Code of Ethical Conduct

HyClone New Zealand's Animal Ethics Committee

September 2013

Revision 4

1 Description of work carried out:

The work carried out at Thermo Fisher Scientific Tauranga Ltd (HyClone New Zealand) consists of managing farm animals which are used to produce biologicals / pharmaceuticals.

2 The aims of this Code of Ethical Conduct are:

To ensure compliance with the Animal Welfare Act 1999 and the Regulations made thereafter;

To ensure section 80 of the Animal Welfare Act 1999 ha relates to Thermo Fisher Scientifics business is understood and complied with so that animals are used only when the benefits are not outweighed by the likely harm to the animals.

To emphasize the responsibilities associated with research, teaching and biotechnology involving the use of live animals.

To promote an attitude which will encourage the welfare and care of animals so that any degree of stress or discomfort produced is reduced to a minimum.

To ensure that projects are not prejudiced by inefficient techniques and lack of care of animals.

To promote a philosophy of seeking ways of:

- reducing the number of animals used to the minimum necessary
- refining techniques so that any harm caused to the animals is minimised and the benefits are maximised
- replacing the use of whole animals with alternative non-living methods where appropriate

These points are referred to in the Animal Welfare Act 1999 as the 3 Rs (reduction, refinement, and replacement)

3 HyClone New Zealand Animal Ethics Committee (also referred to as AEC) procedures are detailed as follows:

a) Current AEC:

Thermo Fisher Scientific NZ has an Animal Ethics Committee, HyClone NZ AEC consisting of five voting members.

The Committee is encouraged to reach decisions when approving protocols and there may be occasions when the decision is not to approve protocols.

Voting members:

Appointed by the CEO and subject to the endorsement by the AEC:

- The Chairperson
- Deputy Chairperson/Secretary and Minute Secretary

External members:

- A representative nominated by the New Zealand Veterinary Association
- A person to represent animal welfare and nominated by an approved animal welfare organisation e.g. RNZSPCA
- A layperson nominated by the local District Council

Non-voting members
The contracted Veterinarian is invited to all AEC meetings.

b) When a member of HyClone Animal Ethics Committee retires or stands down the following process occurs:

i) Chairperson:
A new Chairperson is appointed by the Chief Executive Officer to become a member of the Animal Ethics Committee. This person must be a senior member of staff, but may also be the Chief Executive Officer.

ii) NZVA & RNZSPCA representative:
A request is submitted to the relevant body seeking nomination of a representative to join the Animal Ethics Committee. The new appointee must comply with Section 101, sub-section 5 of the Animal Welfare Act 1999, for the NZVA representative and sub-section 6 of the Animal Welfare Act 1999 for the RNZSPCA representative.

iii) Lay-person:
A request is submitted to the local council seeking nomination for a new representative to join the Animal Ethics Committee. The new appointee must comply with section 101 sub-section 8 of the Animal Welfare Act 1999.

iv) Staff representative (if required):
A request is submitted to the Chairperson seeking nomination for a new representative to join the Animal Ethics Committee. The new appointee must comply with section 101 sub-section 4 of the Animal Welfare Act 1999.

v) Deputy Chair/Secretary:
A new Deputy Chair/Secretary is appointed by the CEO to become a member of the Animal Ethics Committee. This person can be a member of staff with the appropriate knowledge to perform their duties.

c) AEC Meeting Rules:

A quorum is three members and must include a majority of external members.

The Deputy Chairperson/Secretary abstains from voting when there are four Animal Ethics Committee members in attendance at a meeting.

The position of each company appointed member of the Animal Ethics Committee member is reviewed every 3 years and may be renewed. All external AEC members must be renominated every 3 years by their appropriate body. Any concern regarding the potential renewal of a term of office is to be directed to the Chairperson, who will then consult with other Animal Ethics Committee members to determine appropriate action.

