research were monitoring for the onset of flowering and bolting every one to two days.

44. The first incident of non-compliance when a GM brassica plant was allowed to flower occurred in February 2008. This indicates that implementation of control 6.3 was not fully effective. The proposed method for monitoring the site for bolting or flowering plants was itself not assessed for its efficacy by the Trial Manager. Therefore the requirements of control 6.3 were not met as the monitoring method was not scientifically validated.

45. The second incident of non-compliance when a GM brassica plant was allowed to flower occurred in December 2008. GM kale which had been cut off above ground after harvest had regrown and one plant flowered.

46. In their application Crop and Food Research indicated that:

> *The trial will be harvested i.e. removal of entire plants, once marketable heads (approx. 10-15cm diameter) are produced and prior to the opening of any flower buds. The exact harvest date will vary between the different crop types relating to their different maturity dates.*

47. This method was documented in Crop and Food Research's containment facility manual. The Trial Manager deviated from the documented harvesting method by not removing the kale plants in their entirety at harvest, as was done with the broccoli, cauliflower and cabbage plants.

48. The Trial Manager had been conducting an experiment to determine the best way to kill the plants by: cutting the stumps at ground level; digging up stump and root ball to be left on the surface of the ground; composting in the compost bin; and by burying in the ground. All options except the compost bin showed re-growth.

49. One of the GM kale plants, in which the stems of the plants and the associated root system were left in the ground, subsequently flowered.

50. Control 1.12 of the approval states:

> *All living brassica vegetative material the subject of this approval and not retained for research purposes shall be killed by composting, autoclaving or another scientifically validated method.*

51. If this control could be interpreted without reference to the application and/or the containment facility manual it could be argued that the control allows for the experiment to determine the best way to kill kale plants. However this experiment should not have been conducted. The decision document for the approval states:

> *The Committee notes that control 1.12 requires that at the end of each growing season, all GM brassica plants have to be removed from the field test site, and those not retained for research purposes, shall be disposed of using a scientifically validated method*.

52. Nevertheless, even if the experiment was permitted, because the method for killing the brassica was being tested for its scientific validity, the level of uncertainty was high and the Trial Manager should have adjusted the monitoring of the site to suit the experiment. Therefore the monitoring intervals were not appropriate to the developmental stages of the brassica.

53. Broccoli, cabbage, cauliflower and kale are grown as annual crops. However, kale is biennial having a life cycle that normally takes two seasons from germination to senescence (death) of the plant. By not removing the kale in their entirety, the plants re-grew. In effect, the growing season was still continuing for the kale, and control 6.3 (see paragraph 40) still applied.

54. Instead, Crop and Food Research staff were visiting the site as if it were in post-harvest at intervals in line with the requirements of control 6.5, as follows:

> *At the end of each growing season, the entire field test site shall be monitored monthly to detect any GM volunteer plants. A log of these monitoring events shall be maintained and it shall record the date, details of any GM Brassica plants found and any action taken. Any volunteer GM plants found shall be removed and killed in accordance with control 1.12*.

55. Again, as for control 6.3, the proposed method for killing the brassica vegetative material under control 1.12 was not being monitored for its effectiveness, and thus was not scientifically validated. This resulted in the failure at the field test site whereby the GM kale were not being monitored at sufficient intervals to detect flowering.

56. Therefore ERMA New Zealand **recommends that an approval holder should demonstrate to MAF and/or ERMA New Zealand that new techniques used in the implementing of controls placed on a field test have been scientifically validated before the control is implemented.**

Composting of brassica control

57. The third non-compliance relates to the brassica plant observed by MAF on 22 December growing out of the compost area. MAF could not determine whether the plant was GM brassica or not. The requirements of control 1.12 had not been met:

> *All living brassica vegetative material the subject of this approval and not retained for research purposes shall be killed by composting, autoclaving or another scientifically validated method.*

58. ERMA New Zealand informed both MAF and the Trial Manager that, when composting was used, we expected all plant material to be mulched or shredded prior to composting. This was not done.

59. The intent of the control is that brassica material shall be killed. On this basis ERMA New Zealand considers that;

    i) the control is sufficiently clear;

    ii) if the control had been met a brassica plant would not have grown in the compost area;

    iii) however the control wording could be made clearer.

60. ERMA New Zealand recommends that **if the GM brassica field test approval is reactivated, before the field test is re-started, a minor amendment under section 67A of the Act be undertaken by ERMA New Zealand to reword control 1.12 of the approval to specify that plant material must be chipped, shredded or mulched before composting**.

Buffer row in relation to flowering control

61. ERMA New Zealand has identified an issue about control 1.8 of the GM brassica approval which states:

> *Brassica oleracea plants shall be prevented from producing open flowers in the field test site. Plants identified as initiating bolting must either be immediately moved back into a containment structure or killed.*

62. The control applies to **all** *Brassica oleracea;* this includes both the GM control and test plants, and the non GM buffer row brassica plants. The non GM buffer row plants included *Brassica oleracea* (wild type red broccoli, red cauliflower) plants and non-brassica plants.

63. MAF asked ERMA New Zealand twice whether buffer row plants were allowed to flower.

64. ERMA New Zealand advised that they could but did not make it sufficiently clear that only the non brassica buffer row plants could flower. As such, ERMA New Zealand's advice was incorrect and highlights the need to communicate expectations regarding controls.

65. The E&R Report proposed the following wording for the flowering control:

> *No GM or non GM plant belonging to the Brassica oleracea shall be allowed to produce any open flowers in the field test site. Any GM or non GM brassica identified as in the stage of initiating bolting in the field test site shall be removed before any flowers open and shall be either maintained in the containment structure or disposed of in accordance with control 1.12.*

66. ERMA New Zealand required that all brassicas, both GM and non GM, not be allowed to flower. By itself there was no risk with non GM brassica buffer row plants flowering. The rationale was that if either a GM plant was accidently planted amongst the non GM plants or if a GM volunteer was to grow amongst the non GM plants it would not be possible to recognise such a plant as GM, as it could be morphologically identical to the non GM. If such a GM plant could not be detected then it could potentially flower along with the non GM plants and release pollen from the containment facility.

67. A pragmatic reason for not allowing flowering was if non GM brassicas were allowed to flower this would significantly increase the number of volunteer plants in post harvest monitoring that would have to be examined to determine whether or not they were GM.

68. For the Decision ERMA New Zealand replaced '*No GM or non GM plant belonging to the Brassica oleracea shall be allowed to produce any open flowers in the field test site'* with '*Brassica oleracea plants shall be prevented from producing open flowers in the field test site* as it was considered that the wording was sufficiently clear in its intent.

69. ERMA New Zealand considers that;

i) the control is sufficiently clear;

ii) ERMA New Zealand provided partially incorrect advice to MAF in suggesting that non GM plants could flower;

iii) the control wording could be made clearer.

70. Although all work on GMF06001 has been discontinued by Plant and Food Research the approval is valid until 2017. ERMA New Zealand recommends that **if the GM brassica field test approval is reactivated, before the field test is re-started, a minor amendment under section 67A of the Act be undertaken by ERMA New Zealand to reword control 1.8 of the approval to clarify that GM and non GM brassica are not allowed to flower.**

71. ERMA New Zealand recommend that **for any future GM plant field test approvals, ERMA New Zealand specifies in the controls what type of plants, GM and non-GM, can and cannot flower.**

MAF enforcement response

72. MAF's activity has involved several groups or teams within the organisation. The Operations Group is responsible for the technical oversight and inspection of the field test containment facility. The Incursion Response Team was responsible for the risk analysis following the flowering. Following the incursion response the MAF Enforcement Group undertook a criminal liability investigation.

MAF inspection

73. MAF is required to audit the approval holder's systems and processes and measure whether these are sufficient to meet the requirements of HSNO Act controls. At inspection MAF will audit the relevant controls dependant on the current activities at the field test site; for example planting, flowering or harvesting. However, the onus is on the approval holder to meet and maintain the necessary systems.

74. Control 6.2 of the approval states:

> *The MAF Inspector may inspect and audit the field test site at any time to ensure the field test site is complying with this approval. The Operator shall arrange for inspection of the field test site and auditing of its operation to occur:*
>
> *(a) twice during the growing season, including at least once during the period when flowering could occur; and*
>
> *(b) once during the winter season if GM brassicas are planted in the field test site over the winter.*

75. In addition, section 103 of the HSNO Act provides powers of entry for inspection by an enforcement officer to monitor compliance with controls on any new organism in any premises where a new organism approved under the HSNO Act is located.

76. The number of inspections undertaken by MAF exceeded the minimum required by the approval control. Prior to the discovery of flowering GM brassica, MAF had visited the field test site on four occasions, conducting four inspections over a period of nine months.

77. The first planting occurred at the field test site in November 2007. The first MAF inspection on 11 December 2007 determined if the structural and operational requirements of the containment standard and HSNO Act controls were being met. During the audit the Operator and Facility approvals, transfer requests, internal and external audits, training records, field trial registers, access logs, plants and the field trial site were audited against the containment standard and approval controls. MAF was satisfied that the containment facility was operating in compliance with the approval controls.

78. Further inspections were conducted in January and May 2008. The inspections gave MAF confidence that GM plants were removed in a timely manner to prevent pollen being produced in the field. The findings were based on the regularity of recorded visits to the site, the expertise and training in flower structure identification, and the record of plants removed from the field back to the glasshouse.

79. The MAF inspection on 30 January 2008 focused on controls relevant to the monitoring of GM brassica for bolting and flowering. Crop and Food Research's records of the monitoring of brassicas for flowering and bolting were checked. Monitoring was occurring every one to two days throughout January. Inspection of the site confirmed that broccoli plants were within the flowering period and were being removed in a timely manner from the field test site. MAF did not observe any GM brassica flowering at the field test site. A set of training sheets was available on site, showing photographs of flowering and bolting stages for each type of brassica grown in the GM field test.

80. The MAF inspection on 8 May 2008 focused on controls relevant to the harvest of brassica plants from the site. However MAF also audited the facility for compliance with the controls relating to the flowering of brassica. MAF noted in the inspection report that staff had received training on flower initiation and flower development in each of the four different types of GM brassica. The differences between the four types mean that there are varying windows in which plants initiating bolting need to be removed from the field. The field test inspection log showed a minimum twice weekly monitoring of the site for the initiation of bolting. More frequent inspections occurred during the peak broccoli flowering season when daily visits were common.

81. In August 2008 severe weather conditions affected areas throughout the country. MAF undertook an inspection of the site on 7 August 2008 and determined that the field test site was in good condition. There had been no flooding at the site.

82. Following notification by the Soil and Health Association of the possibility that GM brassica were flowering MAF immediately visited the site (22 December 2008). MAF did not find any flowering GM brassica. The bud in question had been removed by the Trial Manager as part of routine monitoring in the morning before the visit. In addition MAF observed a brassica plant growing in the compost area.

83. MAF acted promptly once evidence of the non-compliance was identified. Following notification to MAF by the Trial Manager that the bud had flowered, a further visit to the trial site was undertaken by MAF on 24 December 2008. Photographs of the stem were taken by MAF. A subsequent visit was made by MAF in early February to view the ploughed site.

84. However for future field tests ERMA New Zealand recommends **that MAF should consider more frequently exercising its right to make non-notified visits to field test sites, particularly at critical periods such as when plants may bolt or flower.**

85. **ERMA New Zealand recommends that in order to ensure controls are fully understood, workable and implemented in practice, ERMA New Zealand should be available to attend MAF inspections of field test sites, especially in the first year of operation.**

MAF Incursion response

86. In February 2009 MAF conducted an incursion response following the flowering incident. They visited Plant and Food Research and viewed field test documentation and the site. MAF undertook a risk analysis relating to the potential release of GM brassica pollen in New Zealand. MAF considered the risk of GM brassica crossing with GM brassica, and GM brassica crossing with non-GM brassica.

