

**THE MANUFACTURE, USE,
IMPORT, EXPORT AND
STORAGE OF HAZARDOUS
MICRO-ORGANISMS
GENETICALLY
ENGINEERED ORGANISMS
OR CELLS RULES, 1989**

(as amended to date)

MINISTRY OF ENVIRONMENT & FORESTS

NOTIFICATION

New Delhi, the 5th December, 1989

G.S.R. 1037(E). - In exercise of the powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) and with a view to protecting the environment, nature and health, in connection with the application of gene technology and micro-organisms, the Central Government hereby makes the following rules, namely: -

1. Short title, extent and commencement

(1) These rules may be called the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms Genetically Engineered Organisms or Cells.

¹(2) These rules shall come into operation on the date to be notified for this purpose in the Official Gazette.

2. Application

(1) These rules are applicable to the manufacture import and storage of microorganisms and Gene-Technological products.

(2) These shall apply to genetically engineered organisms/micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc. of which such cells, organisms or tissues hereof form part.

(3) These rules shall also apply to new gene technologies apart from those referred to in clauses (ii) and (iv) of rule 3 and these rules shall apply to organisms/microorganisms and cells generated by the utilisation of such other gene- technologies and to substances and products of which such organisms and cells form part.

(1) These rules shall be applicable in the following specific cases;

- (a) sale, offers for sale, storage for the purpose of sale, offers and any kind of handling over with or without a consideration;
- (b) exportation and importation of genetically engineered cells or organisms;
- (c) production, manufacturing, processing, storage, import, drawing off, packaging and repacking of the Genetically Engineered Products;
- (d) Production, manufacture etc. of drugs and pharmaceuticals and food stuffs distilleries and tanneries, etc. which make use of micro-organisms genetically engineered micro-organisms one way or the other.

(4) These rules shall be applicable to the whole of India.

3. Definitions

In these rules unless the context requires,

¹ Rules came into force w.e.f.1.10.1993 vide Notification S.O.677(E), dated 13.9.1993.

- (i) "Biotechnology" means the application of scientific and engineering principles to the processing of materials by biological agents to produce goods and services;
- (ii) "Cell hybridisation" means the formation of live cells with new combinations of genetic material through the fusion of two or more cells by means of methods which do not occur naturally;
- (iii) "Gene Technology" means the application of the gene technique called genetic engineering, include self-cloning and deletion as well as cell hybridisation;
- (iv) "Genetic engineering" means the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;
- (v) "microorganisms" shall include all the bacteria, viruses, fungi, mycoplasma, cells lines, algae, protodones and nematotes indicated in the schedule and those that have not been presently known to exist in the country or not have been discovered so far.

4. Competent Authorities

- (1) **Recombinant DNA Advisory Committee (RDAC):** This committee shall review developments in Biotechnology at national and international levels and shall recommend suitable and-appropriate safety regulations for India in recombinant research, use and applications from time to time. The committee shall function in the Department of Biotechnology.
- (2) **Review Committee on Genetic Manipulation (RCGM):** This committee shall function in the Department of Biotechnology to monitor the safety related aspect in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms. The Review Committee on Genetic Manipulation shall include representatives of (a) Department of Biotechnology (b) Indian Council of Medical Research (c) Indian Council of Agricultural Research (d) Council of Scientific and Industrial Research (e) other experts in their individual capacity. Review Committee on Genetic Manipulation may appoint subgroups.

It shall bring out Manuals of guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research use and applications including industry with a view to ensure environmental safety. All ongoing projects involving high risk category and controlled field experiments shall be reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines.

The Review Committee on Genetic Manipulation shall lay down procedures restricting or prohibiting production sale importation and use of such genetically engineered organisms of cells as are mentioned in the Schedule.

- (3) **Institutional Biosafety Committee (IBSC):** This committee shall be constituted by an occupier or any person including research institutions handling microorganisms/genetically engineered organisms. The committee shall comprise the Head of the Institution Scientists engaged in DNA work a medical expert and a nominee of the Department of Biotechnology. The occupier or any person including research institutions having microorganisms/

genetically engineered organisms shall prepare with the assistance of the Institutional Biosafety Committee (IBSC) an up-to-date on-site emergency plan according to the manuals/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Coordinating Committee and the ¹[Genetic Engineering Appraisal Committee.]

(1) ²[Genetic Engineering Appraisal Committee(GEAC)]

This committee shall function as a body under the Department of Environment Forests and Wildlife for approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. The Committee shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental Field trials.

