Institutional Biological Safety Committee decision form[1]

Amended under s67A of the HSNO Act on 10 June 2010 and 27 September 2010

Institutional Biological Safety Committee:	HortResearch & Landcare joint IBSC Auckland
IBSC Institution Code:	GMO02/HRA059
ERMA New Zealand code	GMD02088
Application category:	To develop in containment a genetically modified organism under section 40(1)(b) of the Hazardous Substances and New Organisms (HSNO) Act.
Purpose:	These organisms will be developed to understand the response in plants to virus infection by studying the mechanistic interplay between the gene silencing, intron splicing and/or translation pathways, in plants using reporter genes to indicate efficiencies of each pathway.
Applicant:	The New Zealand Institute of Plant and Food Research Limited
Date application received by IBSC:	27/8/02
Considered by what members:	IBSC Committee
Date of consideration:	28 August 2002

1 Summary of the decision:

The application to develop the following organism(s) is [**approved**, with controls] having been considered in accordance with the relevant provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996, the Hazardous Substances New Organisms (Low Risk Regulations) 1998, and the HSNO (Methodology) Order 1998.

The application was considered by the IBSC under delegation from the Authority as provided for under section 19 of the HSNO Act.

[1] This decision form should be used in conjunction with the checklist

The organism(s) [**approved**] are:

Name of the organism:	**What the organism is modified with:**	**Development of the organism involves an approved Schedule 2 host/vector system as in HSNO Regulations. Category requirements are (please specify details of category eg B(b)(i)) -**	**Containment level as in the Australian/New Zealand Standard AS/NZS 2243.3 2002 Safety in Laboratories Part 3: Microbiological aspects and containment facilities** **eg PC1/PC2**
<>	<>	<>	<>
Arabidopsis thaliana	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	1. Category A(a), plant tissue culture where genetic material from pathogens are not used 2. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 3. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 4. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	1. PC1 2. PC2 3. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 4. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research

Nicotiana benthamiana	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	5. Category A(a), plant tissue culture where genetic material from pathogens are not used 6. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 7. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 8. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	5. PC1 6. PC2 7. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 8. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research
Nicotiana tabacum	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	9. Category A(a), plant tissue culture where genetic material from pathogens are not used 10. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 11. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 12. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	9. PC1 10. PC2 11. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 12. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research

Nicotiana clevelandi	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	13. Category A(a), plant tissue culture where genetic material from pathogens are not used 14. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 15. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 16. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	13. PC1 14. PC2 15. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 16. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research
Nicotiana glutinosa	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	17. Category A(a), plant tissue culture where genetic material from pathogens are not used 18. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 19. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 20. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	17. PC1 18. PC2 19. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 20. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research

Lycopersicon esculentum	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	21. Category A(a), plant tissue culture where genetic material from pathogens are not used 22. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 23. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 24. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	21. PC1 22. PC2 23. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 24. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research
Actinidia deliciosa	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	25. Category A(a), plant tissue culture where genetic material from pathogens are not used 26. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 27. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 28. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	25. PC1 26. PC2 27. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 28. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research

Actinidia chinensis	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	29. Category A(a), plant tissue culture where genetic material from pathogens are not used 30. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 31. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 32. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	29. PC1 30. PC2 31. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 32. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research
Actinidia arguta	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	33. Category A(a), plant tissue culture where genetic material from pathogens are not used 34. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 35. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 36. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	33. PC1 34. PC2 35. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 36. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research

Actinidia eriantha	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	37. Category A(a), plant tissue culture where genetic material from pathogens are not used 38. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 39. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 40. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	37. PC1 38. PC2 39. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 40. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research
Vaccinium corymbosum	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	41. Category A(a), plant tissue culture where genetic material from pathogens are not used 42. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 43. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 44. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	41. PC1 42. PC2 43. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 44. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research

Vaccinium ashei	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	45. Category A(a), plant tissue culture where genetic material from pathogens are not used 46. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 47. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 48. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	45. PC1 46. PC2 47. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 48. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research
Vaccinium angustifolium	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	49. Category A(a), plant tissue culture where genetic material from pathogens are not used 50. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 51. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 52. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	49. PC1 50. PC2 51. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 52. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research

Vaccinium macrocarpon	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	53. Category A(a), plant tissue culture where genetic material from pathogens are not used 54. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 55. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 56. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	53. PC1 54. PC2 55. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 56. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research
Malus domestica	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	57. Category A(a), plant tissue culture where genetic material from pathogens are not used 58. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 59. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 60. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	57. PC1 58. PC2 59. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 60. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research