87. The MAF incursion response team concluded that although two flowering events widely separated in time had been identified, nothing suggested the simultaneous flowering of GM plants, and that seed setting had not occurred.

88. MAF considered that potentially heritable material from GM brassica plants could only be present as seed where GM brassica had crossed with non GM brassica. MAF considered a number of factors including: the timing of flowering, wind dispersal and pollen escape on pollinating insects, and concluded that the most probable location of hybrid seed, if present, would be within the field test site.

MAF Enforcement Response

89. On 5 March 2009, MAF issued a Compliance Order (see Appendix 4), under section 104 of the Hazardous Substances and New Organisms Act, requiring Plant and Food Research to undertake action deemed necessary to avoid, remedy, or mitigate any actual or likely adverse effects on people or the environment resulting from the breach of controls. This followed the MAF incursion response conducted at the site.

90. The Compliance Order required a five-year programme of surveillance and soil management confined to the trial site to detect and remove volunteer plants which might contain GM heritable material, and which could later be a source of escape of GM heritable material.

91. Following the incursion response MAF Enforcement conducted a criminal liability investigation into the non-compliance with controls. MAF found that the Trial Manager had not ensured that all controls had been complied with in that a flowering of a GM kale plant occurred in December 2008 and vegetative matter was not disposed of as prescribed. The flowering of a GM broccoli plant in February 2008 was also a non-compliance with controls.

92. The above breaches of the containment controls were prima facie evidence that the Trial Manager had committed an offence under section 109(1)(e)(i) of the HSNO Act. The investigation did not find any criminal liability on the part of the Directors or Officers of Plant and Food Research.

93. After considering the facts of the case MAF determined that the appropriate enforcement response was to issue a formal warning to the Trial Manager of Plant and Food Research. MAF were satisfied that Plant and Food Research had taken steps to mitigate any risks and to put into place procedures to prevent further incidents.

New Zealand Institute of Plant and Food Research Ltd response

94. The HSNO Act control was clear that no GM brassica plants were allowed to flower yet Plant and Food Research's internal controls were not sufficient to prevent this occurring.

95. ERMA New Zealand considers that there was insufficient organisational oversight of the field test or support for field test staff.

96. Plant and Food Research accepted responsibility for non-compliance with the HSNO Act controls and took ownership for the lack of organisational oversight of the GM field test.

97. Plant and Food Research immediately ceased all field trial work on the GM Brassica field test and suspended all other planned GM field trials.

98. After MAF issued the CSR, Plant and Food Research addressed both the corrective actions within MAF's required timeframe. All brassica GM field material was removed and killed by 14 January 2009 and the internal review of procedures in relation to HSNO Act approval controls was conducted by 26 January 2009.

99. The reasons for the breakdown in systems and the chain of events leading to the non-compliance are discussed comprehensively in the Plant and Food Research internal review and will not be reiterated in detail in this inquiry.

100. Plant and Food Research's review report proposed a number of changes designed to improve systems for compliance with HSNO Act approvals across the organisation. The following proposals have been actioned by the organisation:

- the establishment of a Compliance Coordinator who will report to the Chief Operating Officer, to ensure high level institutional oversight and management of compliance, including implementation of appropriate policies and procedures, and training and auditing;
- instituting a policy that the Operator, Manager and Technical Manager of all GM field trials are all different people, thereby ensuring a high level of independent oversight;
- all GM field trials shall involve a multi-disciplinary project team which will meet at regular intervals to review progress; and,
- that the Operator of a containment facility should be a sufficiently senior person to ensure that all GM field trial projects are sufficiently resourced.

101. ERMA New Zealand considers that these measures should assist to prevent a similar recurrence of non-compliant activity for any future field test approvals held by Plant and Food Research.

102. ERMA New Zealand is of the view that any organisation working with new organisms, and not just specific for field tests, should ensure that management have in place checks and balances to ensure HSNO Act requirements are met; and actively support researchers.

103. As standard practice for future field tests ERMA New Zealand **recommends that MAF should consider meeting with approval holders before the commencement of any future approved field test to determine that organisational oversight for the field test is in place.**

104. We note that MAF is the agency responsible for enforcing the new organisms provisions of the Act and ERMA New Zealand cannot require MAF to undertake any compliance activity but, as part of our oversight responsibility, we can make recommendations about the compliance regime for MAF's consideration.

Interaction with Tangata Whenua

105. The HSNO Act requires the Authority in its decision-making to take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga.

106. Ngāi Tahu is Tangata Whenua of the area where the field test was being conducted. Te Rūnanga o Ngāi Tahu (TRoNT) requested regular updates on the field test. This was formalised by Authority with the following control (7.8):

> *The applicant shall provide a specifically written annual update to Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga by 31 July each year during the approval period. This update shall provide information on the progress of the field test and explain how the applicant is addressing any cultural issues raised by Ngāi Tahu in relation to the field test research. A copy of this report should also be provided to Ngā Kaihautū Tikanga Taiao.*

107. To meet the requirements of the control, the approval holder must seek to form and maintain a relationship with Tangata Whenua. ERMA New Zealand considers that it is the approval holder's responsibility to keep Tangata Whenua up to date with progress of the field test.

108. Following identification of the non-compliance at the field test site Plant and Food Research notified the TRoNT HSNO Committee on 12 January 2009 of media coverage. A copy of Plant and Food Research's internal review was also forwarded to TRoNT.

109. TRoNT also expected ERMA New Zealand to communicate with them about the non-compliance at the GM brassica field test site. In March TRoNT advised ERMA New Zealand that it was not kept sufficiently informed of the non-compliance with controls and subsequent activity by MAF and ERMA New Zealand.

110. On 12 March 2009 the Chair of the Authority, Richard Woods, sent a letter of apology to the chairman of the TRoNT HSNO Committee. ERMA apologised for failing to notify Ngāi Tahu of the breach of controls and for not updating Ngāi Tahu on what actions had been taken to mitigate any risk at the field test site. From this point on ERMA New Zealand liaised with the TRoNT HSNO Committee on the progress of MAF's investigation and actions undertaken by ERMA New Zealand.

111. On 3 June 2009, Plant and Food Research senior managers met with TRoNT offering an official apology for the GM breach and to discuss concerns and areas where communication could be improved**.**

112. Upon review of this incident we consider that the approval holder is responsible for liaising with Tangata Whenua about field test activities and ERMA New Zealand is responsible for communicating with Tangata Whenua about any compliance or enforcement activity related to the field test.

113. As part of this inquiry we sought comment from TRoNT on our draft inquiry report. TRoNT commented that the language needed to be strengthened for recommendation 6 to state that "for future field tests MAF must exercise its right to inspect field test sites, and document these visits to ERMA". We agree with the intent of TRoNT's comment but note that ERMA New Zealand can only recommend for MAF to undertake an action.

114. ERMA New Zealand recommends **that representatives from Te Rūnanga o Ngāi Tahu, Plant and Food Research, MAF, and ERMA New Zealand discuss their interactions in relation to the GM brassica field test. The purpose of this is to identify their respective roles and responsibilities, and expectations regarding their interactions for any future field tests.**

Interest group activity

115. The non-compliance with controls was first discovered by representatives of the Soil and Health Association which had been on the site without permission from Plant and Food Research in order to observe the GM field trial.

116. We note that without their observation the non-compliance may not have been identified for some time.

117. However, the interest group itself breached the containment controls of the approval by venturing onto the field test site. Both MAF and Plant and Food Research took no enforcement action on this occasion. ERMA New Zealand registered the unauthorised access to the site as an incident.

118. ERMA New Zealand does not condone **anyone**, including interest groups, entering field test sites without appropriate approval.

CONCLUSION

119. Plant and Food Research were clearly in non-compliance with the controls of the GM brassica approval. However Plant and Food Research accepted responsibility for the non-compliance and took ownership for the lack of organisational oversight of the GM field test. They have initiated a number of changes designed to improve systems for compliance with HSNO Act approvals across the organisation.

120. ERMA New Zealand concurs with the Plant and Food Research research internal review recommendation that all future GM field trials shall involve a multi-disciplinary project team which includes agronomists, plant protection specialists, as well as the immediate Project Manager, Operator and Senior Manager. If this structure were in place for the brassica field test the potential for serious non-compliance to occur would have been minimised. Organisational oversight and support by the approval holder is critical to ensure compliance with HSNO Act controls.

121. MAF is required to audit the approval holder's systems and processes and measure whether these are sufficient to meet the requirements of HSNO Act controls. At inspection MAF will audit the relevant controls dependant on the current activities at the field test site; for example planting, flowering or harvesting. The onus is on the approval holder to meet and maintain the necessary systems. The number of MAF inspections of the field test site exceeded the minimum required by the approval control.

122. ERMA New Zealand has recommended that MAF should consider meeting with approval holders before the commencement of any future approved field test to determine that organisational oversight for the field test is in place. Further, MAF should also consider more frequently exercising their right to make non-notified visits to field test sites, particularly at critical periods such as when plants may bolt or flower.

123. MAF responded promptly when the non-compliance with controls was identified and their enforcement response was thorough and appropriate to address any risk. The immediate response was to ensure all GM material was killed and for Plant and Food Research to address their internal systems. The next step was for MAF to undertake an incursion response when a risk analysis relating to the potential release of GM brassica pollen in New Zealand was undertaken. MAF Enforcement undertook a criminal liability investigation. MAF decided not to prosecute the Trial Manager and instead issued a formal warning to the Trial Manager of Plant and Food Research.

124. MAF's enforcement response is dependent on a number of factors; in this case Plant and Food Research accepted responsibility for non-compliance with the HSNO Act controls and took ownership of the lack of organisational oversight of the GM field test. As such MAF was satisfied that Plant and Food Research had taken steps to mitigate any risks and to put into place procedures to prevent further incidents.

125. ERMA New Zealand has identified that the wording of two controls for the GM brassica approval could be made clearer and accordingly have recommended they be reworded by a technical amendment under section 67A of the HSNO Act if the approval holder re-activates use of the approval. ERMA New Zealand has recommended that we specify what types of plants, GM and non GM, can and cannot flower. ERMA New Zealand is satisfied that the controls are adequate to manage risk.

126. ERMA New Zealand recommends that in order to ensure controls are fully understood, workable and implemented in practice, that ERMA New Zealand should be available to attend MAF inspections of field test sites, especially in the first year of operation.

127. The approval holder should demonstrate to MAF and/or ERMA New Zealand that new techniques used in the implementing of controls placed on a field test have been scientifically validated before the control is implemented.

128. Following the non-compliance at the GM brassica field test site we acknowledge that MAF and ERMA New Zealand did not keep local iwi sufficiently informed of the non-compliance with controls and subsequent activity by our organisations. ERMA New Zealand's learning from this review is that we can improve our processes about notification of incidents to local iwi. We view this as an opportunity to develop positive relationships accordingly, have recommended that we discuss our interactions post the GM brassica field test incident in order to identify our respective roles and responsibilities, and expectations for any future field tests.

GM ALLIUMS CONTROLS

129. On 27 November 2008 an application (GMF06002) from Crop and Food Research was approved to field test over 10 consecutive years, the vegetable allium species onion, garlic and leek with genetically modified agronomic and quality traits in order to assess their performance in the field and investigate the environmental impacts of these plants.

130. Between the writing of the controls for the GM brassica Decision and the controls for the GM alliums Decision ERMA New Zealand fundamentally restructured the layout of the controls; the GM allium controls were grouped by field test activity, ordered in a more logical sequence for the life cycle of the field test. The purpose of this was to assist the approval holder to meet the control requirements and for MAF to audit compliance with the controls (see Appendix 5). ERMA New Zealand seeks to incorporate lessons learnt from the operation of controls to write more effective controls.