The Chairperson will ensure that all members are fully prepared for their role on the AEC. All new AEC members are provided with an induction pack supplied by NAEAC.

A meeting fee is available to all external members, along with a mileage allowance.

The AEC meets at least twice a year, at a time and place confirmed by the Chairperson.

The AEC has the power to co-opt experts where necessary.

A person with the appropriate skills is available to act as AEC minute secretary to ensure that all minutes of the AEC proceedings, its decisions, operations and records are stored and maintained in a satisfactory manner. Thermo Fisher Scientific NZ provides a budget to cover administrative and related costs.

Agenda and accompanying material are circulated to Animal Ethics Committee members at least 5 working days before each meeting.

The Chairperson and one external member may approve any changes to protocols if they are considered to be of a minor nature. The Committee will review any such approvals at the next meeting. Changes of a minor nature would include items such as a short extension to a protocol, or a change that is a specific production change and will not adversely impact the health and welfare of the animals.

The AEC has the power to amend, suspend or revoke protocols where it considers the Code of Ethical Conduct or the requirements of the protocol are not being met.

External members of the HyClone NZ AEC cannot submit a protocol application to the HyClone NZ AEC as they would not meet the criteria of being “not associated with Thermo Fisher Scientific”.

When persons or outside organisations request permission to operate under the HyClone NZ Code of Ethical Conduct, this will only be acceptable if the expertise of the AEC is appropriate for the supervision of such persons or organisations. Similarly, if arrangements cannot be made to monitor the activities of applicants, the request will be declined. To ensure everyone is aware of the requirement, NAEAC suggests that some reference be made to notifying MPI if any such arrangements be made.

A copy of this Code of Ethical Conduct will be available to all Animal Ethics Committee members and to the company directors and stakeholders.

d) Confidentiality:

All members of the AEC will sign a Confidentiality Agreement to ensure they do not disclose Business Information i.e. trade secrets, inventions, processes, formulas, compounds, procedures, data, research, business information and know-how belonging to the Disclosing Party, to any third party without prior written permission from the Committee.

e) Protocol Applications:

Protocol applications will be according to a standard format and will cover all relevant items mentioned in the Animal Welfare Act 1999.

When the AEC review a new or existing protocol, members must reference the relevant parts of Section 100 of the Animal Welfare Act 1999.

Special emphasis will be given to keeping to specific operating procedures and ensuring that all personnel are properly trained.

Hyperimmune (treated animals) protocols are reviewed every 12 months. Donor (non-treated) protocols are reviewed 3 yearly.

If a trial protocol is presented it will be for a fixed period with a well-defined end point and a final report will be made available to the AEC. Any adverse effects of the trial will be reported to the AEC during the term of the trial. This report will summarise the outcomes of the trial in terms of assessing whether the trial purpose was achieved. It will also include comment on any animal welfare issues that may have arisen during the project.

f) Monitoring animal welfare and facilities:

The Manufacturing Manager is responsible for ensuring that animal husbandry meets the required animal welfare standards. At each AEC meeting, the Manufacturing Manager will certify that the health and condition of the relevant animals have been monitored regularly. The AEC does have access to the animal health records that are kept as part of company policy.

External members of the AEC undertake monitoring of the animals, facilities and procedures at least twice per year these are recorded in the Minutes.

Thermo Fisher Scientific hire personnel are who are either Animal Technicians or people that have farming experience who can he trained as Animal Technicians. All training is carried out in-house through the TFS training programme and is documented. Thermo Fisher Scientific has experienced animal handling and farm staff and a contracted veterinarian. Adequate processes are in place to monitor the activities of Animal Technicians, particularly in relation to their adherence to the conditions of protocol approvals.

At the final meeting of each year, an assessment exercise will be held to determine whether the AEC is functioning with optimum effectiveness to the satisfaction of the whole committee. It will be

determined whether there has been sufficient monitoring of animals throughout the year and whether these activities have been recorded in the appropriate way. All conclusions of this exercise will be included in a form that is adequate for the independent audit review required by the Animal Welfare Act 1999.
Statistics on animal use and severity of use will be forwarded to MPI as required.

