



Genetically Altered Animals: Regulation and Statistical Reporting

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Definitions

Genetically Altered Animal

- Harmful Mutants, whether naturally occurring or induced
- Genetically Modified

What is a procedure?

- Birth of a genetically altered offspring
- Not the mating of GA parents!
- Invasive genotyping methods, including if a by-product of marking
- All use in further procedures

Threshold of Regulation

- Equivalent to the skilled insertion of a hypodermic needle
- Not clear what this means in the context of breeding of an animal, where adverse effects are unlikely to be pain

Current regulatory System

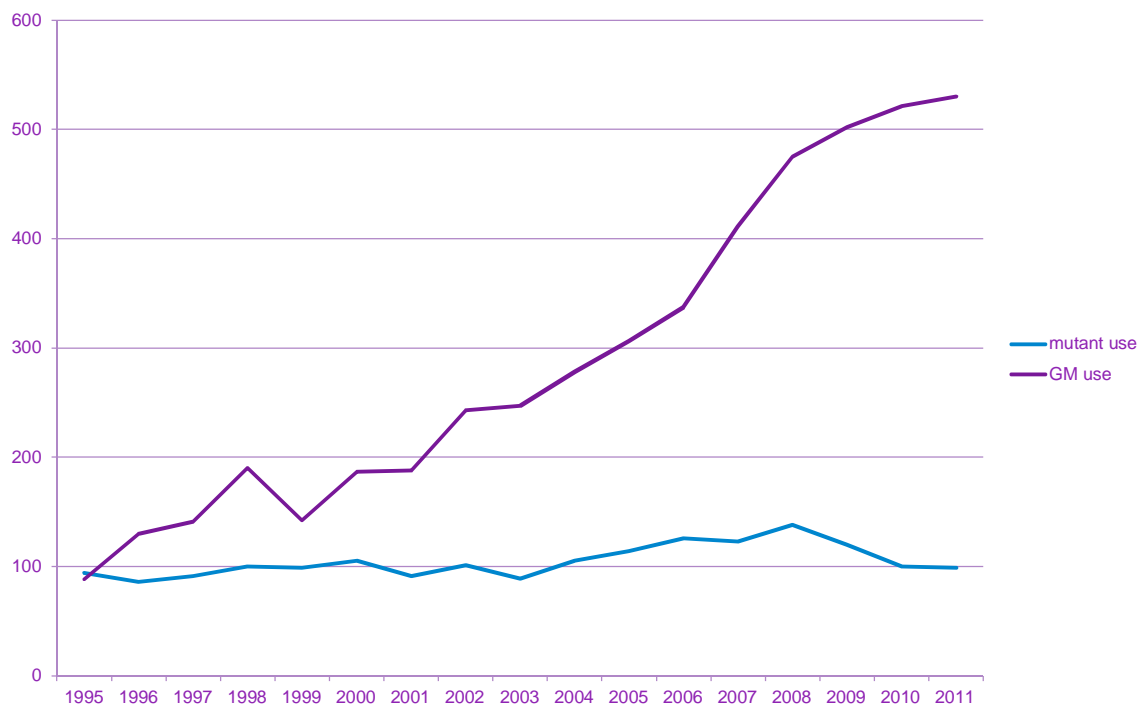
- Breeding is a permissible purpose
- GAA breeding may be a regulated procedure
- Possibility of not regulating the routine breeding of non-harmful strains
- Never taken up!
- In the UK, virtually all genetically altered animal breeding is regulated

What must be regulated?

