ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 23 August 2007, 30 August 2011, 11 November 2011 and 23 June 2014

Date signed: 20 March 2002

Application code	GMC01008
Application category	To import into containment any new organism under section 40(1)(a) of the Hazardous Substances and New Organisms (HSNO) Act 1996
Applicant	University of Auckland
Purpose	To import into containment a range of genetically modified cell lines to study biochemical and cellular events underlying physiological processes in plants and animals.
Date received	21 December 2001
Consideration date	15 February 2002
Considered by	The Genetically Modified Organisms Standing Committee of the Environmental Risk Management Authority (the Authority)

Summary of Decision

The application to import into containment the genetically modified cell lines described below is approved with controls having been considered in accordance with the relevant provisions of the HSNO Act and the HSNO (Methodology) Order 1998.

The cell lines will be imported, maintained and grown in sterile growth media within MAF-registered Physical Containment level 1 (PC1) or Physical Containment level 2 (PC2) laboratories.

Organisms approved

Cell lines derived from the following animal species:

Bos taurus Linnaeus (cattle)

Bos indicus Linnaeus (cattle)

Cricetus cricetus Linnaeus (European hamster)

Canis familiaris Linnaeus (dog)

Cavia porcellus Linnaeus (guinea pig)

Mus spretus Latase (mouse)

Mus musculus Linnaeus 1758 (mouse)

Mesocricetus auratus Waterhouse (golden hamster)

Oryctolagus cuninculus Linnaeus (rabbit)

Ovis aries Linnaeus (sheep)

Rattus norvegicus Berkenhout (Norway or laboratory rat)

Rattus rattus Linnaeus (Ship rat)

Sus scrofa Linnaeus (pig)

Xenopus laevis Daudin (South African clawed toad)

Drosophila melanogaster Meigen (fruitfly)

Trichoplusia ni Hubner (cabbage looper)

Spodoptera frugiperda Smith (fall army worm)

Danio rerio Hamilton-Buchanan (Zebrafish)

Cell lines derived from the following plant species:

Arabidopsis thaliana (Linneaus) Heynh.

Nicotiana tabacum Linneaus

Nicotiana benthamiana Linneaus

Nicotiana glutinosa Linneaus

Nicotiana repanda Willd. ex Lehm

Nicotiana plumbaginifolia Viviani

The cell lines are modified by genetic constructs encoding eukaryotic and/or prokaryotic DNA sequences as described in Annex 1 to this decision. None of the genes used in the modifications will originate from Māori or from native flora and fauna, or from species listed in Appendix 1 of CITES unless accompanied by written approvals from both the importing and exporting countries.

Relevant Legislative Criteria

The application was lodged pursuant to section 40(1)(a) of the HSNO Act. The decision was determined in accordance with section 45, taking into account additional matters to be considered under section 44, and matters relevant to the purpose of the Act, as specified under Part II of the HSNO Act. Unless otherwise stated, references to section numbers in this decision refer to sections of the HSNO Act.

Consideration of the application followed the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology), as specified in more detail below. Unless otherwise stated, references to clause numbers in this decision refer to clauses of the Methodology.

Application Process

Application receipt

The application was formally received on 21 December 2001. The organisms to be imported are defined as low risk (category A or B) under the HSNO Low Risk Modifications Regulations 1998 and therefore the application receipt was not publicly notified, according to ERMA New Zealand policy.

In accordance with clauses 2(2)(e) and 5 of the Methodology and section 58(c) of the HSNO Act the Department of Conservation (DoC) and Ministry of Agriculture and Forestry (MAF) Biosecurity Authority were invited to comment on this application.

Information available for consideration

The documents available for the consideration of this application by the Committee included the application and its appendices; copies of the Containment Manuals for the Faculty of Medicine and Health Sciences, and the School of Biological Sciences at the University of Auckland; an Evaluation and Review (E&R) Report prepared by ERMA New Zealand; and comments from the Department of Conservation. MAF Biosecurity Authority did not have any specific comments on this application.

Decision making Committee

The application was considered by the Genetically Modified Organism Standing Committee of the Authority, appointed in accordance with section 19(2)(b) of the HSNO Act. The Committee comprised the following members: Mrs Jill White (Chair), Mr Colin Mantell, and Ms Jane Lancaster.