Cyphomandra betacea	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	61. Category A(a), plant tissue culture where genetic material from pathogens are not used 62. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 63. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 64. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	61. PC1 62. PC2 63. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 64. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research
Petunia hybrida	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	65. Category A(a), plant tissue culture where genetic material from pathogens are not used 66. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 67. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 68. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	65. PC1 66. PC2 67. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 68. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research

Vitis vinifera	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	69. Category A(a), plant tissue culture where genetic material from pathogens are not used 70. Category B(a) (iii), B(b)(i), B(b)(iii), B(b)(iv)(A) whole plants where genetic material from pathogens are not used 71. Category B(a)(i), B(a)(iii), B(b)(iii), B(b)(iv)(B) where the foreign genetic material is from a pathogen but is well characterised, or 72. Category B(a)(i), B(a)(iii), B(b)(v)(A) where pathogenic determinants are introduced	69. PC1 70. PC2 71. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research 72. PC1 for tissue culture stages in laboratory, PC2 for glasshouse research
Agrobacterium tumefaciens disarmed strains	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	73. Category A(a)	73. PC1

Escherichia coli strains K-12 & B derivatives	Vectors as described in Appendix 1 containing (a) genes of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins or non-translated RNAs that are involved in the virus-response, or (b) single genes from viruses.	74. Category A(a), A(b)	74. PC1

Human Genes:	**YES**	**NO**
Does the proposed development involve human genes?	✓[2]	
If **YES** - is the genetic material derived directly from humans?		✓[2]
If **YES** – is the genetic material derived indirectly from humans ie commercial source?	✓[2]	
If genetic material is derived directly from humans, was ethics committee approval obtained?		
If **YES** – what was the name of the committee, and the date of the approval?		
If **NO** – indicate why not		

Native flora and fauna (section 6d & 8 of the HSNO Act):	**YES**	**NO**
Does the proposed development use genetic material from native flora and/or fauna?		4
Does the proposed development use native flora and fauna as host organisms?		4
If DNA from native flora and fauna is involved, was consultation with Maori carried out?		
If **YES** - provide details of consultation		
If **NO** – indicate why not and what steps were taken instead.		

2 Containment

Describe the containment system (physical and operational).

The organisms are to be contained in an approved *containment facility* (under the Biosecurity Act 1993) in compliance with the Ministry of Agriculture and Forestry (MAF) Biosecurity

[2] June 2010 amendment to remove the exclusion on the use of human genes; human genes must not be derived from persons of Māori origin.

Authority/ERMA New Zealand Standards: 154.03.02: *Containment Facilities for Microorganisms* and 155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species.* In addition the operation, construction and management of the facility is in accordance with the relevant provisions of the Australian/New Zealand Standard (AS/NZS) 2243.3:1995 *Safety in Laboratories* Part 3: *Microbiology* at Physical Containment Level 1 (PC1) for the low risk Laboratory work and Plant House Physical Containment Level 2 (PC2).

3 Identification of the significant risks and costs of the organism

In accordance with section 42 of the Act (rapid assessment), the approach adopted by the IBSC was to identify the circumstances of the genetic modification(s), to evaluate these against the criteria specified in section 41, and to consider whether there are any residual risks of significance that require further consideration. Refer to Annex A for guidance on identifying and assessing significant risks and costs.

Significant risks, costs and benefits identified for assessment and evaluation were as follows, following clauses 9 and 10 of the Methodology, which incorporate sections 5, 6, and 8 of the HSNO Act.

The applicant identified the following risks**:** The ability of genetically modified plants and *Agrobacterium tumefaciens* to establish self-sustaining populations, the survival of *A. tumefaciens* strains on plants that have been genetically modified by them.

After due consideration of the risks identified by the applicant and in accordance with section 42 of the Act (rapid assessment), the IBSC identified that the following areas of potential significant risks warranted further examination by the committee: Significant risks or costs to the environment, significant economic risks or costs, ability to establish an undesirable self-sustaining population in NZ if the organism(s) were to escape from containment and eradicated of such an undesirable self-sustaining population if it was established. These risks and their mitigating factors are discussed below. The assessment of risks took into account clauses 12(a), 12(b), 12(c), 12(d) and 12(e) of the Methodology. The assessment of costs and benefits took into account clauses 13(a), 13(b) and 13(c) of the Methodology.