131. ERMA New Zealand has commenced using the word 'approval holder' instead of 'the Operator' in controls. This is to stress that the responsibility for complying with controls is that of the organisation, not solely the responsibility of the Operator of a containment facility.

132. ERMA New Zealand's comment on the GM alliums controls concerns those controls equivalent to those identified as problematic for the GM brassica approval, as follows.

Planting of seeds

133. ERMA New Zealand notes that for the GM allium approval the buffer row plants can not be alliums, thus removing the possibility for any confusion as with the GM brassica approval:

> *The Operator must ensure that GM alliums are easily recognisable by the planting in the buffer row of morphologically different species (eg, have different foliage) in the adjacent plots. The Operator must ensure that no GM plants of any species and no GM or non-GM alliums are used in any buffer rows.*

Disposal of plant material from the field containment facility

134. The wording of the composting control for the GM alliums approval is more detailed about the Authority's expectations and is prescriptive about the activity required to kill plants:

> *The Operator must ensure that all living GM allium material, either plants or parts of plants, from the field containment facility is killed on-site by composting within a closed container (following chipping, shredding or mulching of material) or another scientifically validated method or transferred to a PC2 containment facility for further research or to be killed. The Operator must ensure that all GM allium material retained for further research purposes is contained under the relevant HSNO Act containment approval for these organisms once they are transferred to the PC2 containment facility.*

Reporting

135. ERMA New Zealand notes that for the GM alliums approval two controls instead of one have been set by the Authority about the relationship between the approval holder and Tangata Whenua. These controls extend the responsibility of Plant and Food Research compared with the control set for the GM brassica approval, as follows:

> *The applicant shall provide a specifically written annual update to Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga by 31 July each year during the approval period. This update shall provide information on the progress of the field test and explain how the applicant is addressing any cultural issues raised by Ngāi Tahu in relation to the field test research. A copy of this report should also be provided to Ngā Kaihautū Tikanga Taiao.*
>
> *Crop and Food Research must provide documented evidence of regular engagement and participation in the field test programme of Te Taumutu Rūnanga to a mutually agreed level to ERMA New Zealand.*

Scientifically validated methods

136. ERMA New Zealand recommended (see paragraph 56, page 10) that the approval holder should demonstrate to MAF that new techniques used in the implementing of controls placed on a field test have been scientifically validated before the control is implemented (recommendation 1). For the GM alliums approval the following controls (3.4, 8.1 and 9.2) require the activity to be scientifically validated:

> *The Operator must ensure that all GM alliums planted in the field containment facility exhibit the approved traits by the use of scientifically validated methods*.
>
> *The Operator must ensure that all living GM allium material, either plants or parts of plants, from the field containment facility is killed on-site by composting within a closed container (following chipping, shredding or mulching of material) or another scientifically validated method or transferred to a PC2 containment facility for further research or to be killed. The Operator must ensure that all GM allium material retained for further research purposes is contained under the relevant HSNO Act containment approval for these organisms once they are transferred to the PC2 containment facility*.
>
> *The Operator must ensure the detection of the onset of bolting or early flower opening by monitoring of the field containment facility, during the period when GM alliums are present. The Operator must ensure that scientifically validated methods are used for monitoring and that staff are trained to detect the onset of bolting or early flower opening. The Operator must ensure that, if bolting or early flower opening is detected, the entire flower head or the whole plant is disposed of as set out in control 8.1. The only exception to control 9.2 are GM A. cepa plants approved under this decision for seed production and these are subject to controls 7.1 – 7.11*.

Conclusion

137. ERMA New Zealand is satisfied that the wording of the controls for the GM alliums approval should assist to prevent similar issues as identified with the GM brassica approval. However it is not always possible to 'second guess' potential issues with the wording of controls. Hence our recommendation that in order to ensure controls are fully understood, workable and implemented in practice, ERMA New Zealand should be available to attend MAF inspections of field test sites, especially in the first year of operation.

Manuka Henare 14 October 2009

Richard Woods 14/10/2009

Dr. Manuka Henare Date	Richard Woods Date
Chair	Chair
Ad hoc Standing Committee	Authority

Appendix 1: Terms of Reference – Ad hoc Standing Committee

Membership: Manuka Henare (chair), Richard Woods, Shaun Ogilvie, Helen Atkins, Deborah Read, Val Orchard.

As agreed by the Committee on 5 March 2009 the terms of reference for the Committee are:

1. The receipt and consideration by the committee of reports from Plant and Food Research, the Ministry of Agriculture and Forestry and the agency in relation to the breaches of controls at the Plant and Food Research GM brassica field test site, Lincoln.

2. The agency, on behalf of the Committee, will undertake an internal inquiry into non-compliance with controls by the approval holder of the GM brassica field test approval.

3. The inquiry will:
   - investigate the adequacy and practicality of the Decision controls;
   - examine the adequacy of compliance and enforcement procedures;
   - identify any issues within or caused by the provisions of the HSNO Act and Regulations, such types of controls;
   - carry out a parallel review of the Decision controls applied to the GM alliums Decision (application code GMF06002); and,
   - consider communication responsibilities to local iwi and hapu stakeholders.

4. The inquiry may:
   - investigate the competency of enforcement officers;
   - examine the adequacy of ERMA New Zealand's policies, including the Methodology, protocols and codes of practice, and administrative procedures; and,
   - investigate the adequacy of other legislation and management systems that impact the safe management new organisms.

5. The Committee will disband once the inquiry is complete and inquiry recommendations are agreed to by the committee.

6. Oversight on the progress of actioning recommendations will be conducted by the GMO Standing Committee.

5 March 2009

Manuka Henare (Chair) Date

Appendix 2: MAF Critical Situation Report.

BIOSECURITY NEW ZEALAND

Critical Situation Report (CSR)

CONTAINMENT FACILITY: Plant & Food Research	**CONTAINMENT FACILITY OPERATOR:** Mary Christey **STANDARD(S) BEING AUDITED:** *Containment Facility for Plants: 2007*	
IMPACT NUMBER: 5356 (ATF: 16603)		
DEPARTMENT AND/OR ROOM: N/A		
BASIS OF AUDIT: Notification from public that GM *Brassica* plants were flowering in Plant & Food Research's field trial site. **ERMA/IBSC APPROVAL: GMF06001**		
AUDITOR: Meghan Heaphy (BSI)	**AREA: Canterbury**	**DATE: 24/12/08**

BACKGROUND:

On the afternoon of the 22/12/08 Soil & Health Association member informed MAF Biosecurity New Zealand (MAFBNZ) that *Brassica* plants from GMF06001 field trial site were flowering.
MAFBNZ inspection of the field trial site occurred shortly after this phone call. MAFBNZ observed Kale plants (GM and non-GM) growing in the field trial and one *Brassica* plant was observed growing in the composting area. There were no GM field trial plants observed flowering. The kale plants (GM and non-GM) observed in the field trial site were re-growth of the field trial plants grown from cut stumps.

At the time of this inspection MAFBNZ were unaware that a GM stem had been removed from the field test site earlier in the day during Plant & Food's routine inspection of the site (as discussed below).

At 9pm on the 23/12/08 MAFBNZ received a phone call from the operator of the field trial stating that after seeing Soil & Health's photos, a GM stem which they had removed on the 22/12/08 due to the stem initiating bolting (during routine inspection of the field trial site) was re-inspected. It was determined that this stem did have an elongated pistil structure, indicating that flowering had occurred.

On the 24/12/08 MAFBNZ inspected the stem that had been removed from the GM plant and it shows bolting had occurred with one long pistil structure developed in one area indicating that an open flower had been produced in the field.

MAFBNZ was notified in early September that the final harvest of kale plants was completed by either composting them in a bin, dug into the ground or left on the surface to rot away.

NON-CONFORMANCES:

The following quotes in italics are taken from HSNO Act approval GMF06001 controls.

Control 1.2 states "*Responsibility for conducting the field test shall be held by an Operator approved in accordance with section 40 of the Biosecurity Act 1993, and the Operator shall be responsible for ensuring that all controls are complied with*".

Control 1.8 states "*Brassica oleracea plants shall be prevented from producing open flowers in the field test site. Plants identified as initiating bolting must either be immediately moved back into a containment structure (control 1.4) or killed (control 1.12)*".

Control 1.12 states "*All living brassica vegetative material the subject of this approval and not retained for research purposes shall be killed by composting, autoclaving or another scientifically validated method*".

Plant & Food containment manual (dated October 2007) states *"At harvest, the buffer rows of non-transgenic plants surrounding the field test will be harvested via hand picking and composted. The plants in the experimental plots will be individually hand lifted and picked. As each plant is removed the details will be recorded to ensure that all plants are accounted for. Any plants in the experimental plots with bolting heads will be completely removed before flowering and autoclaved or the whole plant transferred to the containment glasshouse in secured bag for counting and weighing of heads and plants. Within a week following harvest, the site will be thoroughly checked to ensure that no plants have been left in the soil..."*

SIGNED ..... (OPERATOR) SIGNED Maxleay (MAF Inspector)

CORRECTIVE ACTION REQUIRED:

1) All GM *Brassica* field trial material to be removed and killed by either composting or autoclaving as per HSNO Act approval GMF06001 control 1.12.

2) An internal review of procedures in relation to HSNO Act approval controls to prevent this or similar non-conformances in the future.

DATE CORRECTIVE ACTION TO BE COMPLETED BY: 1) 14th January 2009
2) 26th January 2009

SIGNED Maxleay **(MAF Inspector)**
DATE: 14/01/09

Please note a follow up inspection to this critical situation will be conducted on : TBA

PROOF OF CORRECTIVE ACTION CLOSURE:

1) Email dated 13/01/09
2) Received draft internal review report on 26/01/09
   Received final internal review report on 09/02/09

CLOSURE OF CRITICAL SITUATION:

The CSR report is closed.
Further follow-up action may be taken by MAFBNZ.

DATE 18/2/09 **SIGNED.** Maxleay **(MAF Inspector)**

Appendix 3: Plant and Food Research internal review of procedures in relation to HSNO Act approval controls: ERMA approval GMF06001 Bt Brassica field test.

Internal review of procedures in relation to HSNO Act approval controls: ERMA Approval GMF06001 *Bt Brassica* Field Test

Stevens P, Ashby N, Griffin W, Lewis D, Ferguson I.

January 2009

A report prepared for:
MAF – Biosecurity New Zealand

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Plant and Food Research, Auckland

Lewis D.
Plant and Food Research, Palmerston North

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Plant and Food Research, Lincoln

Plant & Food Research Report SPTS No 2146
Milestone number: 29581

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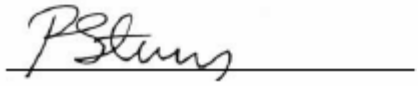
Plant & Food RESEARCH
RANGAHAU AHUMĀRA KAI

This report has been prepared by The New Zealand Institute for Plant and Food Research Ltd (Plant & Food Research), which has its Head Office at 120 Mt Albert Rd, Mt Albert, AUCKLAND. This report has been approved by:



Group Leader, Bioprotection
Date: 5 February 2009

Introduction

On 25 May 2007, the New Zealand Institute of Crop and Food Research (Crop & Food Research) received approval to carry out a field test in containment of genetically modified (GM) organisms under the Hazardous Substances and New Organisms (HSNO) Act 1996. ERMA Approval GMF06001 involved field testing of cabbage, broccoli, cauliflower and kale plants modified for resistance to caterpillar pests like cabbage white butterfly and diamondback moth. Planting of the field test commenced in November 2007 and subsequent audits carried out by MAF BNZ between 11 December 2007 and 7 August 2008 found no non-conformances or required corrective actions.

