


Content

Title :	Regulations for the Field Trial of Transgenic Breeding Livestock (Fowl) and the Bio-Safety Assessment 
Date :	2002.11.15
Legislative :	1.Promulgated on November 15, 2002.
Content :	<p>Article 1</p> <p>This regulation is prescribed according to Article 12-1 of the Animal Industry Act.</p> <p>Article 2</p> <p>The terms as employed in these regulations are defined as follows:</p> <ol style="list-style-type: none"><li>1. Gene transfer: it refers to the genetic recombination or introduce that the individuals, cells, embryos, embryonic stem cells or germ-cells of the breeding stock and fowl undergo because of the transferred gene that has been incorporated into the cells by using genetic engineering or molecular biotechnology.</li><li>2. Transgene: it refers to the recombined gene or the gene, fragments of DNA or RNA that originally do not belong to the given breeding stock and fowl or genetic resource.</li><li>3. Transgenic breeding livestock and fowl: it refers to the breeding stock and fowl or the genetic resource, which is obtained by applying gene transfer technique and incorporates transfer genes, as well as the progeny or clone derived from it.</li><li>4. Field Trial: it refers to the trial carried out by an institute, which is sanctioned by the central competent authorities and which is capable of preventing the leak of transfer gene, for the purpose of bio-safety assessment.</li><li>5. Bio-safety: it refers to the safety of the subjects of the transgenic breeding stock and fowl itself and the flora and fauna, human beings and natural environment that may interact with them.</li></ol> <p>Article 3</p> <p>All the transgenic breeding stock and fowl imported from abroad or produced at home may be proliferate and used only after its owners apply to the central competent authorities for a field experiment and fulfills the bio-safety assessment.</p> <p>The breeding stock and fowl mentioned in the previous article that is used for experiments and study by a research institute is not subject to this restriction.</p> <p>Article 4</p> <p>The bio-safety assessment should include the following items:</p> <ol style="list-style-type: none"><li>1. The objective and background of the study of transgenic breeding</li></ol>

- stock and fowl
2. The Chinese and English terms of the original breeding stock and fowl or genetic resource
  3. The source and general biological characteristics of the original breeding stock and fowl or genetic resource
  4. The name, source, characteristics, and sequence of the transgene
  5. The vector of the transgene
  6. The theoretical ground of the transferring method, the molecular evidence of the transferred gene, related or similar events both at home and abroad and its bio-safety assessment result.
  7. The expression location of the transgene in the cells or tissues of the breeding stock and fowl and the stability of its inheritance and expression
  8. The transgenic breeding stock and fowl's performances, which include the general characteristics, proliferation methods, feeding and managing methods and things deserving special attention
  9. The possibility of transgenic breeding stock and fowl to turn into a public hazard and the precautions to be taken against it
  10. The design of field experiment: it includes the qualitative performance that should be subjected to inspection during the field trial, the explications of the rules of field trial and the precautions against any leak of the transfer gene.
  11. Other items prescribed for assessment by the review board of the transgenic breeding stock and fowl

#### Article 5

The central competent authorities should establish a review board of transgenic breeding stock and fowl (hereunder referred to as review group) to assess the field trial of transgenic breeding stock and fowl and matters related to bio-safety assessment.

#### Article 6

Applicants should make ready with application forms (as attached) to apply to the central competent authorities for the field trial of transgenic breeding stock and fowl and should pay the trial expenses to institutes sanctioned by the central competent authorities. The standard by which the consigned trial is charged is to be prescribed by the central competent authorities.

#### Article 7

The transgenic breeding stock and fowl reviewed and approved in accordance with this direction should be subjected to be reviewed by the competent authorities responsible for food hygiene for approval before it can be consumed.

#### Article 8

The transgenic breeding stock and fowl reviewed and approved in accordance with this direction yet designated for purposes other than human consumption should be subjected to be reviewed by the relevant authorities

for approval before it can be used for its special purposes. It is prohibited for human consumption.

Article 9

The transgenic breeding stock and fowl reviewed yet unapproved in accordance with this direction should induce euthanasia and cremated in a humane way.

Article 10

This regulation goes into effect on the day of its promulgation.

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Data Source : MONISTRY OF AGRICULTURE Laws and Regulations Retrieving System