Significant risks or costs to the environment

The IBSC considered the possible effects of the genetically modified organisms on the environment according to clauses 9(a), 9(c)(i), 9(c)(ii), 10 (a), 10(b) and 10(d). The committee noted that the physical and process containment conditions being used make the likelihood of escape of any genetically modified plants or bacteria very unlikely. The committee could not identify any particular risks to the environment posed by the specific modifications proposed by the applicant. The IBSC identified the only identifiable risk as the establishing of self-sustaining populations capable of interbreeding with existing organisms of the same species or closely related species as a result of escape. The committee noted that none of the plants being modified are native plants, nor do they have close relatives likely to be able to cross-hybridise with these plants that are natives. Therefore in the unlikely event of escape occurring it would not have a major impact on the native fauna of New Zealand. It also noted that the impact of the genetically modified bacteria on the environment are likely

to be minimal since *E. coli* derivatives of strains K12 & B have been demonstrated to be unable to establish a self-sustaining population outside of laboratory culture because of genetic mutations (Smith 1975: Heitkamp et al. 1993) and the *A. tumefaciens* strains being used are disarmed and unable to cause disease on plants. The committee considered the benefits under clause 9(c)(v) and clause 26 and considered that the benefits of the research in terms of increased knowledge outweighed the negligible remaining residual risks or costs to the environment. The ability of these organisms to form self-sustaining populations and the ability to eradicate these organisms are discussed below.

Significant economic risks or costs

The IBSC considered the possible effects of the genetically modified organisms on the economic social and cultural well being and the needs of future generations according to clauses 9(b)(i) and 9(b)(ii) and taking into account the potential of the organisms to cause disease according to clause 10(g). The committee identified the use of genes from pathogens in plants as a possible source of economic risk for the species being altered. It noted that in the case of plant virus genes being inserted into plants that there is a small risk of reconstituting a functional genetically modified virus. It noted however that only single genes will be used and that these genes will not comprise more than two thirds of the virus genome; are not infectious (self-replicating); and are not complemented to become infectious in any organism or cell culture. The IBSC further notes that these plants will not subsequently be infected with complete viruses and that the applicant will use alternative ways to identify if the virus defence mechanisms of these plants are affected-for example by using a non-viral marker gene to identify effects of the virus gene on post-transcriptional gene silencing. The committee has imposed some additional controls to check for inadvertent viral infection in section 5 below to minimise the likelihood of recombination with other viruses. The IBSC considers that with these additional controls the possibility of recombination regenerating an effective transgenic virus particle in these plants is negligible.

The IBSC noted that the use of genes from other pathogens or pests (bacterial, insect and fungal) in plants are unlikely to pose any particular risk to the plants being genetically altered since the risk of reconstituting an active genetically modified pathogen or pest is very unlikely.

The committee considered the process of iwi consultation according to clauses 9(c)(iv) of the methodology and sections 6(d) and 8 of the HSNO Act. The IBSC noted that strictly speaking the current law did not oblige the applicant to undergo consultation with iwi, nevertheless a process of consultation with iwi has occurred and that the applicant has responded to this consultation by altering the research in the application, in particular by withdrawing the use of human genes.

Ability to establish an undesirable self-sustaining population in NZ

The IBSC considered the possible effects of the genetically modified organisms on the environment according to clause 10(e).

The IBSC noted that the applicant identified that the genetically modified plants contains a viral gene and may have the ability to form self-sustaining populations in the unlikely event

of an escape from containment. The committee noted that a number of additional controls and processes used by the applicant will reduce the likelihood of escape namely that:

- Plants will be permitted to flower only when necessary.
- Drainage systems from each containment glasshouse are equipped with silt-trap and rodent traps. In addition, as a precaution against the transport of pollen and seeds out of the glasshouses, staff' are required to wear disposable lab-coats with no pockets and disposable 'bootees'.
- Plants containing viral genes will be separated from any other plants of that species and pollen and seed spread is reduced or prevented by bagging inflorescences when possible or placement of the inflorescences in seed collection tubes

The IBSC has also imposed additional controls (see section 5 of the decision) that will reduce the chance of spread of genetically modified material further. The IBSC noted that it is very unlikely that escaping pollen will land on receptive flowers outside of containment. The committee considers that with these additional controls there is a negligible risk of establishing a self-sustaining plant population in New Zealand.