Purpose of the Application

The purpose of the application was to import into containment a range of genetically modified cell lines to study biochemical and cellular events underlying physiological processes in plants and animals. The cells will be used in studies on viability, proliferation, death and other responses to various stimuli.

In accordance with section 45(1)(a)(i) of the HSNO Act, the Committee determined that this purpose was appropriate under sections 39(1)(h): *such other purposes as the Authority thinks fit*, and 39(1)(g): *maintaining new organisms in containment for diagnostic purposes*, of the HSNO Act 1996.

Consideration approach and sequence

In accordance with clause 24 of the Methodology, the approach adopted by the Committee was to look sequentially at identification, assessment and evaluation of risks, costs and benefits. The decision-making process is described in more detail in the following sections, with reference to legislative requirements under the HSNO Act and Methodology.

Identification of potential significant risks, costs and benefits

Following clauses 9 and 10 of the Methodology (which incorporate sections 5,6,and 8 of the Act), potential significant risks, costs and benefits were identified for assessment and evaluation.

In accordance with sections 5 and 6 of the HSNO Act and clause 9 of the Methodology Order, the Committee has categorised the potential adverse effects of this application under the headings of environmental, human health and safety; and Maori issues and concerns.

Risks to the environment

- Possible adverse effects should cell lines infected with undetected viral agents escape from containment (clause 9(a)).

Risks to human health and safety

- Possible adverse effects associated with handling of cell lines which may be infected with undetected viral agents, or which may (depending on the promoter used) express protein at a high level (clause 9(a)).

Risks to Māori culture

The Committee accepts the conclusion reached in both the application and the ERMA New Zealand E&R Report, that the import into containment of these cell lines does not pose any significant risk to the relationship between Māori and their culture and traditions with taonga. Therefore no further consideration of this aspect is warranted.

Costs and benefits (beneficial effects)

The Committee addressed potential costs and benefits associated with the application, in accordance with the Methodology clauses 9, 10, 13, and 14 and section 6(e) of the HSNO Act. The Committee considered that no significant costs were associated with the import of genetically modified cell lines into containment. The Committee identified the beneficial effects as:

- The benefit of increased scientific knowledge associated with the research
- The possible commercial benefit associated with the research

Adequacy of the proposed containment

In assessing risks, the adequacy of the containment regime was considered (section 45(1)(a)(iii) of the HSNO Act) in relation to the ability of the organisms to escape containment; form self-sustaining populations, and the ease of eradication of any such populations (sections 37 and 44). Risk management techniques were considered in relation to the identified risks (clauses 24 and 12(d)).

Ability to escape containment

The Committee considers that if the genetically modified cell lines intended to be imported were developed in New Zealand, they would meet the characteristics of Category A and B experiments under the HSNO (Low-Risk Genetic Modification) Regulations 1998. Experiments involving the cell lines are thus required to be conducted within a facility registered in accordance with MAF/ERMA New Zealand 154.03.02: Containment facilities for micro-organisms at Physical Containment Level 1 (PC1) (for mammalian, insect, and plant cell lines), and Physical Containment Level 2 (PC2) (for other animal cell lines) as specified in the Australian/New Zealand Standard AS/NZS 2243.3:2002. Safety in Laboratories: Part 3: Microbiological Aspects and Containment Facilities (refer to Controls 1.2 and 1.3 in Annex 2 of this decision).

The Committee notes that the University of Auckland will import the cell lines into one of two laboratories which meet the above requirements. One of these facilities is within the Faculty of Medicine and Health Sciences (MAF reference code 889), and the other within the School of Biological Sciences (MAF reference code 395).

The Committee notes that procedures are set out to prevent accidental removal of genetically modified cell lines from the containment facilities, and that theft of the cell lines is unlikely due to restricted access to the facilities.

The Committee has however imposed additional controls in Annex 2 of this decision relating to transportation and handling of cell lines (controls 1.4, 1.5, 1.6, 1.9, and 1.10), and disposal of microbiological waste. These controls are intended to reduce risks of escape of genetically modified material from containment, and the risk of adverse health effects on laboratory personnel.

The Committee considers that with the containment controls it has imposed (refer to Annex 2 of this decision), it is very unlikely for viable genetically modified cell lines to escape or be removed inadvertently from containment.

Ability of the organisms to establish an undesirable self-sustaining population and ease of eradication

In accordance with sections 44 and 37 of the HSNO Act, the Authority considered the ability of the genetically modified cell lines to establish undesirable self-sustaining populations, should they escape from containment, and the ease with which such populations could be eradicated. In evaluating these matters the Committee took into account the nature of the organisms (clause 22 of the Methodology).