However, this review was instigated as a result of a Critical Situation Report (CSR) issued by MAF- Biosecurity New Zealand (MAF-BNZ) on 24 December 2008 (see Appendix 1). MAF-BNZ issued the CSR following an audit of GM Brassica plants triggered by notification by a member of the public that some plants in the field trial site were flowering. The ERMA approval for this GM field trial has explicit controls in place to ensure that plants do not produce open flowers in the field.

Crop & Food Research merged with The Horticulture and Food Research Institute of New Zealand Ltd (HortResearch) on 1 December 2008 to form The New Zealand Institute for Plant and Food Research Ltd (Plant & Food Research). Immediately following the notification of this breach, Plant & Food Research's newly appointed Chief Operating Officer (responsible for all science operations and staff) took direct control of the response and *inter alia* suspended all GM field trials pending the outcome of the CSR process and a full internal investigation and review.

An internal review team was convened to complete an internal review of procedures relating to HSNO Act approval controls to prevent non-compliances. To ensure independence, the review team was chaired by a member of staff previously from HortResearch, who had no involvement in this or any other GM field trials, but who was familiar with issues relating to compliance and containment. Members of the internal investigation team were as follows:

- Philippa Stevens (Chair) – Group Leader - Bioprotection
- Ian Ferguson – Chief Scientist
- Bill Griffin – Science Group Manager – Plant Breeding & Improvement
- David Lewis – Scientist, Member of Crop & Food Research Institutional Biological Safety Committee (disbanded 30 December 2008 and responsibilities being assumed by new Plant & Food Research compliance framework)
- Nick Ashby - Acting Science Group Manager – Plant and Food biotechnology Group.

The terms of reference for the internal review team are provided in Appendix 2. This report describes the findings of the review and recommendations for corrective actions.

Purpose

To complete an internal review of procedures in relation to HSNO Act Approval controls to prevent this or similar non-conformances in the future.

Process

Members of the internal review team conducted interviews with key personnel responsible for conducting the field trial, as well as line management staff. Discussion with ex-Crop & Food Research staff associated with the trial also took place. Relevant documentation such as the Containment Manual, the Environmental Risk Management Authority Decision (including the detailed controls associated with the Approval) and record sheets were used as a basis for conducting interviews to assess conformance with Approval controls and for developing recommendations for follow-up actions. In conducting the interviews the review team sought 1) to confirm the accuracy of the items of non-conformance identified in the CSR report, 2) to compile information to understand the root causes of the non-conformances and 3) to identify most effectively suitable corrective actions. A set of recommendations for immediate corrective actions were identified as well as proposed changes for improved policies, procedures, individual/management roles and responsibilities aimed at avoiding future non-compliances.

Detailed description of critical situation

The review team has documented below a history of events leading to the critical situation identified in the CSR report issued on 24 December 2008 in order to understand clearly the nature of any non-conformances and to identify appropriate corrective actions.

1. **25 May 2007**. Crop & Food Research was granted approval for field trial GMF06001.
2. **29 November 2007**. First planting (340 plants) under this approval commenced. ERMA New Zealand and the MAF Inspector informed, thereby meeting the requirements of control 7.1 of application GMF06001.

   > *Control 7.1. ERMA New Zealand and the MAF Inspector responsible for supervision of the field test site must be notified in writing when this approval is used for the first time. This field test must commence within five (5) years of the date of this decision.*

3. **11 December 2007.** MAF-BNZ audit of compliance – no corrective actions identified.
4. Additional plantings were made in mid December (72 plants) and late January 2008 (156 plants).
5. **30 January 2008.** MAF-BNZ audit of compliance – no corrective actions identified.
6. **8 May 2008.** MAF-BNZ audit of compliance – no corrective actions identified.
7. **31 July 2008.** Crop & Food Research provided ERMA New Zealand with a report summarising trial results. Harvesting of all plants except for 107 forage kale plants was completed by 31 July 2008 and is detailed in this report (available on the ERMA website).
8. **7 August 2008.** MAF-BNZ audit of compliance following recent severe storms in Canterbury – no corrective actions identified. Over half the 232 forage kale plants had already been harvested by cutting the stems leaving the remaining plant material and root structure but no comments or corrective actions raised.
9. **2 September 2008.** The Trial Manager in Crop & Food Research notified the MAF Inspector that *"we have just completed the final harvest of the kale plants from the field trial. No plants were brought back to the GMO facility but were either put in a compost bin on site, dug into the ground or left on the surface to rot away."*.

   Discussion with the Trial Manager in this review indicated that the above-ground parts of the kale plants were harvested at this time to assess dry matter composition. These data were part of the investigation into agronomic performance of the plants in the trial. Harvesting comprised cutting the stems leaving approximately 150 mm of stem and the associated root system in the ground. The Trial Manager consulted another Crop & Food Research staff member who has expertise in forage brassica to determine normal field practice for harvesting/removing a field of forage kale. She was given the advice

that commercial field practice involves cutting the plants at the stem. The Trial Manager asserts that she was not told that stem cutting was followed by ploughing of the field, although later realised that stem cutting followed by ploughing is normal commercial field practice for removing forage kale. Based on the advice received, the Trial Manager concluded that the harvesting of above-ground parts was an appropriate means of ensuring that the plants were killed and did not expect the cut stems to be capable of producing reproductive growth.

10. **September-December 2008.** The Trial Manager and her technician continued to monitor the field site regularly postharvest. The dates of the monitoring visits and any comments listed in the field trial records are shown in the table below.

Date of post harvest trial monitoring	**Summary of Comments**
26 September 2008	Routine check. Side shoots noted.
1 October 2008	Routine check. No comments.
9 October 2008	Routine check. Side shoots noted.
17 October 2008	Routine check. Two budding apices removed to autoclave bag.
22 October 2008	Routine check. All OK.
10 November 2008	Routine check. All OK.
5 December 2008	Routine check. Two side shoots with closed buds noted.
16 December 2008	Routine check. Regrowth noted and photographed.
22 December 2008[1]	1. Routine check by Trial Manager (est. 1200 – 1300 h) and photographs taken. 2. Audit by MAF (1600-1730 h).

[1]See more details in text below.

11. **21 December 2008.** One this day Steffan Browning, Soil and Health Association spokesperson, claims to have visited the trial and photographed a kale flowering stem that had regrown from a plant cut at ground level (described in Soil & Health Association/GE Free New Zealand Joint Media release 12 January 2009).

12. **22 December 2008.** At midday, the Trial Manager carried out a routine inspection, accompanied by a Plant & Food Research staff photographer. The dates and times on the photographs indicated photographs were taken by between 12:52 and 13:01 h. During this visit the Trial Manager noted that regrowth on one of the cut stems had

initiated bolting and had flower buds on it, so it was immediately removed and placed in an autoclave bag. The Trial Manager has consistently stated that no evidence of open flowers was observed at this time. The autoclave bag was left at the trial site, as the Trial Manager did not have a permit to transfer it to the autoclave for disposal.

According to the MAF-BNZ Critical Situation report, on the afternoon of the same day, Steffan Browning phoned MAF-BNZ to inform them that brassica plants from the GMF06001 field trial site were flowering. Two MAF-BNZ Inspectors initiated an inspection of the site firstly by contacting the Acting Science Group Manager of the Plant and Food Biotechnology Group at approximately 1545 h and then proceeding to the field trial site for an audit (1600-1730 h). During the audit the MAF-BNZ Inspectors were accompanied by the Senior Technician associated with the trial and the Trial Manager arrived at about 1715 h. The MAF Inspector noted in the CSR report that at the time of the audit they were not aware that the Trial Manager had removed a stem from a kale plant earlier in the day. During the inspection MAF-BNZ Inspectors observed GM and non-GM kale plants growing in the field regrowing from stems cut just above ground level. There were no GM plants observed to be flowering.

It was reported that Steffan Browning revisited the site that night and photographed the remains of the broken-off stem (described in Soil & Health Association/GE Free New Zealand Joint Media release 12 January 2009).

13. **23 December 2008**. David William's of *The Press* forwarded Steffan Browning's photographs to the ex-Crop and Food (*sic*. Plant & Food Research) Corporate Communications Manager. The photographs were shown to the Trial Manager who determined that there was a possibility that one structure visible may have been the remains of an open flower but was not able to confirm from the photograph. This prompted the Trial Manager to return to the site to re-inspect the stem that had been placed in autoclave bag the previous day. On re-inspecting the Trial Manager noted that there was an elongated structure which indicated that one floret had indeed flowered. The Trial Manager stated that she had not noticed this structure at the time that she removed the flower bud stem. The Trial Manager informed the Acting Science Group Manager and the Chief Operating Officer of Plant & Food Research at approximately 2100 h that night and was instructed by them to telephone the MAF Inspector immediately, to inform her of this situation, which she did by approximately 2100 h.

14. **24 December 2008.** An article by David Williams, together with photographs appeared in *The Press*.

The MAF-BNZ Inspector returned to the field site in the morning and took photographs of the stem that had been taken off the plant and had been re-inspected by the Trial Manager the previous evening. The CSR report notes that inspection of the stem indicated that bolting had occurred and one elongated pistil structure had developed, indicating that an open flower had been produced in the field. The MAF Inspector noted that the Trial Manager/Operator had told them on this day that they had been conducting an 'experiment' to determine the best way to kill the plants by 1) cutting stumps at ground level; 2) digging up stump and root ball to be left on the surface of the ground; 3) composting in compost bin; 4) buried in compost area in ground. This was a major

deviation to procedures and the Trial Manager/Operator told MAF that all options, except the compost bin, showed re-growth.

All remaining GM kale stems exhibiting regrowth were dug up and autoclaved; other kale plants not exhibiting re-growth were left on site.

15. **12 January 2009.** A press release from Steffan Browning on behalf of Soil and Health stated that they would revisit the site on this day, which he duly did together with Claire Bleakly from GE Free NZ, Radio NZ, TV1 and TV3 reporters and cameraman. No one from Plant & Food Research was present and they apparently climbed over a locked gate on the access track and filmed from outside the fence around the trial. Steffan claimed that at least one experimental plant and one buffer row plant were still evident amongst the weeds.

16. **13 January 2009**. The Trial Manager worked with several other Plant & Food Research staff to dig up and remove any remaining root balls and all remaining non-GM plant material from the guard rows. Most of the material was autoclaved, although small amounts were buried or composted to assess the rate at which decomposition would occur under these treatments. The site was then ploughed on 14 January 2009.

Analysis of non-conformances in CSR

The CSR identified the following non-conformances from HSNO Act approval GMF06001 controls (boldface type has been added to highlight key points):

Control 1.2 states "*Responsibility for conducting the field test shall be held by an operator approved in accordance with section 40 of the Biosecurity Act 1993, and the Operator shall be responsible for ensuring that all controls are complied with*".
Control 1.8 states "*Brassica oleracea plants* ***shall be prevented from producing open flowers in the field test*** *site. Plants identified as initiating bolting must either be immediately moved back into a containment structure (control 1.4) or killed (control 1.12)*".
Control 1.12 states *"All living brassica vegetative material the subject of this approval and not retained for research purposes shall be killed by composting, autoclaving or another scientifically validated method".*
Crop & Food Research containment manual (dated October 2007) states *"At harvest, the buffer rows of non-transgenic plants surrounding the field test will be harvested via hand picking and composted. The* ***plants in the experimental plots will be individually hand lifted and picked****. As each plant is removed the details will be recorded to ensure that all plants are accounted for. Any plants in the experimental plots with bolting heads will be completely removed before flowering and autoclaved or the whole plant transferred to the containment glasshouse in secured bag for counting and weighing of heads and plants. Within a week following harvest, the* ***site will be thoroughly checked to ensure that no plants have been left in the soil****…"*

Analysis of trial records indicated that a key decision was taken by the Trial Manager in September 2008 that resulted in the subsequent non-compliance. It is the view of the review team that the decision by the Trial Manager to harvest the forage kale by cutting the plants off at the stem, and then not subsequently to dig out the remaining stem and roots was a serious error of judgement. It is noted that the Trial Manager was conducting an experiment to determine the best way to kill the plants and Crop &Food management was not aware that this was taking place.