- Creation of new strains
- Breeding of new strains until shown not to have a harmful phenotype
- Breeding of all strains with above threshold phenotype
- Invasive genotyping, even if a by-product of marking
- Use of GA animals

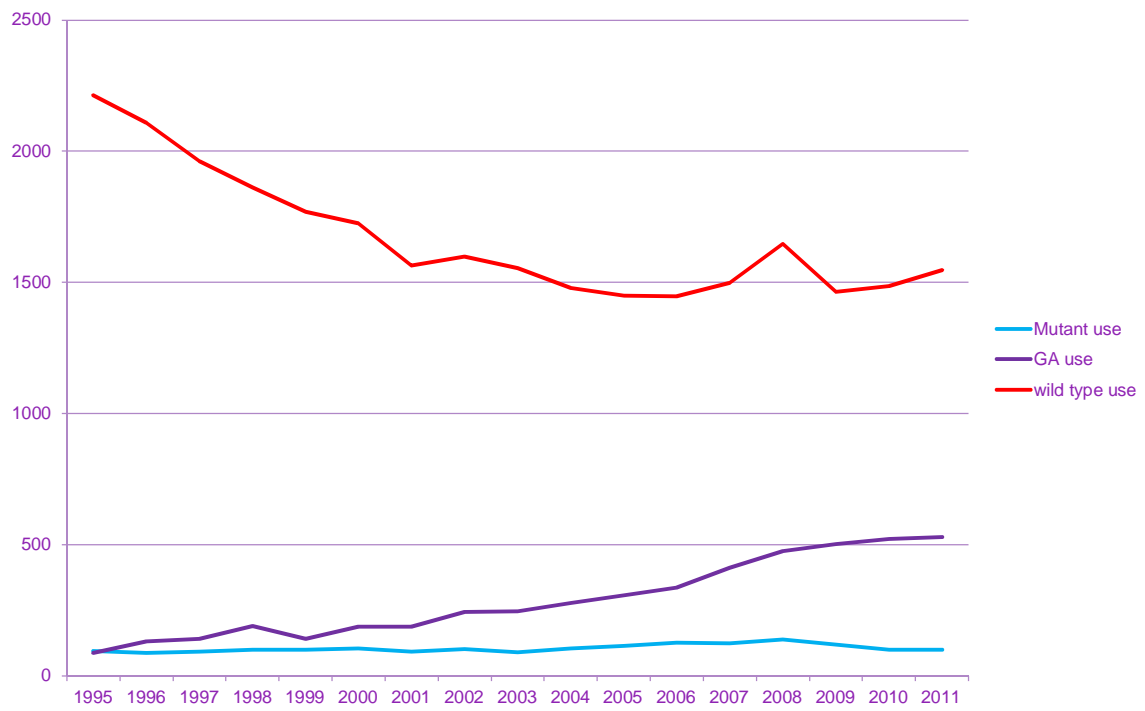
Trends in GA Animal use

Home Office

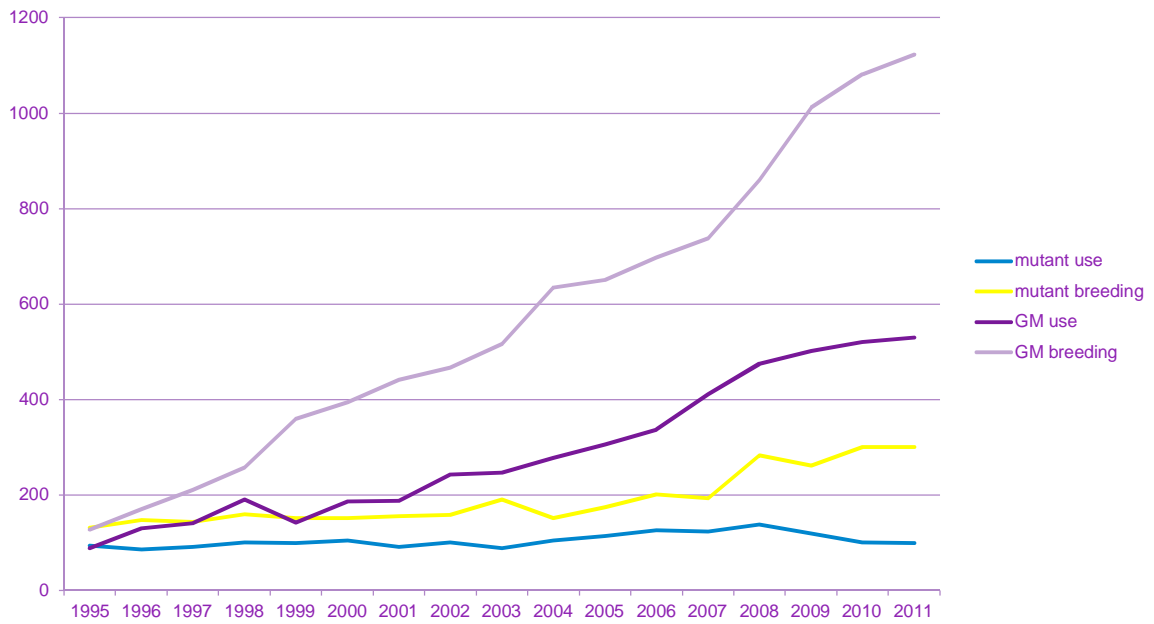


GAA use vs wild type use

Home Office



Trends in breeding vs use



Species of Genetically Modified Animal



2011 Data

Mice	1,528,388
Fish	119,341
Rats	4,514
Amphibians	1,043
Birds	351
Pigs	34
Rabbits	13
Sheep	6

Gerbils?

Future regulation of GA breeding

- Essentially the same
- But Breeding no longer a Permissible Purpose
- Sub-threshold *established* strains do not need to be bred under project authorisation
- Genotyping not regulated if a by-product of marking
- All breeding establishments must be designated (not just those breeding Sch 2 listed species)

Changes to reporting requirements

- Creation of new strains to be reported under the relevant purpose, no longer as “breeding”
- Breeding of established lines under project authorisation counted as “breeding”, although no longer a primary purpose
- For all use of GA animals, the phenotype severity will be reported

Changes to reporting requirements



Creation – Reported under one of the primary purposes and relevant field of research

- Surgical manipulations, super-ovulation etc
- Birth of a genetically modified offspring
- Genotyping if invasive and not a by-product of marking
- Breeding until “established”
- Crossing of two established lines to create a new line

Changes to reporting requirements

Established strain

- Phenotyping carried out after not less than two generations

- Severity classified as

1. Sub-threshold
2. Mild
3. Moderate
4. Substantial



Not regulated

Bred under licence

Determines prospective severity classification of the protocol

Changes to reporting requirements



Breeding of established lines

- Only those with a harmful phenotype
