

# NAEAC POLICY STATEMENT: THE PRODUCTION OF GENETICALLY-MODIFIED ANIMALS

## Purpose

This NAEAC policy statement provides an overview of the requirement for animal ethics committee approval in the production of genetically-modified animals.

As defined in the Royal Commission Report (2001):

**Genetically-modified** is the deletion, change or moving of genes within an organism, or the transfer of genes from one organism to another, or the modification of existing genes or the construction of new genes and their incorporation into any organism.

## The legislation

The welfare of genetically-modified research animals (Gm-animals) is not specifically referred to in the Animal Welfare Act 1999. NAEAC has, therefore, felt it necessary to set out the principles involved in assessing the production of such animals, in order to demonstrate how they should be considered within the context of the Act.

NAEAC regards AECs that are likely to evaluate work involving Gm-animal production as being competent to consider gene-modification protocols for approval. In many ways, such procedures are similar, for example, to experiments with mutagens or the investigation of cytotoxic drugs. Such procedures have been considered adequately by AECs since the introduction of the Animals Protection (Codes of Ethical Conduct) Regulations 1987.

Abbreviated key definitions in the Animal Welfare Act are:

### “Manipulation” –

...

(1) *In this Act, unless the context otherwise requires, the term manipulation, in relation to an animal, means, subject to subsections (2) and (3), interfering with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately –*

(a) *Subjecting it to a procedure which is unusual or abnormal when compared with that to which animals of that type would be subjected under normal management or practice and which involves –*

(i) *Exposing the animal to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition; or*

(ii) *Enforced activity, restraint, nutrition, or surgical intervention; or*

(b) *Depriving the animal of usual care; –*

### “Animal” –

...

(b) *Includes any mammalian foetus, or any avian or reptilian pre-hatched young, that is in the last half of its period of gestation or development; and*

(c) *Includes any marsupial pouch young; but*

(d) *Does not include –*

(i) *A human being; or*

(ii) *Except as provided in paragraph (b) or paragraph (c) of this definition, any animal in the pre-natal, pre-hatched, larval, or other such developmental stage.”*

This definition, therefore, clearly states that the following are not “animals” for the purposes of the Animal Welfare Act: mammalian foetuses in the first half of their gestation period or developmental stage; avian or reptilian pre-hatched young in the first half of their gestation period or developmental stage; pre-pouch marsupial young. In addition, all other animals in the pre-natal, pre-hatched, larval, or such other developmental stages are not considered to be animals for the purposes of the Animal Welfare Act (for example, fish and amphibians are not animals until they are hatched).

The definition of animal is based on the ability of the animal to feel pain or be considered “sentient”.

### **Significance of definitions in producing Gm-animals**

With the above definitions, the question arises whether some methods used in the production of Gm-animals can be defined as manipulations or not. This influences whether AEC approval is required.

It seems to follow that if the foetus or pre-hatched young is not an “animal”, as defined by the Act, then the operation will not be regarded as a “manipulation”, as defined in the Act, and will therefore not require AEC approval.

However, the following points should be noted:

- In mammals the acquisition of eggs following superovulation and the re-implanting of those eggs following modification, is itself a ‘manipulation’. Therefore the procedure requires approval from an AEC.
- In egg-laying avian or reptilian animals the collection of eggs is a normal procedure and any treatment of those eggs in the first half of gestation would not be a manipulation according to the Act. But if such treated eggs are held and then manipulated in the second half of gestation (or after they hatch) AEC approval will be required at that stage.
- In egg-laying animals (other than avian or reptilian animals) any treatment of the eggs would not be a manipulation according to the Act. If such treated eggs are held and hatched, then any subsequent manipulation will then require AEC approval.
- Where a foetus or pre-hatched young becomes an animal (either by reaching the second half of its gestation period or by “emerging”) and there is no subsequent manipulation of the animal, the animal will still be covered by the general provisions of care of the Animal Welfare Act.

### **Defining the ‘gestation period’**

The law is quite clear in allotting a single definition to all vertebrates in that an organism becomes a sentient animal *halfway through gestation* (except with fish and amphibians, where they do not become an animal until after hatching). The units of time used to measure ‘halfway’ are not specified in the Act and could be in days, hours or even smaller units.

The view that any estimate is, at best, an approximation has to be accepted and, equally, no single definition can apply to all species covered by the Act.

There are difficulties in being precise in making general rules for estimating the gestation period, for the following reasons:

*Estimating the beginning of gestation:*

1. When impregnation of the female takes place?  
Many species lay eggs to be fertilised externally and not necessarily immediately after being shed.
2. When male gametes enter the sac?  
Some species store sperm internally for fertilisation at some time in the future.
3. At any time in the series of events leading to the production of a diploid single fertilised egg, for example, the time when the first cleavage of the egg takes place or any other specific stage.

*Acceptance of a 'normal mean gestation period' or 'hatching period'*

In addition to fixing arbitrary limits for gestation, the length of any hatching/gestation periods may be influenced by environmental conditions. It is quite normal for eggs of some species to have extended hatching times as they are adapted to survival with slowing of the developmental process when temperature is reduced. Fertilised hen eggs can be refrigerated with no loss of viability.

*Marsupials, when they are pouched?*

They are clearly sensitive to their environment as they proceed to the pouch. Are they suddenly animals with the first step inside?

*Conclusion*

The concept of 'normal mean time' should be that which is considered to be reasonable by experienced persons. The limits may be plus or minus a day. It is not reasonable for the law to attempt to be more precise. Additionally, most biological processes that involve the progression from one stage to another have to be measured with arbitrary boundaries.

NAEAC  
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