The immediate causes of this error of judgement appear to be driven by two factors:

1. Relatively limited resourcing of the project and other research commitments requiring input at the time of harvest meant that the Trial Manager was under time pressure
2. Given this time constraint, the Trial Manager appears to have relied on informal advice from another staff member, who was not fully aware of the compliance conditions, as to whether stem cutting of forage kale would be sufficient to ensure the 'removal' of forage kale plants, and prevent bolting and flowering. In taking this advice, the Trial Manager concluded, without checking with the MAF Inspector, her managers, or any other party, that the harvesting method used had effectively resulted in 'removal' of viable plants from the field site.

Discussion

Although this harvesting method had already been used prior to the audit carried out by the MAF Inspector on 7 August 2008, and no comments or concerns were raised then, the Trial Manager was in error not explicitly to discuss this. In a trial of this nature, where management of the plants is critical, the proposed approach for ensuring all forage kale plants were effectively removed from the trial site should have been more widely discussed with suitable agronomists and the MAF Inspector, especially as the approach taken was not one described in the Containment manual. The issue is compounded by the fact that the advice received was not in fact complete, and while cutting forage kale stems may indeed be standard commercial practice, this is always followed by ploughing. In addition, the communication with the MAF Inspector at the time of harvest of above-ground plant parts in September was not sufficiently detailed to alert the MAF Inspector that some follow-up was required. The Trial Manager also stated that she did not realise that regrowth of 'vegetative' shoots from the cut stems was a problem, and had made an incorrect assumption that such plants would only produce vegetative growth. In fact, the Trial Manager was regularly recording regrowth of 'vegetative' shoots between September and December but had not informed anyone of this.

It is also the view of the review panel that Crop & Food Research did not have sufficient checks and balances in place for the duration of the trial beginning from 29 November 2007. As there was essentially no formal independent oversight of the trial, the Trial Manager's error of judgement was not identified at an early stage before there was a risk of regrowth from the cut stems of forage kale. The review team considers that this was a significant cause of the non-conformance.

A contributing factor to the lack of sufficient Crop & Food Research organisational oversight was that the Trial Manager was also the Trial Advisor and the Operator. Separation of these roles would have ensured greater oversight for the trial.

In addition, the Trial Manager had several changes of line manager over the course of the previous 12 months and it appears that none of her line managers had regularly visited the site. The Crop & Food Manager leading the Team where the Trial was domiciled, had assumed that all GM material had been removed in September, but had not verified this by visiting the site.

There is no evidence of internal auditing of this field trial by Crop & Food Research, despite reference to internal auditing in the containment manual. The Biological Safety Officer of the Institutional Biological Safety Committee (IBSC – since disbanded) was not specifically aware of an expectation that he was required to conduct internal audits of this field trial, despite being named in the containment manual.

In summary, the Trial Manager appears to have been working in isolation on this work with little oversight from Crop & Food Research management, so the fact that documented systems in manuals were not being adhered to was not identified by the organisation.

Furthermore, on the 5 February 2009 the review team and Plant & Food Research management were advised that re-inspection of historical photos by the Trial Manager on the 5 February 2009 indicated that earlier breaches of controls may have occurred. This discovery has further reinforced our dissatisfaction with the way this trial has been conducted and justifies the immediate application to cancel the approval of the Operator (recommendation 1), suspension of all GM field trials (recommendation 3) as well as the other associated recommendations (see next section).

Recommendations for Corrective Actions

As a result of this review, a number of corrective actions and recommendations are proposed. The specific non-conformances that these seek to address are also summarised in the Table below.

1. Taking into account the serious error of judgement of the Trial Manager (who was also the Operator and Trial Advisor) it is recommended that Plant & Food Research apply to MAF to cancel the current Operator approval relating to this work and suspend all further work under this approval.
2. As a serious error of judgement by an individual person was identified as a significant contributor to the non-conformance, it is recommended that a subsequent investigation on the conduct of the Trial Manager is carried out as prescribed in the relevant Terms and Conditions of Employment.
3. Noting the range of issues identified in this review of ex-Crop & Food Research's operation of Approval GMF06001 for a *Bt Brassica* Field Test, it is strongly recommended that Plant & Food Research suspends all other GM field trials until restructuring and confirmation of roles and responsibilities with respect to compliance are completed, to ensure proper organisational oversight.
4. Although the scope of this review specifically related to non-conformance with Approval GMF06000, it is recommended that Plant & Food Research undertakes a thorough review of all systems and Policies relating to conduct of GM Field trials and other research that involves compliance.
5. Taking into account the recent formation of Plant & Food Research, the review team endorses the current restructuring proposal to establish a new position of "Compliance Coordinator", to report directly to the Chief Operating Operator, to ensure high level institutional oversight and management of compliance, including implementation of appropriate policies and procedures, training and auditing.
6. It is recommended that Plant & Food Research institute a policy that the Operator, Manager and Technical Manager of all GM field trials are all different people, thereby ensuring a higher level of independent oversight.
7. It is recommended that all future GM field trials shall involve a multi-disciplinary project team which includes agronomists, plant protection specialists, as well as the immediate Project Manager, Operator and Senior Manager and this team meets quarterly to review progress. Minutes of these meetings should be taken and filed with trial records.
8. It is recommended that the containment manuals for all future GM field trials should be revised to outline explicit procedures for internal audits and to include a checklist for the audits (see example attached in Appendix 3). This section should replace the current brief reference in the Containment manual for GMF06000 to the role of the BSO and the IBSC which has been disbanded with the merger of Crop & Food Research and HortResearch.

9. It is recommended that the internal auditing process for GM (and other HSNO) compliance should form part of Plant & Food Research's overall internal audit and risk management framework under the responsibility of the Chief Finance Officer and ultimately the Board of Directors' Audit and Risk sub-committee.
10. It is recommended that the Operator of containment facilities should be a sufficiently senior person to ensure all GM field trial projects are adequately resourced, including ensuring that staff involved in internal audits are resourced and trained to carry out this role.
11. It is recommended that the Operator is responsible for ensuring that all GM field trials have a detailed project plan signed off by the appropriate Senior Manager in advance, and that this plan outlines the critical points in the trial life-cycle where internal audits will be pre-scheduled (e.g. planting, harvesting).
12. It is recommended that Trial Managers provide the approved project plan to MAF-BNZ Inspectors at the start of each season to clarify expectations and timing of inspections.

Table 1. Summary of non-conformances identified by MAF, root cause identified and proposed action. Further details are provided above.

Control Number	Description of non-conformance	Root cause of non-conformances	Proposed corrective action
1.2	Operator did not ensure compliance with all controls	Operator did not follow documented systems and procedures Lack of independent oversight over trial and very little separation between trial management and trial conduct	• Taking into account the serious error of judgement of the Trial Manager (who was also the Operator and trial advisor) it is recommended that Plant and Food Research apply to MAF to cancel the current Operator approval relating to this work and suspend all further work under this approval. • It is recommended that Plant & Food Research institute a policy that the Operator, Manager and Technical Manager of all GM field trials are all different people, thereby ensuring a higher level of independent oversight. • It is recommended that all future GM field trials shall involve a multi-disciplinary project team which includes agronomists, plant protection specialists, as well as the immediate Project Manager, Operator and Senior Manager and this team meets quarterly to review progress. Minutes of these meetings should be taken and filed with trial records. • It is recommended that the containment manual for all future GM Field trials should be revised to outline explicit procedures for internal audits and include a checklist for the audits (see example attached). This section should replace the current reference to the role of the BSO and the IBSC which has been disbanded with the merger of Crop and Food Research and HortResearch. • It is recommended that the Operator of containment facilities should be a sufficiently senior person to ensure all GM field
1.8	Plants permitted to produce open flowers	Serious error of judgement by Trial Manager in using an inappropriate method for removing kale plants from the field, relying on advice without discussing/checking with Inspector Time pressure and small project team were contributing factors. Insufficient training in and awareness of policies and procedures	
1.12	Material not being retained for research purposes was not killed in prescribed way	Serious error of judgement by Trial Manager in using an inappropriate method for removing kale plants from the field, relying on advice without discussing/checking with Inspector	

			trial projects are adequately resourced, including ensuring that staff involved in internal audits are resourced and trained to carry out this role. • It is recommended that the Operator is responsible for ensuring that all GM field trials have a detailed project plan signed off in advance by line management up to and including the COO, and that this plan outlines the critical points in the trial life-cycle where internal audits will be pre-scheduled (e.g. planting, harvesting). • It is recommended that Trial Managers provide the approved project plan to MAF-BNZ Inspectors at the start of each season to clarify expectations and timing of inspection.

Appendix 1

Critical Situation Report (CSR)

CONTAINMENT FACILITY: Plant & Food Research	**CONTAINMENT FACILITY OPERATOR:** Mary Christey
IMPACT NUMBER: 5356 (ATF: 16403)	**STANDARD(S) BEING AUDITED:** *Containment Facility for Plants: 2007*
DEPARTMENT AND/OR ROOM: N/A	

BASIS OF AUDIT: Notification from public that GM *Brassica* plants were flowering in Plant & Food Research's field trial site.

ERMA/IBSC APPROVAL: GMF06001

AUDITOR: Meghan Heaphy (BSI)	**AREA: Canterbury**	**DATE: 24/12/08**

BACKGROUND:
On the afternoon of the 22/12/08 Soil & Health Association member informed MAF Biosecurity New Zealand (MAFBNZ) that *Brassica* plants from GMF06001 field trial site were flowering.
MAFBNZ inspection of the field trial site occurred shortly after this phone call. MAFBNZ observed Kale plants (GM and non-GM) growing in the field trial and one *Brassica* plant was observed growing in the composting area. There were no GM field trial plants observed flowering. The kale plants (GM and non-GM) observed in the field trial site were re-growth of the field trial plants grown from cut stumps.

At the time of this inspection MAFBNZ were unaware that a GM stem had been removed from the field test site earlier in the day during Plant & Food's routine inspection of the site (as discussed below).

At 9pm on the 23/12/08 MAFBNZ received a phone call from the operator of the field trial stating that after seeing Soil & Health's photos, a GM stem which they had removed on the 22/12/08 due to the stem initiating bolting (during routine inspection of the field trial site) was re-inspected. It was determined that this stem did have an elongated pistil structure, indicating that flowering had occurred.

On the 24/12/08 MAFBNZ inspected the stem that had been removed from the GM plant and it shows bolting had occurred with one long pistil structure developed in one area indicating that an open flower had been produced in the field.

MAFBNZ was notified in early September that the final harvest of kale plants was completed by either composting them in a bin, dug into the ground or left on the surface to rot away.

NON-CONFORMANCES:

The following quotes in italics are taken from HSNO Act approval GMF06001 controls.

Control 1.2 states "*Responsibility for conducting the field test shall be held by an Operator approved in accordance with section 40 of the Biosecurity Act 1993, and the Operator shall be responsible for ensuring that all controls are complied with*".

Control 1.8 states "*Brassica oleracea plants shall be prevented from producing open flowers in the field test site. Plants identified as initiating bolting must either be immediately moved back into a containment structure (control 1.4) or killed (control 1.12)*".

Control 1.12 states "*All living brassica vegetative material the subject of this approval and not retained for research purposes shall be killed by composting, autoclaving or another scientifically validated method*".