The AEC veterinarian evaluates practices and facilities at least twice a year, and will report any issue to the AEC Committee, these observations will be recorded in the Minutes. The contracted veterinarian oversees all animal health and welfare issues at all other times.

Procedures and policies are in place to ensure that animal facilities and practices are in accordance with good practice and scientific knowledge.

4 Report of Non-Compliance:

a) Any member of an Animal Ethics Committee who believes that the Committee or the Code Holder is failing to comply with the Animal Welfare Act 1999 or with any regulations made under the Animal Welfare Act 1999 or with the Code of Ethical Conduct, may report the non-compliance to the Director General.

i) A member of an Animal Ethics Committee who makes a report under sub-section (a) in good faith is not to be liable to any civil or criminal proceedings or to any disciplinary proceedings by reason of having made that report.

b) In the event of a member of the AEC, a member of staff, or a member of the public reporting any non-compliance or animal welfa e concerns to either the AEC or to Thermo Fisher Scientific NZ, a full and thorough investigation will be held and the findings documented and reported to all the AEC members. Any approach by an animal welfare inspector will immediately be advised to the Animal Ethics Committee. The Animal Ethics Committee members will be kept fully informed of progress throughout the investigation. Any member may call a specific meeting of the Animal Ethics Committee to review the issues. Any other complaint received regarding animal welfare will be communicated to the Animal Ethics Committee as soon as practicable. If received directly by Thermo Fisher Scientific NZ or a member of the AEC the following is the action that will be taken:

i) Respond immediately to determine any current animal welfare concerns that need to be remedied to mitigate any suffering.

ii) Report to Management who will conduct a preliminary investigation as to the cause and likely affect.

iii) Corrective action will be determined as appropriate.

c) Upon receiving from the Committee a report as to non-compliance with this Code of Ethical Conduct, the Code Holder shall immediately consider the report and take appropriate action thereon, which may include in-house disciplinary action, and / or reference of the report to the Ministry for Primary Industries with a view to a prosecution.

d) If for any reason the performance of any Animal Ethics Committee member should be considered inadequate in the role, this concern is to be directed to the Chairperson. A sub-committee will meet to review the situation. The sub-committee will consist of 2 external members and the Chairperson. If the Chairperson is the member in question, an AEC member elected by the remaining AEC members will replace the Chairperson.

5 Responsibilities of Thermo Fisher Scientific New Zealand:

a) Thermo Fisher Scientific NZ shall not conduct, or permit any person to conduct on its behalf, whether on its own premises or elsewhere, any research, experimental, diagnostic, toxicity, or potency testing work involving the manipulation of any live animal, or teaching involving the manipulation of any live animal, unless that work or teaching is carried out in accordance with this Code.

b) Thermo Fisher Scientific NZ shall bring every protocol to the attention of the Animal Ethics Committee for its prior approval in sufficient time to enable adequate consideration thereof.

c) All Acts of Parliament, Regulations or Bylaws pertaining to the obtaining, holding, possession, care and treatment of animals are to be complied with.

d) Every such protocol shall specifically refer to such of the following matters as are relevant to the protocol:

i) Whether any alternative to the manipulation or use involving reduction, refinement or replacement, has been considered, and is reasonably practicable. If so, why such alternative is not being adopted;

ii) In what respect the work proposed is likely to result in the extension of the body of knowledge relevant to the health and welfare of humans, or animals or the productivity of animals;

iii) What factors have been taken into account in the choice of animal species and the weighting given to such factors? Where standard works of reference have been relied on, these should be identified;

iv) The decision as to the number of animals involved, to ensure that it should be the minimum necessary to provide a scientifically interpretable result, consistent with the level of accuracy required;

Consideration must be given to:

- The design of the study;
- The level of accuracy necessary in the results;
- The possible confounding effects of animal variation;
- The needs of statistical analysis.