The Committee concurs with the E&R Report (section 5.3.3), that if the modified cell lines escaped, they are very unlikely to survive and establish a self-sustaining populations because of their dependence on specific culture conditions for survival.

However, the Committee notes that genetically modified animal cell lines could survive outside of containment if placed inside an immuno-compromised animal by surgery or injection. Because the applicant may need to inject cells into animals as part of their research, the Committee has included an additional control (control 1.9). This control permits the injection of genetically modified cells into vertebrate laboratory animals so long as approval is obtained from the Institutional Animal Ethics Committee, and the animals are contained within containment facilities which are registered with MAF under MAF/ERMA New Zealand standard 154.03.03. Containment facilities for vertebrate laboratory animals. This control also requires that the animals shall be destroyed and disposed of according to the procedures described in MAF/ERMA New Zealand standard 154.03.03.

The Committee also notes that plant cells could survive outside of containment if they were induced to form shoots and roots. The Committee has therefore imposed an additional control (control 1.10) to ensure that this does not occur. Control 1.10 states that genetically modified plant cells shall not be induced to grow into whole plants (that is, plants with roots and/or shoots).

The Committee is satisfied that the controls imposed within this decision ensure that inadvertent loss of material from containment is very unlikely, and given that cell lines would be very unlikely to survive outside of containment, the Committee concludes that eradication of the cell lines would not be necessary.

Assessment of potential significant risks and costs

The risks and their associated costs assessed were those identified as potentially significant, having regard for those matters set out in clauses 9 and 10 of the Methodology. Risks were considered in terms of the requirements of clause 12 of the Methodology, including especially the assessment of consequences and probabilities, the impact of uncertainty and the impact of risk management. Costs were considered in terms of clause 13 of the Methodology.

The evidence available was largely scientific in nature and was considered in terms of clause 25 of the Methodology. This evidence comprised principally that provided by the applicant and additional evidence set out in the Evaluation and Review Report prepared by the staff of ERMA New Zealand.

Environmental Effects

Under clause 12(a) of the Methodology, the Committee considers that if cell lines infected with viral agents should escape from containment there is potential for adverse effects associated with the viral agents infecting humans, animals, and plants.

Under clause 12(b) of the Methodology, the Committee considers that given the containment regime and controls imposed within this approval (clause 12(d)), the escape of any modified cell lines from containment is very unlikely (clause 12(c)). The Committee considers that should cell lines infected with viral agents escape from containment, the magnitude of any adverse effect would be minimal or minor, and the overall risk (and its associated costs) would be negligible (clause 12(c)).

Human health effects

Under clause 12(a) of the Methodology, the Committee considers that there is potential for adverse effects to laboratory personnel associated with handling of cell lines that may contain infectious agents (clause 12(a)). The Committee has therefore imposed additional controls (1.5 and 1.6) which are aimed at preventing researchers coming into direct contact with the cells, the culture medium, or aerosols from the cultures. The Committee also requires that any cell lines found to contain infectious agents should be destroyed (control 1.8). The Committee considers (under clause 12(b)) that given the containment regime and the additional controls imposed within this decision (clause 12(d)), it is very unlikely that adverse effects to human health associated with cell lines containing infectious agents would occur (clause 12(c)). The Committee notes that there is uncertainty associated with the magnitude of such an effect (clause 12(e) and concurs with the E&R report which concludes that the magnitude (clause 12(c)) of any adverse effect would depend upon the nature of the infectious agent involved, and that the magnitude could be larger and more widespread if the agent was pathogenic and was able to spread (clause 12(c). The Committee therefore considers that the magnitude of an effect on human health and safety of cell lines infected with viral agents would be minimal or minor, and the overall associated risk and its associated costs would therefore be negligible (clause 12(c)).

