

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

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January 2009

A report prepared for:
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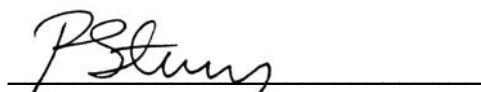
Plant & Food Research Report SPTS No 2146
Milestone number: 29581

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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:

A handwritten signature in black ink, appearing to read 'P. Stuns', is written over a solid horizontal line.

Group Leader, Bioprotection

Date: 5 February 2009

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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).

¹See 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 Williams 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	<ul style="list-style-type: none"> • 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	

			<p>trial projects are adequately resourced, including ensuring that staff involved in internal audits are resourced and trained to carry out this role.</p> <ul style="list-style-type: none">• 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.
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Appendix 1



Critical Situation Report (CSR)

CONTAINMENT FACILITY: Plant & Food Research		CONTAINMENT FACILITY OPERATOR: Mary Christey	
IMPACT NUMBER: 5356 (ATF: 16603)		STANDARD(S) BEING AUDITED: <i>Containment Facility for Plants: 2007</i>	
DEPARTMENT AND/OR ROOM: N/A			
BASIS OF AUDIT: Notification from public that GM <i>Brassica</i> 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
<p>BACKGROUND:</p> <p>On the afternoon of the 22/12/08 Soil & Health Association member informed MAF Biosecurity New Zealand (MAFBNZ) that <i>Brassica</i> 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 <i>Brassica</i> 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.</p> <p>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).</p> <p>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.</p> <p>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.</p> <p>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.</p>			
<p>NON-CONFORMANCES:</p> <p>The following quotes in italics are taken from HSNO Act approval GMF06001 controls.</p> <p>Control 1.2 states "<i>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.</i>"</p> <p>Control 1.8 states "<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 (control 1.4) or killed (control 1.12).</i>"</p> <p>Control 1.12 states "<i>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.</i>"</p>			

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 *Middleleaf* (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 *Middleleaf* (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:

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 materials any
 - 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.