In general, duplication of experiments involving live animals should only be contemplated when it is considered that the original study requires scientific verification or was flawed or inadequate in some way which would invalidate its conclusions;

v) The source from which the animals are to be obtained, their movement and transportation and measures to ensure their welfare and humane treatment;

vi) The responsibilities of the persons undertaking, supervising and responsible for manipulation and selection of animals, and their care and disposal;

vi) The measures to be taken to ensure the health and welfare of animals before, during and after manipulation, including the adequacy and cleanliness of housing, caging and equipment; the provision of food and water; prevention of overcrowding and prevention and control of disease;

viii) The measures to be taken to minimise pain or distress; including abandonment of any manipulation and the humane destruction of animals where pain or distress cannot be held within reasonable levels;

ix) Consideration should be taken into account for the multiple use of animals.

x) Any other aspects of the protocol that the applicant considers ought to be brought to the attention of the committee;

e) Thermo Fisher Scientific NZ shall in all respects comply with the regulations which relate to the keeping of sufficient records and the supply of statistics and other data to the Director-General of Primary Industry;

f) Every protocol shall clearly identify the persons involved in carrying it out and those responsible for the manipulations and shall be signed by them. They shall be responsible to ensure that all personnel involved in the manipulation and ca e of animals are aware of their obligations under this Code of Ethical Conduct. Every person signing the protocol shall provide appropriate information as to their experience with the procedures proposed in the application and shall confirm that they have read this Code of Ethical Conduct and will abide by it;

g) In addition to containing an appropriate scientific and technical justification and description of procedures sufficient to enable the Animal Ethics Committee to have an adequate understanding of the protocol and addressing any other matters referred to in paragraphs (d) and (f) above, every protocol shall include an explanation in non-technical language fully describing the purposes and anticipated benefits of the work;

h) Thermo Fisher Scien ific NZ shall fully and promptly comply with any decision of the HyClone AEC and shall take into account any report of the HyClone AEC;

i) Thermo Fisher Scientific NZ shall indemnify each member of the HyClone AEC against any claim whatsoever arising out of any act done or omission made in good faith in pursuance, or purported pursuance of this code;

6 Change History:

4	Entire document	Updated to TFS Tauranga Ltd. Changed MAF to MPI
	3a	Removed 2 non-voting members. Added Committee encourages consensus, then majority voting. Changed non-voting members, removed minute secretary and consultant vet. Added contracted vet invited to meetings. Added there may be occasions when a decision is made not to approve a protocol/
	3e	Protocol reviews – Hyperimmune 12 monthly, Donor 3 yearly Added reporting any adverse effects.
	3c	Change meeting frequency to 'at least twice a year' Added notify MPI if any arrangements regarding outside organisations is made
	3f	Changed Donor Ops Manager to Manufacturing Manager. Changed to twice times a year and recorded in the Minutes Changed contracted vet responsibilities and split between contracted vet and AEC vet. Added AEC vet attend at least twice a year.
	3f para 3	Added TFS Animal Technicians and farm staff
	5d ix)	Added multiple use of animals

ThermoFisher SCIENTIFIC

HyClone New Zealand Animal Ethics Committee

This is to certify that the Code Holder undertakes to conform to all the requirements of the Animal Welfare Act 1999 and will ensure that all persons involved in the animal manipulations and carrying out of these activities are appropriate persons according to the Act. It is accepted that the Code Holder is also responsible for distributing information on the requirements of the Animal Welfare Act 1999 to the Animal Ethics Committee to help ensure that the Animal Ethics Committee follows the requirements of the law.