The applicant has further noted that *A tumefaciens* may be able to form a self-sustaining population. The IBSC notes that the *Agrobacterium* strains to be used are disarmed and therefore are no longer pathogenic on plants. The committee notes that there is uncertainty about whether laboratory strains of *Agrobacterium* can survive and establish self-sustaining populations. The IBSC notes that ERMA New Zealand has previously indicated that non-pathogenic *A. tumefaciens* is an approved Schedule 2 host vector systems in the HSNO (Low-Risk Genetic Modification) Regulations and so is considered appropriate for PC1 laboratory containment so long as non-pathogenic viral vectors are used. The applicant has restricted the strains of *A. tumefaciens* to be used for the research to disarmed strains that fall under this low risk category. The IBSC considers that the containment conditions for this approved host are sufficient to make an escape from containment very unlikely. The applicant also identified the possible survival of *A tumefaciens* on transgenic plants as a potential route for escape of the genetically modified *A tumefaciens*. The IBSC noted that the long period of axenic culture of transformed plants in tissue culture and the procedures following the transformation events make the survival of disarmed *A tumefaciens* on transgenic plants unlikely but not impossible. The committee acknowledged that there is uncertainty over whether *A tumefaciens* would survive for any length of time on transgenic plants and considered that the containment conditions in place for the genetically modified plants will make the escape of *A tumefaciens* by this route very unlikely.

The IBSC considered the likelihood of the plant virus genes being inserted into plants as a source for reconstituting a functional genetically modified virus. It noted that only single genes will be used and that these genes will not comprise more than two thirds of the virus genome; are not infectious (self-replicating); and are not complemented to become infectious in any organism or cell culture. The IBSC further noted that these plants will not subsequently be infected with complete viruses and with the additional control imposed in section 5 below (to check for inadvertent viral infection) the committee considers that the possibility of recombination regenerating an effective transgenic virus particle in these plants is negligible.

Eradication of an undesirable self-sustaining population if it was established
The IBSC considered the possible effects of the genetically modified organisms on the environment according to clause 10(f). It noted that in general only one antibiotic is used to transform genetically modified bacteria and that should self-sustaining populations of genetically modified bacteria be established that there are several antibiotic and other antibacterial agents that could be used to attempt to eradicate these bacteria. The IBSC further noted that should any self-sustaining plant populations be established there are several means including different herbicides that could be used to attempt to eradicate these plants. The IBSC noted that in the very unlikely event that a new genetically modified virus was generated and escaped from containment, the options for eradication of that virus would involve eradication of any infected plant hosts (for example by using herbicides). It further noted that it considers this risk of escape is negligible for the same reasons outlined when considering the possible effects of the genetically modified organisms on the environment according to clause 10(e).

Iwi consultation
This research proposal has undergone a process of consultation with local iwi Maori. This consultative process comprised of two meetings (6/6/02 and 28/6/02) with mandated iwi representatives from Ngati Whatua and Hauraki, other hapu and iwi representatives, Mt. Albert joint HortResearch and Landcare IBSC representatives, and the applicant for this proposal. During this consultative process the applicant agreed to withdraw the use of human genes such that no human genes would be used during this proposed research.

In 2010, the applicant consulted with iwi representatives regarding the need to use specific human genes to progress the research and has obtained their agreement for the use of specific human genes, excluding those derived from Māori.

4 Controls

In considering all the matters to be addressed detailed in the Third Schedule Part I Containment Controls for Development and Field Testing of Genetically Modified Organisms of the HSNO Act, the IBSC approval of the organism(s) is subject to the following controls:

1) The operation, management and construction of the facility shall be in accordance with the:

a) The MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms* and 155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*.

b) Australian/New Zealand Standard (AS/NZS) 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities, at Physical Containment Levels 1 & 2 (PC1 & PC2).

2) The facility shall be approved and registered by MAF Biosecurity Authority as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standards 154.03.02: *Containment Facilities for Microorganisms* and 155.04.09: *Containment Facilities for New Organisms*

(including genetically modified organisms) of Plant Species, and additional controls as listed below.

3) All culture products and associated materials shall be autoclaved or incinerated before being disposed of.

4) If for any reason a breach of containment occurs the applicant shall notify the facility Supervisor and ERMA New Zealand immediately the event is noticed (and at least within 24 hours of the breach being detected) and shall immediately implement a contingency plan for the recovery and eradication of any organisms or viable material that has escaped.