- Plus, in the UK, all breeding carried out under project authorisation
- How will the UK deal with existing Regulated breeding of longstanding strains which have not been phenotyped?

Phenotyping

- Cage side
- Simple, not Shirpa etc
- Involve animal care staff
- 4 categories of severity
 - Sub-threshold
 - Mild
 - Moderate
 - Substantial

Retrospective Reporting Requirements

- Species
- Place of birth
- Genetically altered with or without a harmful phenotype
- Primary purpose or breeding of established lines
- Whether for creation of a new strain

- Actual severity at the end of the procedure

Actual Severity Reporting

For all procedures, including regulated breeding

- At the end of the procedure
 - Time of culling for breeding stock?
- UK plans to collect sub-threshold severity in addition to non-recovery, mild, moderate and substantial
- Simple process. Informed by named people, AWB etc
- Actual severity, not the severity of the protocol

Death – retrospective reporting

- In general, animals which die on procedure will be returned as Substantial Severity, with exceptions:
- Unless known that did not suffer prior to death
- Not procedure related??
- Implications for GA breeding stock

Genotyping

- Invasive genotyping methods are regulated procedures
- Use of such methods means that breeding must be regulated, regardless of phenotype?

New Return of Procedures

- Article 30 requires data on breeding, supply, killing etc to be recorded
- For sub-threshold, unregulated breeding no mechanism available at present
- New Data collection targeted at Establishment Licence holder
- Every five years, or annually?

When does it all change?

- New Act from January 2013
- New return of procedures and retrospective reporting of severity from 2014
 - Data gathered for procedures completed during 2014
 - Submitted during 2015
- New Data collection targeted at Establishment Licence holder begins 2017
- EU will collect and publish data annually, not every 3 yrs.