_____ _____

Date

Chairperson
HyClone Animal Ethics Committee

ASP/G-4 Code of Ethical Conduct - MSDAH Animal Ethics Committee v4.0

MSD Animal Health

Summary

Objective
This Code of Ethical Conduct (CEC) is to cover the activities of Schering-Plough Animal Health Ltd, trading as MSD Animal Health, (MSDAH) and any New Zealand associated organisations.

Background
The main business of MSDAH is to manufacture and distribute a range of animal health products, for domestic and farm animals, with an emphasis on vaccines and parasiticides.
MSDAH requires animals in the process of developing new products, and meeting regulatory obligations for those under current production. Animals most likely to be used are rabbits, guinea pigs, mice, sheep, cattle, pigs, deer, and chickens. On occasions other species may also be required.
This code is written to comply with the Animal Welfare Act 1999

s 9(2)(a)

Owner 07/Nov/13.

Expert 07NOV13.

Procedure

1.0 THE ANIMAL ETHICS COMMITTEE (AEC)
General Manager Operations , AEC Chair

a Purpose
According to the Animal Welfare Act 1999 (The Act), an AEC will be set up to approve projects, protocols and procedures, to regulate the use of animals.

b Matters Not Covered Elsewhere
In accordance with The Act, section 102, any procedure not covered by this CEC, or The Act, must be decided by the committee.

c Enquiries
Members are not authorized to speak for the committee. All enquiries (whether from Media, the general public, industry or otherwise) must be directed to the Chairperson.

d Membership
The AEC will be made up of at least the following members:

- Chairperson - Appointed by the General Manager (GM), subject to the endorsement of the AEC. The AEC must provide a clear reason for any rejection of the proposed Chairperson. The Chairperson will be a senior member of staff.
- Manager of the animal facility, if such a facility exists
- Nominee of an approved animal welfare organisation
- Lay person nominated by the Local Territorial Authority
- Veterinarian nominated by the New Zealand Veterinary Association.

The GM will appoint other staff members to the AEC as is appropriate.

NOTE **Independence**
External nominees must be independent of MSDAH

e Period of Appointment
Internal members are appointed due to their role in the organisation. They will remain on the committee as long as the GM feels their presence is valuable.
External members are appointed for a period of 3 years. At the expiry of those 3 years, they may be re-appointed at the agreement of both parties, following their formal nomination by the relevant body.

It is important that external appointments do not expire at the same time. In order to avoid this, external appointments may on occasion be made for 1 - 4 years.

f Induction for New External Members
New external members will be given an induction by the Chairperson. This will cover the following points.

- MSDAH business and major product lines.
- Distribution of MSDAH markets, and impact on testing requirements.
- Makeup of the AEC, and current members.
- Major projects currently running under AEC approval.
- Operating methods of the AEC.

An induction pack should be prepared for the new member. The type of material could include:
- Copy of this CEC.
- Copy of Part 6 of The Animal Welfare Act 1999.
- NAEAC induction pack for new AEC members.
- Copy of the procedure 'The Processing of Documents Requiring AEC Approval'.
- Publications showing MSDAH products.
- Publications about MSDAH NZ and world wide.
- Organisational chart.
- Confidentiality agreement.

g Remuneration
An honorarium will be paid to all external members. This will cover meeting attendance and preparatory work. Expenses for travel may also be paid. In each case, honorarium expenses will be negotiated with the Chairperson.

h Confidentiality
All external members will be required to sign a confidentiality agreement, before they begin performing member duties.

Nothing in this agreement will prevent the member raising legitimate concerns as detailed in The Act Section 103. (see also section 8 below)

Note that internal members are bound by the confidentiality clause in their employment agreements.

i Conflicts of Interest
If any member is perceived to have a conflict of interest, they should raise the matter with the Chairperson in the first instance (or the GM in the event that the Chairperson believes he/she has a conflict).

If following the discussion with the chairperson (or GM as the case may be) a conflict is agreed, the affected party will remove themselves from the committee, whenever the matter in question is discussed.

j Parenting arrangements
MSDAH will allow piggybacking arrangements for MSDAH associated organisations, but generally, will not be involved in third party piggybacking arrangements.

