SAFETY ADMINISTRATION REGULATION ON GENETIC ENGINEERING

(Published by the State Science and Technology Commission of the People's Republic of China and Enforced from December 24, 1 993)

Order of the State Science and Technology

Commission of the People' s Republic of China

No. 17

Safety Administration Regulation on Genetic Engineering is hereby Published and enforced.

SONG JIAN
Chairman
State Science and Technology
Commission of China
December 24, 1993

CONTENTS

SAFETY ADMINISTRATION REGULATION ON GENETIC ENGINEERING

Chapter One: General Principles

1. This regulation is aimed at promoting research and development of biotechnology in China, tightening safety control of genetic engineering work, guaranteeing public health of common citizens and genetic engineering workers, preventing environmental pollution, and maintaining ecological balance.

2. The genetic engineering items covered in this regulation include recombinant DNA technology using the vector system, and direct introduction of heterologous DNA into organisms by using physical or chemical means. The following genetic manipulations are not included.

(1) Cell fusion technology and protoplast fusion technology.

(2) Traditional hybridization and propagation technology.

(3) Variation induction technology, in vitro fertilization technology, cell or embryo culture technology.

3. The regulation is applicable to all genetic engineering work underway in the territory of the People' s Republic of China, including experiments, pilot tests, industrial production, release of genetic engineered organisms and utilization of finished genetic engineering products.

The genetic engineered organisms imported from outside China when being adopted in genetic engineering work in China, should abide by this regulation.

4. The State Science and Technology Commission is responsible for the nationwide genetic engineering safety work. A national genetic engineering safety committee has been set up to handle safety supervision and coordination.

Relevant administrative departments under China' s State Council carry out safety administration of genetic engineering work according to the related regulations within their own responsibility scopes.

5. Safety administration of genetic engineering work is carried out on the basis of safety class control and classification approval, which means that different categories of genetic engineering work should be approved by relevant administrative departments.

Chapter Two: Safety Classes and Safety Evaluation

6. According to potential risk levels, genetic engineering work is divided into four safety classes:

Safety class I: genetic engineering work of this class has no threat to human health and ecological environment.

Safety class II: genetic engineering work of this class has low.level risk to human health and ecological environment.

Safety class III: genetic engineering work of this class has intermediate-level risk to human health and ecological environment.

Safety class IV: genetic engineering work of this class has high.level risk to human health and ecological environment.

7. The technical and environmental standards of different safety classes for different categories of genetic engineering work are formulated by relevant administrative departments of the State Council of China, and then submitted to the national genetic engineering safety committee for record.

8. Institutions carrying out genetic engineering work should conduct safety evaluation to assess potential risk, determine safety class and work out corresponding safety control methods and measures.

9. Institutions carrying out genetic experimental research should conduct evaluation on DNA donors, vectors, hosts and genetic engineered organisms. The evaluation should be focused on the pathogenicity, carcinogenicity, chemical resistance, transfer possibility, and effects on environment of target genes, vectors, hosts and genetic engineered organisms, and on determining biological control and physical control classes.

10. Institutions carrying out genetic engineering pilot experiments or industrial production should conduct safety evaluation on the physical barriers of the equipment and facilities of the culture, fermentation, separation and purification processes according to genetic engineered organisms safety class, to determine the safety class of pilot experiments or industrial production.

11. Institutions carrying out the release of genetic engineered organisms should conduct evaluation on the safety of genetic engineered organisms, the purpose of the release, ecological environment conditions of the release site, releasing methods, monitoring means and control measures, to determine the safety class of the release.

12. Using finished genetic engineering products should conduct biological tests for safety evaluation, which will determine the possible impact of genetic engineering products on the public health and ecological environment.

Chapter Three: Application and Approval

13. Institutions carrying out genetic engineering work should submit applications to relevant administrative departments at different levels according to genetic engineering products' utilization scope and safety class before being approved to kick off.

14. Institutions carrying out safety class I and safety class II genetic engineering experiment research should get approval from the heads of their institution ' s administration. The work of safety class III should be examined by chief administrators of the institutions and then be submitted to relevant departments under the State Council for approval. The work of safety class IV should be examined by relevant State Council departments and then be submitted to the national genetic engineering safety committee for approval.

15. Genetic engineering pilot experiments of safety class I should get approval from chief administrators at the institutional level. The work of safety class II should be approved by responsible State Council departments. The work in safety class m should be approved by relevant State Council departments and be submitted to the national genetic engineering safety committee for record. The work in safety class IV should be examined by relevant State Council departments and submitted to the national genetic engineering safety committee for approval.

16. Genetic engineering industrial production, release of genetic engineered organisms and utilization of genetic engineering products, if in safety class I to m scope, should be approved by relevant administrative departments under the State

Council and submitted to the national genetic engineering safety committee for record. The work in safety class 1V should be examined by relevant administrative departments of the State Council and submitted to the national genetic engineering safety committee for approval.

17. Institutions carrying out genetic engineering work should go through the following application procedures:

(1) The chief of the planned genetic engineering project should evaluate the safety of the project and fill in the application form.

(2) The academic committee of the institution should conduct technical evaluation on the application.

(3) Application should be submitted along with technical documents.

18. All genetic engineering work meeting the following requirements should be given approval and certificates issued at the same time.

(1) No doubt has been found on the safety evaluation of the project applied.

(2) No threat to the public health and ecological environment has been found if the genetic engineering project applied has adopted safety control measures which are up to modern scientific and technological standards, according to the requirement of its safety class.

(3) The project chief and staff members are qualified for conducting genetic engineering work and have acquired necessary professional knowledge and safety operation knowledge. They have no hesitation in carrying out the obligations specified in this regulation.

(4) The project accords with relevant state regulations and laws.