5) The Authority or its authorised agent or properly authorised enforcement officers, may inspect the facilities at any reasonable time.

5 Additional controls *List any additional controls*

- In order to contain pollen and seed within the containment facility, inflorescences must be enclosed so as to prevent seed and pollen escape.
- Plants containing viral genes must be kept separately from other plants of the same species to prevent those viral genes being transferred to other plants.
- To limit the possibility of recombination with other viral genes, all plants showing symptoms of viral infection must be destroyed

Signed: ……..…… 28/8/02

(on behalf of the institution)

Chairperson, HortResearch & Landcare joint IBSC Auckland

Amended June 2010
The decision was amended to remove the exclusion of the use of human genes. Human genes may be used but must not be derived from persons of Māori origin.

_____ 10 June 2010

Mr Rob Forlong Date
Chief Executive, ERMA New Zealand

Amended September 2010
The decision was amended to improve the clarity of the additional control for auditing.

_____ 27 September 2010

Mr Rob Forlong Date
Chief Executive, ERMA New Zealand

Checklist

NB- this checklist should be completed by the IBSC, and signed and dated by the Chair of the IBSC and returned to ERMA New Zealand with the decision form.

- Sections referenced indicate sections of the Hazardous Substance and New Organisms Act 1996
- Clauses referenced indicate clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998

		Yes	No	N/A
1	**Legislative criteria for the application**			
1.1	The application was lodged pursuant to section 40(1)(b) of the HSNO Act. The decision was determined in accordance with section 42 (rapid assessment) and matters relevant to the purpose of the Act, as specified under Part II of the HSNO Act	4		
1.2	Consideration of the application followed the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology). Unless otherwise stated, references to clauses in this decision refer to clauses of the Methodology.	4		
1.3	Was any expert advice sought under clause 17?		4	
1.5	If **YES** – name of the expert			
1.6	If **YES** – was the applicant informed under clause 18?			4
2	**Consideration of the application**			
2.1	The IBSC holds delegation from the Authority as provided under section 19 of the HSNO Act.	4		
2.2	The purpose is appropriate under section 39(1)(a) of the Act: The development of any genetically modified organism.	4		
2.3	Does the IBSC consider the information provided by the applicant relevant and appropriate to the scale and significance of the risks, costs, and benefits associated with the application (as required by clause 8 of the Methodology)?	4		
2.4	If **NO** – discuss			4
3	**Sequence of the consideration**			
3.1	In accordance with section 42 of the Act (rapid assessment), the approach adopted by the IBSC was to identify the circumstances of the genetic modification(s), to evaluate these against the Regulations established under section 41 of the Act, and to consider whether there are any residual risks of significance that require further consideration.	4		
4	**Identification of significant risks**			

		Yes	No	N/A
	NB Since applications that are considered under section 42 do not require balancing of adverse and beneficial effects, this section concentrates on identifying <u>significant</u> risks and costs as a basis for ensuring the adequacy of the proposed controls. *The relevant risks are those specified in clauses 9-10, and reference should be made to the relevant clauses. Significant risks are those risks that the IBSC considers are not negligible (i.e. they require active management beyond the normal requirements of the specified physical containment level).* *In most circumstances the default controls will be adequate to contain the organism(s), and there will not be any significant residual risks. However, there may be some cases where the IBSC considers that this is not the case and where additional controls should be applied. In this case the IBSC may choose to present a full assessment of the significant residual risks. Annex A provides a suggested format for this.*			
4.1	Are there any significant risks or costs to the environment?		4	
4.2	Are there any significant risks or costs to human health?		4	
4.4	Are there any significant risks to Maori and their taonga?		4	
4.5	Are there any significant economic risks or costs?		4	
4.6	If the organism(s) were to escape from containment, would they be able to establish an undesirable self-sustaining population in NZ?	4		
4.7	Would the organism(s) be easily eradicated if an undesirable self-sustaining population established?	4		
	If YES is checked in any of 4.1-4.6, or if NO is checked for 4.7, please list the risks identified on the decision form and discuss how they were assessed in terms of likelihood and consequence, and what controls were imposed to manage them. Refer to clauses 12 and 13.			
5	**Applications involving native flora and fauna**			
5.1	Does the application use genetic material from native flora and/or fauna?		4	
5.2	Does the application use native flora and fauna as host organisms?		4	
5.3	In accordance with section 8 of the Act, was consultation with Maori carried out?	4		