MSDAH AEC will not approve projects for non-associated third party organisations, unless MSDAH staff maintain (some form of) oversight of the work.

When work is contracted to other organisations, it will be the responsibility of that organisation's AEC to approve and monitor the work.

NOTE **Piggybacking**
Piggybacking is where the MSDAH AEC would approve projects for third-party organisations, generaly where that organisation does not have an AEC.

2.0 AEC MEETINGS
AEC Chair, AEC Secretary

a Meeting Participation
MSDAH is a private commercial organisation. Only those invited are permitted to attend AEC meetings. Invitations must be approved by the Chairperson, or General Manager.

b Chair
The Chairperson is appointed by the GM. In the chairperson's absence, the GM will appoint a replacement.

c Secretary
The Chairperson will nominate a secretary from the internal appointments. The secretary will prepare an agenda, take and distribute minutes of the meeting. The secretary will store all AEC records, as covered in section 5 below.

d Meeting Frequency
Meetings are held monthly. The committee can change the frequency of meetings, depending on workload. A normally scheduled meeting will be cancelled if there are no applications, or other pressing matters for the committee to consider.

e Meeting Attendance
It is expected that members, both internal and external will attend all normal scheduled meetings, unless they are on leave, or away on business.
When the member is unable to attend a meeting, they must notify the chairperson as early as possible.

f Quorum
A quorum (for normal meetings and teleconferences) shall be 2 external members plus the Chairperson. For external members who are unable to attend, but have had adequate time to prepare, proxy votes will be acceptable, and count towards the quorum.

g Distribution of Agendas and Proposals
The Secretary will distribute these at least 3 days prior to the meeting. Where proposals are distributed less than 3 days before a meeting, they will only be tabled with the agreement of the members.

h Decision Making Process
This AEC will always aim for full agreement. When doubt arises, proposals will be referred back to the authors. However, if after referral and discussion, full agreement cannot be reached, the decision to reject/accept the proposals will be based on the votes of the majority of external members.

i Decision Making Between Meetings
In the case of urgent proposals one of the following methods will be used.

a) Extra meeting. This would be appropriate for unfamiliar work, particularly if involving high ethical cost.

b) Teleconference. Appropriate where justification is high (eg. work required by regulatory authorities), or where ethical cost is low.
Where approval is given on teleconference, minutes will be taken, and confirmed at the next regular meeting.

3.0 MAKING AN APPLICATION TO THE AEC
AEC Members, Study Director

a Requests to be in Writing
All requests to the AEC must be in writing, and in the correct form.

Details of this process are contained in ASP/G-7 'The Processing of Documents Requiring AEC Approval'. ASP/G-7 requires AEC approval each time it is reviewed, or altered.

The author of any AEC request/proposal/protocol, is encouraged to be present at the meeting at which the request is to be considered.

b Approval
Approval of the proposal will be confirmed in writing by the AEC secretary. This approval note will be sent to the author of the proposal.

c Maximum Approval Period
The maximum period for any AEC approval will be 3 years from the date of approval. Continuation of any project beyond this time will require a fresh application.

d Amendments
Where a project is approved but later found to require changing, the author should contact the chairperson. If changes are minor, and do not impact on animal welfare, the chairperson in consultation with at least one external member, may give approval to continue. The chairperson will then report to the AEC at the next meeting.

If changes are major or impact on animal welfare, a new application must be made to the AEC. This application need only cover the proposed changes. The application number will generally be the same as the original, but with a suffix. For instance, if the original application was AEC 23/03, the first amendment will be AEC 23/03a.

e Termination of an Approval
If the AEC believes that the work being carried out under an approval is in breach of legislation, or of the terms of the approval, the leader of that project should be called to a meeting with the AEC. This meeting should be held at the earliest possible date, and all available members should be in attendance.