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Plant & Food containment manual (dated October 2007) states *"At harvest, the buffer rows of non-transgenic plants surrounding the field test will be harvested via hand picking and composted. The plants in the experimental plots will be individually hand lifted and picked. As each plant is removed the details will be recorded to ensure that all plants are accounted for. Any plants in the experimental plots with bolting heads will be completely removed before flowering and autoclaved or the whole plant transferred to the containment glasshouse in secured bag for counting and weighing of heads and plants. Within a week following harvest, the site will be thoroughly checked to ensure that no plants have been left in the soil..."*

SIGNED ..... (OPERATOR) SIGNED ..... (MAF Inspector)

CORRECTIVE ACTION REQUIRED:

1) All GM *Brassica* field trial material to be removed and killed by either composting or autoclaving as per HSNO Act approval GMF06001 control 1.12.

2) An internal review of procedures in relation to HSNO Act approval controls to prevent this or similar non-conformances in the future.

DATE CORRECTIVE ACTION TO BE COMPLETED BY: 1) 14th January 2009
2) 26th January 2009

SIGNED ..... (MAF Inspector)
DATE: 16/01/09

Please note a follow up inspection to this critical situation will be conducted on : TBA

PROOF OF CORRECTIVE ACTION CLOSURE:

CLOSURE OF CRITICAL SITUATION

DATE ..... **SIGNED**..... **(MAF Inspector)**

Appendix 2

TERMS OF REFERENCE

Investigation and follow up of breach of controls of GM Brassica field trial

19 January 2009

Purpose
To complete an internal review of procedures in relation to HSNO Act Approval controls to prevent this or similar non-conformances in the future

Outcome
A report to SMT containing assessment of causes of breach and recommendations on follow-up action.

Note that all GM field trials are suspended pending completion of this investigation and actions are put in place to prevent recurrences.

Process
1. Convene an internal review team to consult with:
   - Scientific, operational and management staff responsible for GM Brassica field trial as well as additional staff where appropriate (including Mary Christey, Robert Bruan, Jan Grant, Matthew Cromey, Colin Eady, Steve Lorimer, Prue Williams)
   - MAF and ERMA staff
   - Communications staff (Roger Bourne)
   - Chief Operating Officer.

2. Develop draft recommendations and provide to relevant staff for feedback including:
   - Identification of the root causes of the compliance failures
   - Recommendation of immediate corrective actions to deal with the identified causes
   - Recommendations for improvements to policies, procedures, review and monitoring processes, and/or individual and management roles and responsibilities, aimed at avoiding future compliance failures.

3. Consider feedback and revise recommendations.

4. Provide set of recommendations to SMT for consideration by the morning of Monday 26 January 2009.

Proposed Team Composition
Philippa Stevens (Chair), Nick Ashby, Bill Griffin, David Lewis, Ian Ferguson.

Timelines
Report to be with SMT by 26 January 2009.
MAF deadline for internal review 26 January 2009.

Appendix 3

DRAFT AUDIT/CHECK LIST FOR PLANT & FOOD RESEARCH GM FIELD TRIALS

Operators

1. Named Operator understands responsibilities and actions
2. Named Trial Manager understands responsibilities and actions
3. Named training officers understand responsibilities and actions
4. Appropriate MAF and ERMA officials identified
5. List of permanent or long-term staff authorised and trained to work on the trial maintained
6. List of temporary staff and visitors authorised and trained to work/visit on the trial maintained.

Prior to trial commencement

7. Structure of the containment facility appropriate and complies with MAF and ERMA requirements
8. Operating procedures used appropriate and comply with MAF and ERMA requirements
9. Containment Manual developed and approved by MAF prior to commencement of the field test
10. MAF has a copy of current version of the Containment Manual
11. Trial Manager has a copy of the current version of the Containment Manual
12. ERMA and the MAF notified in writing when this approval is used for the first time
13. Copies of correspondence with ERMA held, verified by inspector at audit.

Review

14. Internal 6-monthly audit of all systems completed by Operator with all appropriate staff and recorded
15. All changes documented and inserted into the front of the Containment Manual and controlled copied of the manual to be updated. Any major procedural changes need prior approval from MAF Inspector.
16. Version number and issue date of Containment manual recorded on each page
17. Master document held and if changes become numerous, new issues distributed to all appropriate staff
18. On anniversary of commencement of the field trial, staff involved with facility read the Containment Manual and reviewed procedures. Staff are evaluated to ensure understanding of the manual and procedures.

19. 6-monthly MAF audit ensured, including access to all appropriate staff and records
20. Containment Manual updated as directed by MAF.

Change of "Operator"

21. MAF and ERMA informed of any matters which may affect the long-term management of the field test including:
    - Changes in the key personnel such as the Trial Manager or Operator
    - Changes in the management structure of Plant & Food Research that may affect the management of the field test
    - Any event or circumstance that would affect the capacity of Plant & Food Research to meet the requirements of the controls agreed
    - Changes in the land use or ownership
    - Verification from ERMA and MAF of receipt of such notification and copies all such correspondence held by Plant & Food Research.

Training

22. Confirm training officers
23. All trainees listed
24. Training schedules signed and dated by trainees and trainers.

Trial Site

25. Confirm the field test site size
26. The boundaries of the containment facility in which the field test is conducted are marked by a permanent feature (or GPS location details)
27. Fence erected capable of excluding public access and large grazing animals (for example sheep, cattle and other large herbivores) to the field test site
28. Gates closed at all times and locked whenever there are no authorised persons present
29. Small grazing animals (for example rabbits and birds) excluded by enclosing the trial site with weed cloth, installing bird scaring devices at appropriate developmental stages, and spraying the plant materials with appropriate commercial bird repellent
30. Staff only access those areas for which they are trained
31. All equipment used within the field test site cleaned after use
32. All staff footwear cleaned before exit
33. Security monitoring of the field test site carried out regularly
34. Site location provided confidentially to appropriate stakeholders (e.g. Iwi, direct neighbours)
35. All site visitors logged and accompanied by an approved user at all times.

Plant material

36. MAF supplied with details of all lines to be tested, at least thirty working days prior to proposed planting dates
37. Prior to planting, MAF verified details of lines to be tested against the approved organism description and confirmed with the Operator
38. Plant & Food Research hold copy of correspondence with MAF
39. Trial confined to named plant species and introduced genes
40. Plant material confirmed as GM seedlings, or GM cuttings derived from plants grown from seed or cuttings from *in vitro* shoots
41. Register of GM lines planted and grown in the field maintained
42. The Plant Register recorded:
    - Identity of plant lines (species, cultivar or breeding line and details of genetic modification)
    - Identity of person responsible for the plant(s)
    - Date of planting in the field position of each plant within the field test site
    - Date of transfer of plant(s) or viable plant material to and from the containment structure and the field date and method of final disposal of plant(s)
43. Plants used in the buffer rows not genetically modified and phenotypically different from the GM brassicas planted at the same location.

Plant material transfer

44. Permit for plant transfer to or from the field obtained from MAF
45. Single/multiple transfer approval obtained at MAF discretion
46. All plant material transferred securely and under double containment
47. Inventory of all plant materials transferred checked to ensure nothing lost in transit, including accounting for all GM seed
48. If discrepancy noted, then Contingency Plan implemented
49. All plant transfers recorded and verified by MAF Inspector at 6 monthly audit
50. All plants in containment reconciled with Plant Register at 6 monthly audit.

Trial period

51. Trial site monitored every 3-4 days during period of active plant growth to detect the onset of bolting or early flower opening
52. No GM plants or any other food crops grown within the field test site consumed by any person, or deliberately fed to animals (other than insect species that may be the subject of this field test and related research)

53. Experimental plants individually hand lifted, picked, recorded, moved back into containment within sealed autoclave bags, including all bolted plants and any apical flower buds
54. All postharvest assays and extractions performed within the containment greenhouse facility or containment biotechnology laboratories
55. On completion of these assays, all plants autoclaved or re-potted and kept for seed production
56. Autoclaving at 10 psi for at least 20 minutes, or killed in the field by composting
57. Autoclaved material disposed of into general rubbish
58. Autoclave marine certification carried out annually by a registered inspector
59. All GM and control plant parts harvested from the field and not required for further propagation or analysis placed in autoclave bags and killed as above
60. Field test site inspection and audit by MAF arranged:
    - Twice during the growing season, including at least once during the period when flowering could occur
    - Once during the winter season if GM plants are planted in the field test site over the winter
61. Monitoring log kept and available for MAF inspection, including:
    - Date of monitoring inspections and name of the inspector
    - Number of bolting or early flowering plants detected, and action taken to contain these materialsany
    - Unanticipated discrepancy in the number of GM plants remaining in the field test site
    - If an unanticipated discrepancy is found, notification of MAF within 24 hours and all non-test plants found recorded
    - If any non-test plants are found , management and disposal as above
62. On completion of each growing season field test, or in the event of premature ending of the field test, MAF informed
63. On completion of each growing season field test, or in the event of premature ending of the field test, all GM plants not retained for research purposes killed in accordance with above
64. All buffer row plants and any rotational crops planted within the field test site composted on the field test site, or ploughed into the field test site
65. Within a week following harvest, site thoroughly checked to ensure that no plants have been left in the soil
66. On completion of each growing season field test, or in the event of premature ending of the field test, the field test site left fallow for the remainder of the season
67. In the following season, site sown with a cover crop (such as grass or cereal)

68. The site monitored monthly for at least one year following removal of the last GM plant

69. All volunteer GM plants found during this monitoring removed and killed as above

70. These monitoring events logged; recording date, details of any GM plants found and actions taken.

Reporting

71. Written report on the progress of the field test provided to ERMA 31 July of each year during the approval and monitoring period. Information requirements will be as agreed with ERMA and may include, but not be limited to:

    - Field test activities
    - Any unanticipated events
    - Any issues with controls
    - Proposed activities for the next year where relevant
    - Any relationship development and management initiatives undertaken with local Iwi
    - All educational and public awareness activities undertaken with Māori more generally
    - All educational and public awareness activities undertaken with community groups
    - All scientific publications, conference presentations and key findings resulting from this field test, including impacts research.

72. Specifically written annual update to appropriate Maori groups provided by 31 July each year during the approval period. This update shall provide information on the progress of the field test and explain how the applicant is addressing any cultural issues raised by Maori in relation to the field test research. A copy of this report should also be provided to Ngā Kaihautū Tikanga Taiao.

Contingency Plan

73. Process for managing the retrieval or killing of any viable material, and provision for natural disasters verified by MAF during approval process

74. Any interference with the field test site or any non-compliance with agreed controls, whether an approved organism escapes from containment or not, notified to the MAF Inspector responsible for supervision of the field test site within 24 hours.

Completion of Trial Site Approval period

75. XX consecutive calendar years from the first planting, all GM plants removed from field test site and final post-harvest monitoring commenced

76. ERMA notified of date of cessation of field test, including postharvest monitoring period

77. Copies of correspondence with ERMA held by Plant & Food Research
78. One inspection (minimum) by MAF to verify that no further volunteers are growing – at a time deemed appropriate (possible late spring/early summer) plus further audit if re-growth occurs (equates to 11 years (minimum): 10 years + 1 year postharvest monitoring)
79. If during the initial monitoring period, any volunteer GM plants are found, the monitoring will be extended for a further X years from the date when the last volunteer GM plant is found
80. For the duration of this monitoring period, no material of the GM species planted and the entire field test site shall be monitored monthly to detect any GM volunteer plants
81. These monitoring events logged; recording date, any GM plants found and actions taken
82. Any volunteer GM plants found removed and killed as above
83. Field test postharvest monitoring concluded
84. Field test site deregistered following MAF approval and verification in writing that the field test site released from postharvest monitoring and site registration cancelled
85. All trial site operation records and processes maintained for a minimum of 5 years following deregistration.

Appendix 4: MAF Compliance Order issued under the authority of the HSNO Act 1996.