		Yes	No	N/A
	If **YES**, please provide a discussion below about who was consulted, their status and the results of the consultation. Consultation was carried out - the application was considered (using an interim process) by an Auckland region Maori consultative committee that is in the process of being formally set up by discussions between mandated iwi representatives and the Mt. Albert joint HortResearch and Landcare IBSC. In the discussion with iwi the applicant agreed to withdraw the use of human genes from the final submitted application (the use of human genes was proposed in the original draft used for consultation). In 2010, the applicant consulted with iwi representatives regarding the need to use specific human genes to progress the research. The applicant has obtained their agreement for the use of specific human genes, excluding those derived from Māori.			
6	**Applications involving human DNA**			
6.1	Does the application use genetic material obtained indirectly from human beings? (ie from a genebank)		4	
6.2	Does the application use genetic material obtained directly from human beings?		4	
6.3	If **YES** is answered to 6.2 - has approval from an Ethics Committee been obtained?			4
7	**Assessment against the criteria for low risk genetic modifications**			
7.1	Does the IBSC consider that the development of **each** of the genetically modified organisms described in the application meet the criteria for a low-risk genetic modification specified in the regulations made under section 41 of the Act, being the HSNO (Low Risk Genetic Modification) Regulations 1998?	4		
8	**Containment of the organisms**			
8.1	In carrying out its consideration did the IBSC considered the adequacy of containment in accordance with section 42(2) and the magnitude and probability of the potential adverse effects (risks and costs?). *NB The IBSC should include details of the modifications and state which Category of the low risk regulations that they fall within.* *The IBSC should also specify the level of containment relevant to that category (the controls relevant to the level of containment are detailed at the end of the decision form). Note that the IBSC may add additional controls where I considers these are necessary to ensure containment, but that controls relevant to the physical containment level set in the Regulations cannot be removed.*	4		

		Yes	No	N/A
8.2	Will the containment facility be operated and constructed in accordance with the: (a) the Australian/New Zealand Standard AS/NZS 2243.3:2002 Safety in Laboratories: Part 3: Microbiological aspects and containment facilities at Physical Containment Levels PC1 and PC2; (b) the MAF Biosecurity Authority/ERMA ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms* and 155.04.09: *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*	4		
8.3	Are any additional measures proposed because of the particular nature of the organism(s) or the proposed procedures?	4		
	If **YES**, these are: The committee recommends the removing or bagging of inflorescences from genetically modified plants containing genes of viral origin where this is practical to reduce the chance of spread of pollen or seeds or the use of seed collection tubes to minimise the risk of spread where this is not possible. Where practical the transgenic plants containing viral genes should also be separated from any other non-transgenic plants of that species (eg in a different sub-compartment) and the applicants should ensure that there is a sufficiently large buffer area around the glasshouse facility that does not contain plants of the same species, that this buffer area is regularly inspected for the presence of these species and that they are eradicated when identified. The applicants should ensure that the genetically modified plants expressing virus genes be inspected on a regular basis for the development of symptoms of virus infection with other viruses to limit the possibilities of trans-viral gene recombination occurring in the plant and that transgenic plants expressing such symptoms are destroyed.			
8.5	Are there any other matters that may affect the adequacy of containment such as the expected time frame for the project, and external matters such as the potential for sabotage?		4	
	If **YES,** please discuss			4
9	**Decision** In this section **YES** confirms approval – if any of the answers to 9.1-9.4 are **NO**, then the application is declined.			
9.1	The IBSC is satisfied that pursuant to section 45(1)(a)(i) of the Act, this application is for one of the purposes specified in section 39(1) of the Act, being section 39(1)(a): The development of any genetically modified organism?	4		

		Yes	No	N/A
9.2	Based on analysis of the information provided, and having considered the characteristics of the organisms and the modifications and the criteria for low-risk genetic modification detailed in the HSNO (Low Risk Genetic Modification) Regulations 1998, it is the view of the IBSC that the organism(s) meet the criteria for rapid assessment (as per section 42(2)).	4		
9.3	The IBSC is satisfied that the proposed containment regime together with any additional controls imposed will adequately contain the organism(s) as required by section 42(2) of the Act?	4		
9.4	In accordance with clause 36(b) of the Methodology the IBSC records that, in reaching this conclusion, it has applied the following criteria from the Methodology: Where relevant briefly discuss relevant clauses of the Methodology • clause 9 - • clause 10 – minimum standards criteria (sections 36 and 37) • clause 12 – evaluation of assessment of risks (to meet requirements of section 41) • clause 21 – the decision accords with the requirements of the Act and regulations	4		
9.5	The application for development of a genetically modified organism (detailed) is thus [**approved**], with controls as detailed on the decision document.	4		