If at the conclusion of this meeting the work still appears to be in breach, the project will be terminated. The chairperson will give the study director written notice that the project is terminated. No further manipulations will be allowed on this project.

If the study director is subsequently able to provide information, or to make changes to the project, which indicate compliance, the AEC may consider reinstatement of the approval.

4.0 COMMUNICATION
AEC Members

a Open Communication
Open communication between the AEC and MSDAH will be facilitated by the presence of a senior staff member on the committee.
Copies of all minutes and annual reports will be provided to the GM.

b Contact Points
AEC members requiring information about animal facilities, or animal care practices can contact either the Chairperson, or the animal facility manager directly.

c AEC Input into Organisational Decisions Affecting Welfare
The AEC will be kept informed of organisation changes, and changes to facility design, which might impact on animal welfare.

d Company Procedures
All company procedures regarding animal care and use are open to the AEC and will be made available on request.
Any procedures relating to animal welfare will require review & approval by the AEC

e AEC Recommendations to MSDAH
From time to time the AEC may wish to make recommendations to MSDAH. These should be put in writing, signed by the Chairperson and sent to the GM.

The GM will make a written response to the AEC, at the next scheduled meeting. If there is not sufficient time for the GM to make a considered response before the next meeting, he will provide a written acknowledgement and a timetable for a response.

5.0 PROJECT MONITORING
Animal Services Manager, AEC Members, Study Director

a Project Commencement
(i) No manipulations will be started (except as in point (ii) below), without the operators having sighted the signed AEC approval.
(ii) In the event that a project must start immediately after approval is granted, the operator may commence after verbal confirmation from the AEC chairperson or secretary that the work has been approved, provided the approval note is forwarded immediately following the conversation.

b Approval Conditions
The study director is responsible for ensuring the project is carried out in accordance with any and all conditions of the approval.

c AEC Monitoring of Approvals
AEC monitoring of the work being carried out on animals occurs in a number of ways:
• The manager of the animal facility is an AEC member. This member's presence in the animal facility gives ongoing monitoring of adherence to both this code, and individual approval conditions.
• Other members are encouraged to observe procedures, and have unhindered access to do so. To organise access, members should contact the study director, or animal facility manager as appropriate. Any such visits will be recorded in the minutes of the subsequent AEC meeting.
• Study directors of trials lasting more than a year must provide a progress report to the AEC on an annual basis, as provided in section 5d.
• By requiring a veterinarian to review, and approve staff as competent, before they can carry out manipulations un-supervised. Notification of training and approval, is given at each AEC meeting.

d Project Reports
Study directors will provide a report within 3 months of the end of each trial. These reports will detail:
• The number of animals used, including review of original severity grading
• Brief description of the results, including any unexpected outcomes
• Summary of the value/understanding gained as a result of the work

For projects taking a number of years, study directors will submit an annual progress report.

NOTE **Adverse Events**
Serious adverse events that impact animal welfare, or undermine the project purpose must be notified promptly to the AEC Chair.
Other events must be documented in the appropriate section of the AEC trial report.

e Monitoring Animal Usage
The study director is responsible for monitoring the numbers of animals used, and ensuring this does not exceed the number approved.

Animal usage data will be collected in accordance with the Animal Welfare Regulations 1999, (or any subsequent updates), and supplied (by the AEC Secretary) to the relevant government body, as required under the regulations.

f Reporting Animal Usage
A report on actual animal usage will be provided by the Animal Services Manager to the AEC on a monthly basis. This will include:
- Number of animals used
- Number used for multiple trials
- Details of unexpected deaths (or culls) of animals on test.
- Extra animals used for training staff.

g Document Retention
The chairperson will ensure that all minutes, approval documents, animal usage records are retained, and stored in a retrievable manner.

All documents related to AEC activity will be kept for 7 years.