BIOSECURITY NEW ZEALAND

5 March 2009

The New Zealand Institute for Plant & Food Research Limited
Mt. Albert Research Centre
120 Mt. Albert Rd.
Mt. Albert
Auckland 1025

To Whom It May Concern:

COMPLIANCE ORDER ISSUED UNDER AUTHORITY OF THE HSNO ACT 1996

In accordance with section 104 of the Hazardous Substances and New Organisms Act 1996 I hereby serve you with the attached Compliance Order.

Please feel free to direct any questions you have regarding the Order to me. My direct dial number is 04 894 4209. I have also sent a copy of the Order and this letter to Nick Ashby.

Yours faithfully

Angela Kidd
Enforcement Officer

Copy to: Nick Ashby

Ministry of Agriculture and Forestry
Te Manatū Ahuwhenua, Ngāherehere

MAF BIOSECURITY NEW ZEALAND
BORDER STANDARDS
Pastoral House, 25 The Terrace, 2526, Wellington, 6140, New Zealand
Telephone: 64-4-894 0100, **Facsimile:** 54-4-894-0728, **Web:** www.biosecurity.govt.nz

COMPLIANCE ORDER

(ISSUED UNDER AUTHORITY OF THE HAZARDOUS SUBSTANCES AND NEW ORGANISMS ACT 1996)

Section 106, Hazardous Substances and New Organisms Act 1996

To: The New Zealand Institute for Plant & Food Research Limited
Mt Albert Research Centre
120 Mt Albert Road
Mt Albert
Auckland 1025

1. The reasons for this order are:

To require The New Zealand Institute for Plant & Food Research Limited to undertake action that is necessary to avoid, remedy, or mitigate any actual or likely adverse effects on people or the environment resulting from the breach of controls imposed by an approval granted under the Hazardous Substances and New Organisms Act 1996 (ERMA application code GMF06001), namely controls 1.8 and 1.12. The text of these controls is as follows:

1.8 *Brassica oleracea* plants shall be prevented from producing open flowers in the field test site. Plants identified as initiating bolting must either be immediately moved back into a containment structure (control 1.4) or killed (control 1.12).

1.12 All living brassica vegetative material the subject of this approval and not retained for research purposes shall be killed by composting, autoclaving or another scientifically validated method.

2. The action required to be taken is:

Within a site comprising the trial plot, the guard rows or buffer zone and adjacent shed, composting and burial areas (referred to here as the controlled site), follow the actions described here and in Schedule 1:

i. The contents of the compost bin and the top layer of soil on which the compost bin is located is to be transferred to autoclave bags and destroyed by autoclaving
ii. Leave the controlled site soil undisturbed for a period of approximately 18 months, i.e. without ploughing, sowing or other cropping. This measure to ensure any inadvertently buried immature seed would decompose
iii. During this 18 month period apply a regime of broadleaf-selective herbicide to kill any germinating brassicas, at a frequency preventing emerging brassica from flowering
iv. Also during this 18 month period, on a monthly basis visual surveillance, removal and destruction of Brassica volunteer plants within the controlled

site. Note: it is recognised that sward management will significantly impact the effectiveness of surveillance

v. In Spring, 2010, and at intervals described in (d) of this notice, until Autumn 2013, the ground to be ploughed to a depth of 30 cm, and irrigated within 7 days if there is insufficient rain to stimulate germination of dormant seeds. Sufficient rain is defined as greater than 5mm.

vi. Visual surveillance, removal and testing for GM construct of Brassica volunteer plants within the controlled site to be undertaken at 3 to 5 weeks after each ploughing. Testing to be conducted at a MAF approved facility

vii. Cleaning, wash-down and dusting of machinery and implements visiting the site

viii. Detailed recording of plants observed and removed, Records of testing completed and results of testing

ix. Appropriate audit of these measures, coordinated with any MAF Facilities Approval and ERMA post-harvest monitoring protocol requirements

x. Cycle of surveillance to be continued for up to 5 years after the last detection of GM construct Brassica volunteers at the controlled site.

3. The date on or before which action must be taken or cease is:

3.1 The timing of the actions required will comply with the following table:

Date	*Soil management*	*Volunteers*	*Comment*
2009-2010	Soil undisturbed	Apply broadleaf selective herbicide in a regime to be approved by an Enforcement Officer. Monthly search for volunteers	Broadleaf herbicide application programme to be agreed. Buried immature seed decomposes
2009-2010	Soil undisturbed	Monthly search	Buried immature seed decomposes
Spring 2010, no later than end September.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Dormant seed stimulated to germinate then any volunteers tested for GM construct
Summer 2010/11, no later than end December.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Testing of brassica volunteers for GM construct
Autumn 2011, no later than end February.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Testing of brassica volunteers for GM construct
Spring 2011, no later than end September.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Testing of brassica volunteers for GM construct

Summer 2011/12, no later than end December.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Testing of brassica volunteers for GM construct
Autumn 2012, no later than end February.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Testing of brassica volunteers for GM construct
Spring 2012, no later than end September.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Testing of brassica volunteers for GM construct
Summer 2012/13, no later than end December.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Testing of brassica volunteers for GM construct
Autumn 2013, no later than end February.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Testing of brassica volunteers for GM construct
Spring 2013, no later than end September.	Plough, then irrigate within 7 days if insufficient rain	Search conducted at 3-5 weeks after ploughing	Testing of brassica volunteers for GM construct

3.2 No action is required to be taken before the **12th of March 2009**

4 The rights of appeal under section 125 of this Act;

You have the right to appeal to the District Court against the whole or any part of this order by lodging a notice of appeal with the District Court in Christchurch in accordance with section 125 of the Hazardous Substances and New Organisms Act 1996, not later than the 14th of April 2009. If you lodge an appeal you may apply to the District Court for a stay of the compliance order until the determination of the appeal.

5. The name of the enforcement officer serving this notice is:

Angela Kidd

6. The name and address of the agency whose enforcement officer served this order is:

Ministry of Agriculture and Forestry
Pastoral House
PO Box 2526
25 The Terrace
Wellington
New Zealand

Note: If you do not comply with this order or do not lodge a notice of appeal with the District Court you may be liable to prosecution under section 109 of the Hazardous Substances and New Organisms Act 1996

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Angela Kidd
Enforcement Officer

5th March 2009

Appendix 5: GM alliums controls

The purpose of this approval is:

> *To field test over 10 consecutive years, the vegetable allium species onion, garlic, and leek with genetically modified agronomic and quality traits in order to assess their performance in the field and investigate the environmental impacts of these plants.*

Organism Description:

Host organism:
Allium cepa L. (onion, shallot), *Allium fistulosum* L. (spring onion), *Allium ampeloprasum* L. (leek), *Allium sativum* L. (garlic), seedlings, bulbs, cloves or seeds (*Allium cepa* only)
Modified using:
Standard plasmid vectors used in plant transformation.
Genetic material may be:
Genomic or complementary DNA derived from plants, bacteria, fungi, animals and viruses (see exclusions).
Regulatory elements, reporter and selectable marker genes and other features:
All elements will be commonly used in plant transformation and include: • Promoters (constitutive or inducible) (such as CaMV35S, OCS, NOS, Ubiquitin promoter, Actin promoter, promoters isolated from onion genome) • Operators • Regulatory elements (including RNAi sequences) • Binding and enhancer sequences (eg, TMV omega enhancer sequence) derived from plants, bacteria or plant viruses Other features associated with insertion or removal of foreign genetic material or with gene or protein expression. Limited to the following: • Multiple cloning sites • Polyadenylation signals • Splice sites • Transcriptional activators • Transcriptional responsive elements • Transcriptional terminator sequences • Secretory and targeting signals • Intron signals that function to increase gene expression • Recombination sites and flanking sequences • Insulator elements Fluorescent or colourimetric reporter genes such as: • green fluorescence protein (gfp) • gus

Selectable marker genes such as:

- antibiotic resistance genes (eg, *nptII*, *hyg*)
- herbicide resistance genes (eg, *bar*, *CP4*)
- nutrient selectable genes (eg, *pmi*)

Characteristics of the plants field tested (Approved Traits):

Plants may be field tested if they are modified for the following characteristics (as shown by appropriate laboratory or glasshouse tests):

- decreased susceptibility to one or more allium insect pest
- decreased susceptibility to one or more allium fungal or bacterial pathogen
- decreased susceptibility to one or more allium viral pathogen
- decreased susceptibility to one or more herbicide
- altered pungency, colour or carbohydrate metabolism
- inducible flowering (flowering only after the application of a chemical inducer)

Plants may produce RNA silencing-inducing sequences or short sequences to be used as enzyme inhibitors.

Multiple traits may be stacked as long as the combination of traits does not fall under the exclusions of the organism description.

Null segregant offspring of the above GM plants can be used in the field test.

Exclusions :

Plants with the following modifications will not be field tested:

- Modifications that use DNA from humans or from native flora and fauna.
- Modifications that would result in the production of known vertebrate toxins or the production of infectious viral particles.
- Modifications that result in alliums which do not have true-to-type phenotypes in relation to flowering and seed characteristics (except for alliums modified for delayed or chemically-induced flowering as described in control 3.3).

In order to provide for the matters detailed in Part I of the Third Schedule to the Act, *Containment Controls for Importing, Developing or Field Testing of Genetically Modified Organisms*, the approved organisms are subject to the controls set out below.

References to providing information or reports to ERMA New Zealand shall mean the Chief Executive of ERMA New Zealand or any such other person nominated by the Authority for this purpose.

The terms Operator and Inspector have the meanings given in the MAF/ERMA New Zealand Standard *Containment Facilities for Plants:2007*[1] (the Plant Containment Standard).

[1] Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand.

The terms 'containment structure' and 'containment facility' have the same meaning as defined in section 2(1) of the Act.

1 Requirements of the MAF-ERMA New Zealand Standard:

1.1 The containment facility for the field test ('the field containment facility') must be managed and approved as a containment facility under section 39 of the Biosecurity Act 1993.

1.2 The field containment facility must be operated and maintained in accordance with all of the following controls, and the MAF/ERMA New Zealand Standard *Containment Facilities for Plants: 2007*[2] (the Plant Containment Standard).

1.3 Responsibility for conducting the field test must be held by an Operator approved in accordance with section 40 of the Biosecurity Act 1993. The Operator is responsible for ensuring that the field containment facility and authorised staff meet all the relevant requirements of the Plant Containment Standard and the controls listed in this Appendix. The containment facility manual must be updated to incorporate all these controls.

1.4 The Operator must ensure that the MAF Inspector has access to inspect and audit the field containment facility at any reasonable time to ensure the field containment facility is in full compliance with this approval. The Operator must arrange for inspection of the field containment facility and auditing of its operation to occur twice during the growing season:

(a) at least once during the period when flowering could occur; and

(b) once during the winter season if GM alliums are planted in the field containment facility over the winter.

2 Integrity of containment:

2.1 The Operator must ensure that at all times only persons authorised by the Operator shall have access to the field containment facility. The Operator must maintain measures to restrict unauthorised access to the field containment facility that include:

(a) a fence that restricts public access by enclosing the site in which the GM alliums are to be planted;

(b) gates must be closed at all times and locked whenever there are no authorised persons present; and

(c) a record of the entry of authorised personnel into the field containment facility.

2.2 The Operator must ensure that the integrity of the fence enclosing the site[3] is maintained at all times.

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[2] Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand.

2.3 The Operator must ensure that no visible vegetative GM allium material can escape on equipment removed from the field containment facility.

2.4 The Operator must ensure the contingency plan for the retrieval or killing of any viable GM allium material that has escaped is implemented immediately in the event of release of viable GM allium material from the field containment facility.

2.5 The Operator must ensure the MAF Inspector is informed within 24 hours of the discovery of any interference with the field containment facility or any non-compliance with the controls, whether or not viable GM allium material has escaped from containment.