Chapter Four: Safety Control Measures

19. Institutions carrying out genetic engineering work should formulate safety control measures and work out safety operation regulations in accordance with safety class.

20. Institutions carrying out genetic engineering work should work out relevant safety measures to handle waste materials according to the safety class. The remaining genetic engineered organisms should be killed before discharge to prevent spread and environment pollution.

21. Institutions carrying out genetic engineering work should formulate measures to prevent emergency accidents. The measures should be listed as part of safety operation regulations.

22. Genetic engineered organisms should be stored in specific containers. The storage site should have its physical control fit in with their safety class.

The storage of genetic engineered organisms of safety class VI should be supervised by specific person.

Institutions carrying out genetic engineering work should compile a list of storage catalogues for inspection.

23. Transporting or transferring genetic engineered organisms should guarantee that specific containers used fit the safety class of the organisms. It should also be guaranteed that transportation or transfer strictly abide by relevant state laws and regulations on transporting or mailing of biological materials.

24. Institutions or individuals carrying out genetic engineering work should write down a detailed safety control record and keep the record for a period of no less than 10 years for inspection.

25. Institutions if causing harm to the public health or causing environment pollution due to carrying out genetic engineering work must take immediate measures to prevent the harm of the pollution from spreading and report to relevant administrative departments.

Chapter Five: Legal Responsibilities

26. In any of the following cases, relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violation.

(1) The genetic engineering project begins operation without approval.

(2) Equipment, apparatus, laboratories which do not fit in with regulations have been used.

(3) Violation of safety operation regulations of genetic engineering work.

(4) Violation of other rules under this regulations.

27. The approval office staffs who has direct responsibility for neglecting duties, receiving briberies or practicing irregularities will be punished with administrative disciplinary measures by the higher authorities.

28. The responsible unit of those violating this regulation and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses. In case a crime is caused, those who are directly responsible for will take criminal responsibilities according to laws.

(1) Causing serious environment pollution.

(2) Causing damage or harm to the public health.

(3) Causing severe damage to ecological resources and ecological balance.

29. The staffs in the approval office and specialists who are involved in the approval process are responsible for keeping the technical secrets for applicants.

Chapter Six: Supplementary Articles

30. The meaning of the special terms in this regulation

(1) DNA, short for deoxyribonucleic acid, is the genetic material for storing genetic information of living things.

(2) Gene, is a functional and structural unit of genetic information which controls characteristic of living things. It is the DNA section with genetic information.

(3) Target gene is the heterologous DNA fragment for the modification of genetic constitution of host cells, and for the expression of genetic information of host cells.

(4) Vectors are the DNA molecules capable of transferring heterologous DNA into host cells and capable of self-duplication.

(5) Host cells or receptor cells are those cells into which recombinant DNA molecules have been introduced.

(6) Recombinant DNA molecules are hybrid molecules which consist of heterologous DNA and vector DNA.

(7) Organisms refer to the living cells or living things which can propagate or can transfer genetic materials.

(8) Recombinants refer to the organisms into which the heterologous DNA have been introduced with natural factors or artificial means to change their genetic constitution.

(9) Variants refer to the organisms whose genetic materials are changed by natural factors or artificial factors.

(10) Recombinant DNA technology refers to the technology which artificially modifies the genetic constitution of the organisms with vector systems. e. g. the recombination of heterologous DNA and vector DNA with enzymes and the recombinant DNA molecules is transferred into host cells to multiply heterologous DNA and express its function.

(11) Genetic engineered organisms refer to the organisms coming from the genetic manipulation of genetic engineering, including genetic engineered animals, plants and microorganisms.

The following variants and recombinants do not belong to genetic engineered organisms:

The living organisms coming from cell fusion and protoplast fusion.

The animals and plants coming from traditional hybridization technology.

The living things whose genetic constitution has been changed by physical and chemical inducing technology, and the living things which have teratogeny in their chromosome structure and number.

(12) Genetic engineering products are products with genetic engineered organisms, its components or products coming from the expression of target gene in genetic engineered organisms.

(13) Genetic engineering experimental research refers to laboratory-scale research work on genetic engineering conducted within a control system.

(14) Genetic engineering pilot experiments refer to experiments or pilot production in a control system aimed at testification, supplimentation of relevant data, determination and perfection of technical rules (product specifications and operation processing rules), to test the key technology for large scale production, before the application of genetic engineering experiment research results into industrial production (falling into production pattern and appraisal).

(15) Genetic engineering industrial production refers to commercial production of drugs, agricultural chemicals, veterinary chemicals, fodders, fertilizers, food, additives, raw material of the chemical industry in the control system by using genetic engineered organisms. It also includes utilizing genetic engineering in the technical processes of metallurgy, oil exploration and the recycling of waste materials.

(16) Release of genetic engineered organisms refers to research, production and application of genetic engineered organisms in an open system, including releasing genetic engineered organisms into natural ecological environments, such as cropland, grazing land, forests, mineral deposits and water areas. etc.

(17) Utilization of genetic engineering products refers to putting genetic engineering products into market for sales or for utilization by human being.

(18) Control system refers to the operation system established through physical and biological controls.

Physical control refers to airtight sealing of the equipment, special installation design and safety operation which aim at reducing the spreading of potentially dangerous DNA donors, vectors and host cells or genetic engineered organisms to the environment to the lowest level.

Biological control means using genetic modification to reduce to the lowest level the abilities of vectors and host cells with potential risks to survive, propagate and transfer outside the control system. Any operation system not fitting in with the above mentioned control conditions is called an open system.

31. Relevant administrative departments of China’ s State Council should formulate

their own detailed implementation measures according to this regulation within the scope of their responsibilities.

32. This regulation is explained by the State Science and Technology Commission of China.

33. This regulation is enforced from the date of publication.