Under clause 12(a) of the Methodology, the Committee considers that there is potential for adverse effects to laboratory personnel associated with handling of cell lines that may express toxins (resulting from high level protein expression) (clause 12(a)). The Committee notes that the cell lines to be imported will contain DNA from a broad range of species, using a range of promoters and, some of these promoters may result in high levels of protein expression in the cells. However, the Committee notes that vertebrate toxins with LD50 scores of less than 100μg/kg will not be introduced, nor will high-level expression of other toxin genes be permitted. In addition, complete viral genomes will not be introduced into the cell lines. The Committee has imposed additional controls on the handling (1.5 and 1.6 as described above) of cell lines to ensure that researchers will not come into direct contact via skin or airways with products produced by the cell lines. The Committee considers (under clause 12(b)) that given these additional controls and the containment regime imposed within this decision (clause 12(d)), it is very unlikely that adverse effects to human health associated with cell lines expressing toxins would occur (clause 12(c)). The Committee notes that there is uncertainty associated with the magnitude of such an effect (clause 12(e) and concurs with the E&R report which concludes that the magnitude (clause 12(c)) of any adverse effect would depend upon the nature of the toxin involved. The Committee further considers that the effect is likely to be local as only laboratory personnel who come into contact with it would be adversely affected and the magnitude is consequently minimal or minor, and the overall associated risk and its associated costs would therefore be negligible (clause 12(c)).

The Committee notes that in the event that the cell lines are subject to additional modifications, or infection with genetically modified organisms, then a higher level of containment may be required. These modifications would require additional development approvals from ERMA New Zealand, where additional controls and containment conditions can be specified.

Assessment of benefits (beneficial effects)

A benefit is defined in clause 2 of the Methodology Order as "the value of a particular positive effect expressed in monetary or non-monetary terms". Benefits that may arise from any of the matters set out in clauses 9 and 10 of the Methodology were considered in terms of clause 13.

Under clause 13(a), the Committee considered the primary benefit associated with this application to be increased scientific knowledge (non-monetary) gained through the study of biochemical and cellular events underlying physiological processes in plants and animals. The Committee notes that while the magnitude and expected values of this benefit (clause 13(b)) is uncertain, immediate benefits are likely to accrue directly to the applicant (clause 13(c)). The Committee notes that there may be a possible future commercial benefit associated with the research.

Overall evaluation of risks, costs and benefits

The overall evaluation of risks, costs and benefits set out below was carried out having regard to Clauses 22 and 34 of the Methodology and in accordance with the tests in clause 26 of the Methodology and section 45 of the Act.

Clause 34 of the Methodology sets out the approaches available to the Authority in evaluating the combined impact of risks costs and benefits i.e. weighing up risks, costs and benefits.

The Committee is satisfied that the organisms can be adequately contained (sections 45(1)(a)(iii) and 44(b) of the HSNO Act), under the controls required by this decision (refer to Annex 2). In relation to the additional matters to be considered under section 37 of the HSNO Act, the Committee considers that it is very unlikely for viable genetically modified cell lines to escape or be removed inadvertently from containment and form a self-sustaining population, and that eradication would be unnecessary given the strict culture requirements of the cell lines.

The Committee is also satisfied that, given the containment and additional controls imposed within this decision, the probability of any adverse human health effects occurring is very unlikely.

The Committee has formed the view that risks associated with the application are individually and cumulatively negligible. The Committee had regard to the risk characteristics (clause 33) but they did not materially alter the overall evaluation. The Committee has therefore considered this application in terms of clause 26 of the Methodology, and thus considers that the benefits associated with the importation and use of the modified cell lines in containment outweigh the costs. In reaching this conclusion, the Committee considered all the possible beneficial and adverse effects of the organisms (and any inseparable organisms) in accordance with sections 45(1)(a)(ii) and (iii) of the HSNO Act.

The Committee considers that it is inappropriate to impose a restricted time limit on this approval because the approval is likely to be used by a range of researchers over a period of time. The Committee also notes that the controls imposed within this approval have been used in previous approvals, and as such do not consider that it is necessary for the applicant to report to ERMA New Zealand on the exercise of the controls imposed by this decision.

In addition, the Committee considers that additional controls to measure or monitor for adverse effects are not necessary in this case since the work will be conducted within containment facilities.

Decision

The application for importation into containment of cell lines derived from those organisms listed on pages 1 and 2 and modified as described in Annex 1 of this decision, is thus approved in accordance with section 45(a) of the HSNO Act. As required under section 45(2) the approval is subject to controls (as listed in Annex 2 of this decision).