3 Approval of GM allium material for planting:

3.1 The Operator must obtain from the MAF Inspector, approval (under section 39 of the Biosecurity Act, 1993) to plant GM alliums in the field containment facility at least 30 working days before the planting takes place. For the approval to be granted the Operator must provide to the MAF Inspector a written request outlining the nature of the genetic modification, the scientifically validated methods used to assess the phenotype of the GM alliums (in accordance with proposed controls 3.2 and 3.3) and a unique organism description for the GM alliums to be planted. The MAF Inspector must verify the details of the GM alliums against the approved organism description of the approval and confirm this with the Operator. The Operator must provide to ERMA New Zealand a unique organism description of the GM alliums to be field tested for the ERMA New Zealand register.

3.2 The Operator must ensure that all GM alliums planted in the field containment facility are not derived directly from tissue culture (it is noted that cloves of garlic from a plant derived from tissue culture is considered to be second generation and not derived directly from tissue culture).

3.3 The Operator must ensure that all GM alliums planted in the field containment facility are phenotypically true-to-type with respect to flowering or seed characteristics by the use of scientifically validated methods. GM alliums with modified characteristics for flower induction, eg, flowering only after the application of a chemical inducer, are approved for field testing as long as all other flowering and seed characteristics are phenotypically true-to-type.

3.4 The Operator must ensure that all GM alliums planted in the field containment facility exhibit the approved traits by the use of scientifically validated methods.

4 Transfer of GM allium between the field containment facility and PC2 containment facilities:

4.1 The Operator must ensure that when transferring GM allium plant material, which includes seeds, seedlings and bulbs, between PC2 containment facilities and the field

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[3] The GM-allium site is a defined area within the field test containment facility, which does not overlap with the GM-brassica site, and which can be up to 2.5 ha at any one time.

containment facility, that all the GM alliums are secured and double-contained (the packaging requirements listed in section 8.2.7 of the Plant Containment Standard do not apply).

4.2 The Operator must ensure that no GM allium plants escape during the transfer between PC2 containment facilities and the field containment facility by checking on arrival at the receiving facility that all packages are accounted for and that the packaging is closed. If a discrepancy in the number of packages is found or the packaging is opened, the contingency plan must be implemented (control 2.4).

5 Register of GM alliums within the field containment facility:

5.1 The Operator must ensure that a register of GM allium lines planted and grown in the field containment facility is maintained. The following records must be kept for each plant line:

(a) the identity of the plant line (species, cultivar or breeding line and details of genetic modification);

(b) the identity of the authorised person responsible for the plant(s);

(c) the date of planting in the field containment facility;

(d) the location of rows of the plants within the field containment facility;

(e) the date of transfer of all living GM allium material, either plants or parts of plants, between PC2 containment facilities and the field containment facility; and

(f) the date and method of final disposal of plant(s).

6 Planting of seeds:

6.1 The Operator must not permit the planting of GM allium seeds in the field containment facility when wind is equal to or greater than 20 km per hour at the field containment facility.

6.2 The planting site is limited to 2.5 hectares in size at any one time. The boundaries of the field containment facility in which the field test is conducted must be marked by a permanent feature (or GPS location details). GM plants and buffer row plants cannot be planted any closer than 10 metres to the boundary, this 10 metre area is to be grazed or mowed to facilitate the detection of escapee or volunteer GM plants.

6.3 The Operator must ensure that GM alliums are easily recognisable by the planting in the buffer rows[4] of morphologically different species (eg, have different foliage) in the adjacent plots. The Operator must ensure that no GM plants of any species and no GM or non-GM alliums are used in any buffer rows.

[4] Plants that are grown around the experimental plots to control for any edge effects. These are planted as part of the experimental design and serve no containment or risk mitigation purposes.

6.4 The Operator must ensure that GM alliums are easily recognisable by the planting of morphologically different species (eg, have different foliage) as rotational crops. The Operator must ensure that plants used in rotation with the GM alliums are neither GMOs nor non-GM alliums.

7 Seed production within pollination cages:

7.1 Only *A.cepa* is approved for flowering and seed production. No other *Allium* species are allowed to flower or produce seed under this Decision.

7.2 The Operator must ensure that the MAF Inspector inspects and endorses all pollination cages as suitable for the containment of all insects capable of carrying pollen. This must occur at the beginning of each planting season in which the cages will be used.

7.3 The Operator must demonstrate to the MAF Inspector that insects carrying pollen do not move through the mesh of the pollination cages.

7.4 The Operator must demonstrate to the MAF Inspector before the first use of the pollination cages that insecticide can penetrate through the mesh of the pollination cages and kill all the insects contained within the pollination cages.

7.5 The Operator must demonstrate to the MAF Inspector that the pollination cages can not be dislodged. The cage covering should be dug into the ground in such a way as to avoid dislodgement of the cage by wind, and reduce the horizontal movement of soil fauna and surface dwelling animals that might remove fallen pollen on the soil surface. The contingency plan must be immediately implemented in the event that a pollination cage is dislodged in any way that would permit the escape of insects capable of carrying pollen (control 2.4).

7.6 The Operator must ensure that all developing flowers are detected at least two weeks before flowers are due to open, by the weekly inspection of the plants that are approved to flower. The Operator must ensure that no pollen escapes from the *A. cepa* flowers by placing pollination cages over the flowering plants at least two weeks before flowers are due to open. The Operator must ensure that plants approved to flower and enclosed in pollination cages are at least 20 metres from the boundary of the field containment facility.

7.7 The Operator must ensure that no insects capable of carrying pollen escape when they are introduced into the pollination cages.

7.8 The Operator must ensure that no staff or any other person enters the pollination cages during the period that the cages contain the introduced insects.

7.9 The Operator must ensure that no seeds produced in the pollination cages are released in the pollination cages by harvesting all seed heads prior to the shedding of seeds from the seed capsules. The Operator must ensure that all seed heads are collected from the plants approved to flower before authorising the removal of the enclosing pollination cages. The Operator must ensure that pollen does not escape from the pollination cages by the spraying of insecticide in the pollination cages immediately before the harvesting of the seed heads to kill all insects capable of carrying pollen.

7.10 The Operator must ensure that onion plants to be allowed to flower are protected from insects by a prophylactic spraying regime of an insecticide, as per manufacturers recommendations, from the time the onions are planted until they are enclosed by the pollination cage.

7.11 The Operator must ensure that the pollination cages have a double layer of mesh and with a perforation size as small as practicable and of no more than 2 mm.

8 Disposal of plant material from the field containment facility:

8.1 The Operator must ensure that all living GM allium material, either plants or parts of plants, from the field containment facility is killed on-site by composting within a closed container (following chipping, shredding or mulching of material) or another scientifically validated method or transferred to a PC2 containment facility for further research or to be killed. The Operator must ensure that all GM allium material retained for further research purposes is contained under the relevant HSNO Act containment approval for these organisms once they are transferred to the PC2 containment facility.

8.2 All plant material remaining in compost containers during and at the completion of the field test shall be ploughed into the field containment facility or transferred to a PC2 contaiment facility for further research.

8.3 The Operator must ensure that all buffer row plants and any non-GM rotational crops planted within the containment facility are composted or ploughed into the ground within the field containment facility for the duration of the field test (including the final post-harvest monitoring period).

8.4 The Operator must ensure that all GM alliums are removed from the field containment facility or killed on-site at completion of the field test (as per control 8.1), a maximum of ten (10) consecutive calendar years from the activation of the decision by Crop and Food Research, and that final monitoring commences (control 9.5).

9 Monitoring:

9.1 The Operator must ensure that pollination cages are inspected daily for damaged or dislodgment which could result in the escape of insects carrying pollen from the pollination cages. Honeybees (*Apis mellifera*) will be excluded from pollination cages.

9.2 The Operator must ensure the detection of the onset of bolting or early flower opening by monitoring of the field containment facility, during the period when GM alliums are present. The Operator must ensure that scientifically validated methods are used for monitoring and that staff are trained to detect the onset of bolting or early flower opening. The Operator must ensure that, if bolting or early flower opening is detected, the entire flower head or the whole plant is disposed of as set out in control 8.1. The only exception to control 9.2 are GM *A. cepa* plants approved under this decision for seed production and these are subject to controls 7.1 – 7.11.

9.3 The Operator must ensure a monitoring log is kept and made available for inspection by the MAF Inspector. This log must include:

(a) the date of monitoring inspections and the name of the person undertaking the monitoring;

(b) the number of bolting or early flowering plants detected outside pollination cages and the action taken to contain the bolting or early flowering plants; and

(c) the date, details and locations of any volunteer alliums found and the action taken.

9.4 The Operator must ensure that all volunteer allium plants are detected by the monthly monitoring to commence at the end of each growing season. The area to be monitored includes the field containment facility, including a 10 metre wide strip immediately around the facility and the track from the field containment facility to the road. The Operator must ensure the disposal, in accordance with control 8.1, of all detected allium volunteer plants.

9.5 The Operator must ensure that a monitoring period of a minimum of two (2) calendar years begins at the completion of the field test, and if in that period any allium volunteer plants are detected a new two (2) year monitoring period must begin from the date of the most recent detection of an allium volunteer plant. The planting of any allium plants in the field containment facility for the duration of the final monitoring period is prohibited. The Operator must ensure the detection of allium volunteer plants by the monthly monitoring of the field containment facility, which includes a 10 metre wide strip immediately around the facility and the track from the field containment facility to the road for the duration of the final monitoring period. The Operator must ensure, in accordance with control 8.1, the disposal of all detected volunteer allium plants found during the final monitoring period.

10 Reporting:

10.1 The Operator must ensure the notification in writing to ERMA New Zealand and the MAF Inspector the activation of this approval.

10.2 The Operator must ensure that ERMA New Zealand and the MAF Inspector is promptly informed of any matters which may affect the long term management of the field containment facility including:

(a) changes in the key personnel such as Operator of the field containment facility or the principal investigator responsible for the field test;

(b) changes in the management structure of the applicant, (Crop and Food Research) that may affect the management of the field test;

(c) any event or circumstance that would affect the capacity of the applicant to meet the requirements of any controls set out in this Appendix; and

(d) changes in the use of land immediately surrounding the field containment facility or ownership of the field containment facility site.

10.3 The Operator must ensure that a written, annual, progress report of the field test is provided to ERMA New Zealand by 31 July of each year of the operation of the field containment facility and the subsequent monitoring period. The Operator must ensure content of the progress report is as agreed with ERMA New Zealand at the beginning of each new financial year (1 July to 30 June), and must include, but is not limited to, the following:

(a) field test activities;

(b) any unanticipated events;

(c) any issues with controls;

(d) proposed activities for the next year where relevant;

(e) any relationship development and management initiatives undertaken with Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga;

(f) all educational and public awareness activities undertaken with Māori more generally;

(g) all educational and public awareness activities undertaken with community groups;

(h) all scientific publications, conference presentations and key findings resulting from this field test, including impacts research; and

(i) environmental effects testing programme and results from this programme.

10.4 The Operator must provide a specifically written annual update to Te Rūnanga o Ngāi Tahu and Te Taumutu Rūnanga by 31 July of each year of the operation of the field containment facility. The Operator must ensure that the update provides information on the progress of the field test and explain how Crop and Food Research is addressing any cultural issues raised by Ngāi Tahu in relation to the field test research. The Operator must ensure that a copy of this update is provided to Ngā Kaihautū Tikanga Taiao.

10.5 Crop and Food Research must provide documented evidence of regular engagement and participation in the field test programme of Te Taumutu Rūnanga to a mutually agreed level to ERMA New Zealand.

10.6 The Operator must notify ERMA New Zealand of the completion of the final monitoring of the field containment facility and that all controls have been complied with.