6.0 FACILITIES MONITORING
AEC Chair, AEC Members

a Access to Facilities
MSDAH animal and research facilities are open to AEC members. Any members wishing to view facilities should contact the Animal Facility Manager.

b Veterinary Scrutiny
A consulting Veterinarian will visit the animal facilities not less than twice per year, to check on animal welfare and husbandry. A written report will be provided to the AEC and GM.

c AEC Inspections
In addition to the inspections detailed in 6b, the AEC will visit and inspect each company owned animal facility at least once per year. Such visits will be recorded in the minutes of the subsequent AEC meeting.

d Audit findings
The AEC will be notified verbally of any audit findings relevant to animal welfare, or the conduct of animal trials, at a subsequent AEC meeting.

7.0 ANIMAL MANAGEMENT PRACTICES
Animal Services Manager

a Written Procedures
All aspects of the breeding, holding and manipulating of animals will be covered by written procedures. Where these procedures have a direct impact on animal treatment/manipulations, they will be reviewed and approved by the AEC.

If a proposal calls for activities not covered by existing procedures, these activities must be detailed in the application to the AEC.

b Staff Qualification
(a) Laboratory Animal Facilities
These facilities will be managed by staff with appropriate veterinary or animal care qualifications or experience.

(b) Large Animal Facility
These facilities will be managed by staff with appropriate veterinary or livestock qualifications or experience.

c Staff Training
All staff will be trained against written procedures. For animal manipulations, this will be in accordance with SOP/SW 10/013: Training in Restricted Animal Procedures.

d Off Site Farm Work
When projects approved by the AEC are to be carried out on commercial farms, the applicant must be confident that adequate standards of care will be provided. These trials must be supervised by either a suitably qualified member of staff, or be under the control of a contract veterinarian at the location.

e New Staff
New staff will undergo a formal induction process. The induction manual will identify the key procedures against which the person will be trained.
The AEC will be notified of any new staff who will be involved in animal manipulations.

f Disciplinary Procedures
If it is found that staff members have not followed the conditions of approval, the disciplinary process will be as detailed in the MSDAH business procedure 'Disciplinary Procedure Ref. BP/HR/01.'

8.0 COMPLAINTS PROCEDURE
General Manager Operations , AEC Chair, AEC Members

a Application of Section 8.
This section is written to cover complaints from current AEC members. Complaints from any other party should be directed to the GM.

b Making a Complaint
All complaints will be put in writing, and sent to the chairperson of the AEC.
In the absence of the Chairperson, the complaint will be forwarded to the GM.

If the complaint concerns the chairperson, it should be sent directly to the GM, who will assume the role of the chairperson as detailed in 8c & 8d below.

c Response
The chairperson will respond in writing within 5 working days and will make a decision as to appropriate action within 6 weeks.

Note: Where the complaint relates to an animal welfare issue, The Chairperson will investigate, and respond within 3 working days.

Where appropriate the matter will be discussed at the next committee meeting.

The chairperson will bear in mind the need for confidentiality (of the complainant), when considering the correct action.

d Response not Satisfactory
If the complainant is not satisfied with the result of the chairperson's decision he/she may request a review by the GM. This must also be in writing.

The GM will meet with the complainant within 10 working days, and respond in writing within 10 working days of that meeting.

If at the end of this process the complainant is still not satisfied, and believes there is a case of non-compliance by the code holder (against the CEC, or the Act) that person should report the non-compliance to the Director-General, as covered by section 103 of The Act.

9.0 AMENDMENTS TO THIS CODE
AEC Chair

a The MSDAH AEC can make minor amendments to this code, without consulting the Director-General. However the Director-General must be given details of all such changes at the end of each year (these must be received by the Director-General by 31 March of the following year).

10.0 Distribution of This Procedure
AEC Secretary

a Parties to Receive Copies.
Copies of this CEC will be distributed to the GM, and to all active AEC members.