{SIGNATURE}

Chairperson, HortResearch & Landcare joint IBSC Auckland
28/8/02

Appendix 1 GMO02/HRA059 Details on modifications included in this application

Vector system(s):

We will use vectors that shall only contain one or more of the following elements, and involve genetic modifications that meet Category A experiments in the Hazardous Substances and New Organisms (Low-Risk Genetic Modifications) Regulations 1998:

3.3.1 Promoters and Terminators

3.3.1.1 Promoter, operator, and enhancer sequences and/or terminator sequences derived from bacterial, insect, fungal and/or plant (or their viruses) genes; and ethanol-, copper-, steroid- or tetracycline- inducible promoters.

3.3.2 Reporter genes

Gene products that can be assayed by one or more of the following techniques:

3.3.2.1 Visual colour or fluorescence
3.3.2.2 Spectrophotometrically
3.3.2.3 Histochemically
3.3.2.4 Affinity purification
3.3.2.5 Immunological detection

And do not produce proteins that are pathogenic to vertebrates, or vertebrate toxins that have an LD_{50} less than 100 ug/kg, or are involved in vertebrate cellular differentiation.

3.3.3. Selectable marker genes

Fully characterised genes (i.e., genes whose sequence and function are known) that confer the ability to:

3.3.3.1 Tolerate or deactivate antibiotics
3.3.3.2 Tolerate or deactivate metabolic inhibitors
3.3.3.3 Synthesise essential amino acids

And do not produce proteins that are pathogenic to vertebrates, or vertebrate toxins that have an LD_{50} less than 100 ug/kg, or are involved in vertebrate cellular differentiation.

3.3.4. Origins of replication

3.3.4.1 Origin of replication loci derived from Escherichia coli, Pseudomonas aeruginosa, and Shigelle flexneri replicons
3.3.4.2 Bacteriophage origins of replication

3.3.5 Other features

3.3.5.1 Multiple cloning site
3.3.5.2 bacteriophage cos sites
3.3.5.3 Bacterial plasmid genes necessary for maintenance of bacterial artificial chromosomes

3.3.5.4 Polyadenylation signals
3.3.5.5 Transcriptional activators, enhancers, responsive elements, receptor elements, and terminator sequence
3.3.5.6 Secretory signals
3.3.5.7 Compartmental localisation/targeting signals, e.g., nuclear localisation signals
3.3.5.8 Intron sequences to alter gene expression
3.3.5.9 Ribosomal binding sites and/or Kozak sequences
3.3.5.10 Site specific recombinase systems such as Cre/Lox
3.3.5.11 Lambda att sites
3.3.5.12 Specific recognition sites for proteolytic cleavage
3.3.5.13 Telomere sequences
3.3.5.14 T-DNA region of Agrobacterium tumefaciens (not including the vir region)
3.3.5.15 Additional genetic material as described below

3.3.6 *Agrobacterium tumefaciens*

Disarmed hosts of *A. tumefaciens* containing a subsection of the vectors described above, being binary plant transformation vectors, carrying candidate additional genetic material (as described below). Binary plant transformation vectors carry origins of replication that can function in *A. tumefaciens* but lack some of the crucial virulence genes required for pathogenicity of *A. tumefaciens*. The vectors used in *A. tumefaciens* will then be introduced (or parts of them) into the plant species.

Additional genetic material

The additional genetic material used to modify the bacteria and plants in this application will contain one or more of the following elements:

3.3.7.5 Genes from living organisms

Single genes (cDNA or genomic fragments) of human (excluding those derived from Māori persons), mammalian, insect, fungal, plant or bacterial origin encoding proteins that are involved in the virus-response, including gene silencing, intron splicing and/or translation pathways and/or pathways involving non-translated RNAs.

3.3.7.6 Genes from viruses

Single genes from viruses such that the single genes or gene constructs: do NOT comprise more than two thirds of the virus genome; are NOT infectious (self-replicating); and are NOT complemented to become infectious in any organism or cell culture. Plants expressing genes from viruses will be examined for a change in response to a plant virus gene and/or a non-infectious reporter. Plants expressing genes from viruses will NOT be infected with infectious (self-replicating) viruses.