_____ Date: 20 March 2002

Mrs Jill White
Chair, Decision-making Committee of the Authority

Amendment: November 2006
Changes to controls:

- Addition of footnotes to the containment facility references and the Australian/New Zealand containment facility references to "future proof" the decision
- Standardise the wording of the breach of containment control
- Removal of the control regarding inspection of facilities by the Authority, its agent or enforcement officers

_____ Date: 23 August 2007

Dr Kieran Elborough
Chair, GMO Standing Committee

Amendment: August 2011
Removal of the reporting component of control 1.8.

_____ 30 August 2011

Richard Woods Date
Chair, Decision Making Committee,
Environmental Protection Authority

Amendment: October 2011
Removal of control 5.3 which referred to University of Auckland's containment manuals.

11 November 2011

_____ _____

Deborah Read Date
Chair, Decision Making Committee,
Environmental Protection Authority

Amendment: June 2014
Addition of genetically modified *Mus musculus* cell lines to the approved organisms list.

23 June 2014

Louise Malone
Chair, Decision Making Committee,
Environmental Protection Authority

Date

Annex 1: Organism modifications

Cell lines

Cell lines derived from the organisms listed on page 1 and 2 of this approval are modified by plasmid vectors or disabled viral vectors that are integrated into chromosomes.

Integrated viral vectors shall not be able to produce infective particles or infect human cells. These vectors shall only contain one or more of the following elements, and involve genetic modifications that meet Category A or Category B experiments as defined in the Hazardous Substances and New Organisms (Low-Risk Genetic Modifications) Regulations 1998:

Promoters

Promoter, operator, and enhancer sequences derived from bacterial, yeast, insect, amphibian, plant, fish and mammalian genes, or from viruses.

Reporter genes

Well-characterised[1] gene products that can be assayed by one or more of the following techniques:

1) Visual colour or fluorescence, e.g., green fluorescent protein
2) Spectrophotometrically
3) Histochemically
4) Enzyme-linked immunosorbent assays (ELISA)
5) Thin layer chromatography
6) Liquid scintillation counting
7) Affinity purification, e.g., biotinylation, histidine affinity tags
8) Immunological detection, e.g., epitope tags

And do not produce proteins that are toxic (have an LD_{50} less than 100 µg/kg) to vertebrates.

Selectable marker genes

1. Well characterised genes that confer the ability to tolerate or deactivate:
   (a) Antibiotics, e.g., against hygromycin, neomycin
   (b) Metabolic inhibitors, e.g., against methotrexate, histidinol
   (c) Vertebrate toxins
2. Well characterised genes that confer the ability to synthesise essential metabolites, e.g., His3, Trp1, Ura3

   And do not produce proteins that are toxic (have an LD_{50} less than 100 µg/kg) to vertebrates.

Origins of replication

1. ColE1 or the pUC origins of replication derived from *Escherichia coli* plasmids.
2. Origins of replication from bacteriophage, *Saccharomyces cerevisiae*, mammalian or insect viruses.

[1] Well characterised means that the sequence and function of the gene is known

Other features

1. Multiple cloning site
2. Polyadenylation signals
3. Transcriptional activators
4. Transcriptional responsive elements
5. Transcriptional terminator sequences
6. Secretory signals
7. Intron sequences that function to increase gene expression
8. Ribosomal binding sites and/or Kozak sequences
9. Viral packaging signals, e.g., Ψ+
10. Viral long terminal repeat sequences
11. Cre/Lox recombinase system

Donor DNA

These vectors may contain DNA sourced from prokaryotes or eukaryotes provided that the donor DNA shall not come from:

1. New Zealand native or endemic macroflora and macrofauna, or species valued by Māori that are sourced from New Zealand
2. Māori people
3. Species from Appendix 1 of CITES (http://www.cites.org), unless accompanied by written approvals from the importing and exporting countries.

And that the donor DNA shall not include:

1. Genes encoding vertebrate toxins that have an LD50 of less than 100 µg/kg
2. More than two thirds of a complete viral genome
3. Sequences that will produce particles able to infect humans
4. Sequences that will produce particles able to infect humans and contain sequences coding for proteins known to be directly involved in uncontrolled cell growth in mammalian cells.

Annex 2: Controls required by this approval

In order to satisfactorily address the matters detailed in the Third Schedule Part I: Containment controls for importing, developing or field testing of genetically modified organisms[2] of the HSNO Act, and other matters in order to give effect to the purpose of the HSNO Act (section 45(2)), the Authority's approval of this application is subject to the following controls:

1. To limit the likelihood of any accidental release of any organism or any viable genetic material[3]:

1.1 The person responsible for the particular research area and/or the person responsible for the operation of the containment facility shall inform all personnel involved in the handling of the cell lines of the Authority's controls.

