APPENDIX 1

CHECKLIST TO ASSIST AECS IN ADDRESSING APPLICATIONS FOR GENETICALLY MODIFIED AND CLONED ANIMALS

Applications for genetically modified and cloned animals must still be subjected to all the conditions required by the *Code*. Some additional points for consideration by the AEC for the generation of genetically modified animals include:

1. Is this a new genetically modified or cloned animal being created?

   If yes, has it been done elsewhere? What checks have been made eg literature search etc? Would it be more efficient to outsource this production? If done elsewhere, it would reduce numbers if the genetically modified progeny were purchased from an existing colony as the initial breeding stock would not be required.

2. Detail of the numbers of the breeding stock required to produce the genetically modified progeny

   This will be large in comparison to the number of animals with the correct phenotype or genotype that will be produced and must be included in the justification of the project, that is, the benefit of the research versus the impact on the animals.

3. Have the relevant permits been obtained from the OGTR if required?

4. Does the institution have the appropriate facilities eg PC2 to house these animals?

5. What is the genetic modification that is proposed?

   - If experimental use of an already developed genetically modified strain, a phenotype report should be available that characterises the modification and any known or expected adverse side effects and the care required to address these effects.
   - If a new strain, detail of the expected impact on the animal's phenotype should be included.

6. What special care, if any, is required for these animals?

   For example, if heart failure develops at six months of age as a result of genetic modification, will the animal be killed at five months before this occurs? That is, will there be defined humane end points?

7. What monitoring systems will be put in place to detect any unexpected adverse effects to characterise the phenotype?

Several appendices are provided as example monitoring forms. Which is most appropriate to this case? Monitoring needs to detect events such as adverse impact, increased mortality and failure to thrive but should not be adversely invasive. It should aim to measure physical status, nutritional status and behaviour and should include whole of life monitoring. In the case of a new strain, several generations should be monitored to ensure phenotypic stability. AECs need to balance these factors.

8. Frequency of reporting to AEC

All adverse animal welfare events are to be reported.

9. Techniques for genotyping

Has the least invasive method been considered? If the less invasive methods are not possible, have the more invasive techniques been justified? For example PCR analysis versus tail biopsy.

10. Techniques for the generation of the genetically modified animal

Are there SOPs in place, are they appropriate and ensure adequate care of all animals involved?

11. Development of a phenotype report for a new genetically modified strain

This is essential and the application should outline a satisfactory method for accomplishing this.

12. Determination of when the new strain becomes a 'normal' breeding colony

This requires AEC approval and factors to consider include:

- is the phenotype and genotype stable and well characterised?
- are there any special care requirements?
- what is the environment that the animals will be exposed to? A phenotype stable in the laboratory may not be in the field.
- what is the impact on the environment into which they will be placed? Will this affect the wild type if breeding occurs?

13. Publication of information of the existence and characterisation of a new genetically modified strain

This is essential to avoid duplication elsewhere.