1.2 All work involving cell lines covered by this approval shall be performed in a facility registered as a Physical Containment Level 1 (PC1) or Physical Containment Level 2 (PC2) under MAF/ERMA New Zealand Standard Facilities for Microorganisms and Cell Cultures:2007a.

1.3 The construction and operation of the containment facilities ('the facility') in which the organisms are maintained, shall be in accordance with the:

(a) MAF/ERMA Standard: Facilities for Microorganisms and Cell Cultures:2007a. at Laboratory Physical Containment Level 1 (PC1) for mammalian, insect and plant cell lines, and at Physical Containment Level 2 (PC2) for other animal cell lines.

(b) Australian New Zealand Standard AS/NZS 2243.3:2003 Safety in Laboratories: Part 3: (Microbiology), at Laboratory Physical Containment Levels 1 and 2.

Additional controls

1.4 The minimum requirement for packaging for transportation of the organisms by all modes (ie air, land and sea) from overseas and for transfers between facilities, is that the organism shall be packaged according to Packing Instruction No. 650 of the International Air Transport Association (IATA) Dangerous Goods Regulations (refer to MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02[4]). All containers must be clearly labelled with the name, address and phone number of both the sender and the recipient.

1.5 Disposable laboratory gloves shall be worn when handling the cells and culture medium.

1.6 Any work that may result in the production of aerosols shall be carried out in a Class II Biological Safety Cabinet.

1.7 Microbiological waste shall be chemically sterilised or autoclaved before disposal.

1.8 Cell lines found to contain infectious agents shall be destroyed by autoclaving.

1.9 Genetically modified cells may be injected or otherwise introduced into vertebrate laboratory animals so long as approval is first obtained from the Institutional Animal Ethics Committee and the animals are contained in MAF-registered containment facilities that are constructed, operated and managed in accordance with MAF/ERMA New Zealand standard Facilities for Microorganisms and Cell Cultures:2007a. Containment Facilities for

[2] Bold headings refer to *Matters to be Addressed by Containment Controls for Development and Field Testing of Genetically Modified Organisms*, specified in the Third Schedule of the HSNO Act 1996.

[3] Viable Genetic Material is biological material that can be resuscitated to grow into tissues or organisms. It can be defined to mean biological material capable of growth even though resuscitation procedures may be required, eg when organisms or parts thereof are sub lethally damaged by being frozen, dried, heated, or affected by chemical.

Vertebrate Laboratory Animals. When they are no longer required the animals shall be destroyed and disposed of according to the procedures described in this standard.

1.10 Genetically modified plant cells shall not be induced to grow into whole plants (ie, plants with shoots and/or roots).

2. To exclude unauthorised people from the facility:

2.1 The identification of entrances, numbers of and access to entrances, and security requirements for the entrances and the facility shall be in compliance with the requirements of the standards listed in control 1.3.

3. To exclude other organisms from the facility and to control undesirable and unwanted organisms within the facility:

3.1 The exclusion of other organisms from the facility and the control of undesirable and unwanted organisms within the facility shall be in compliance with the standards listed in control 1.3.

3.2 Genetic material derived from species listed in Appendix 1 of CITES (http://www.cites.org) shall not be used unless accompanied by written approvals from both the importing and exporting countries.

4. To prevent unintended release of the organism by experimenters working with the organism:

4.1 The prevention of unintended release of the organisms by experimenters working with the organisms shall be in compliance with the standards listed in control 1.3.

5. To control the effects of any accidental release or escape of an organism:

5.1 Control of the effects of any accidental release or escape of a cell line shall be in compliance with the standards listed in control 1.3.

5.2 If a breach of containment occurs, the facility operator must ensure that the MAF Inspector responsible for supervision of the facility has received notification of the breach within 24 hours.

6. Inspection and monitoring requirements for containment facilities:

6.1 The inspection and monitoring requirements for containment facilities shall be in compliance with the standards listed in control 1.3.

6.2 The containment manual shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with the MAF/ERMA NZ Standard Facilities for Microorganisms and Cell Cultures:2007a.

7. Qualifications required of the persons responsible for implementing those controls:

7.1 The training of personnel working in the facility shall be in compliance with the standards listed in control 1.3.