The composition of the Committee shall be

- (i) Chairman-Additional Secretary Department of Environment Forests and Wildlife

Co-Chairman Representative of Department of Bio-technology

- (ii) Members: Representatives of concerned Agencies and departments namely Ministry of Industrial Development, Department of Biotechnology and the Department of Atomic Energy.

- (iii) ³[Expert members. - Director General-Indian Council of Agricultural Research, Director General-Indian Council of Medical Research, Director General-Council of Scientific and Industrial Research, Director General Health Services, Plant Protection Adviser, Directorate of Plant Protection, Quarantine and storage, Chairman, Central Pollution Control Board or their representatives not below the rank of Joint Secretary and three outside experts in individual capacity.]

- (iv) Member Secretary: An official of the Department of Environment, Forest and Wildlife.

The Committee may co-opt other members/experts as necessary.

The committee or any person/s authorised by it shall have powers to take punitive actions under the Environment (Protection) Act,1986.

- (4) **State Biotechnology Co-ordination Committee (SBCC):** There shall be a State Biotechnology Coordination Committee in the States wherever necessary. It shall have powers to inspect, investigate and take punitive action in case of violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee shall review periodically the safety and control measures in the various industries/institutions handling genetically engineered Organisms/Hazardous microorganisms. The compositions of the Coordination Committee

¹ Subs. by G.S.R. 613 (E), dated 16.07.2010 (w.e.f. 22.07.2010).

² Subs. by G.S.R. 613 (E), dated 16.07.2010 (w.e.f. 22.07.2010).

³ Subs. by G.S.R. 1(E), dated 23-12-2010 (w.e.f. 3-1-2011).

shall be:

- | | | |
|--------|--|--------------------|
| (i) | Chief Secretary | - Chairman |
| (ii) | Secretary, Department of Environment | - Member Secretary |
| (iii) | Secretary, Department of Health | - Member |
| (iv) | Secretary, Department of Agriculture | - Member |
| (v) | Secretary, Department of Industries and Commerce | - Member |
| (vi) | Secretary, Department of Forests | - Member |
| (vii) | Secretary, Department of Public Works/ Chief
Engineer, Department of Public Health Engineering. | - Member |
| (viii) | State Microbiologists and Pathologists | - Member |
| (ix) | Chairman of State Pollution Control Board | |

The Committee may co-opt other members/experts as necessary.

- (5) **District Level Committee (DLC):** There shall be a District Level Biotechnology Committee (DLC) in the districts wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous microorganisms and its applications in the environment.

The District Level Committee/or any other person/s authorised in this behalf shall visit the installation engaged in activity involving genetically engineered organisms, hazardous microorganisms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activities with a view to meeting any emergency. They shall also prepare an off-site emergency plan.

The District Level Committee shall regularly submit its report to the State Biotechnology Coordination Committee/ ¹[Genetic Engineering Appraisal Committee.]

The District Level Committee shall comprise of: -

- | | | |
|--------|---|-------------------|
| (i) | District Collector | - Chairman |
| (ii) | Factory Inspector | - Member |
| (iii) | A representative of the Pollution Control Board | - Member |
| (iv) | Chief Medical Officer (District Health Officer) | - Member Convenor |
| (v) | District Agricultural Officer | - Member |
| (vi) | A representative of the Public
Health Engineering Department | - Member |
| (vii) | District Microbiologists/Pathologist (technical expert) | - Member |
| (viii) | Commissioner Municipal Corporation | - Member |

The Committee may co-opt other members/experts as necessary.

¹ Subs. by G.S.R. 613 (E), dated 16.07.2010 (w.e.f. 22-07-2010).

5. Classification of microorganisms or genetically engineered product

- (1) For the purpose of these rules, microorganisms or genetically engineered organisms, products or cells shall be dealt with under two major heads; animal, pathogens and plant pests and these shall be classified in the manner specified in the Schedule.
- (2) If any of the microorganisms, genetically engineered organism or cell falls within the limits of more than one risk class as specified in the Schedule, it shall be deemed to belong exclusively to the last in number of such classes.

6. Microorganisms laid down in the schedule are divided into the following

- (i) Bacterial Agents;
- (ii) Fungal Agents;
- (iii) Parasitic Agents;
- (iv) Viral, Rickettsial and Chlamydial Agents;
- (v) Special Category.

7. Approval and prohibitions

- (1) No person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms or genetically engineered organisms/substances or cells except with the approval of the ¹[Genetic Engineering Appraisal Committee.]
- (2) Use of pathogenic microorganisms or any genetically engineered organisms or cells for the purpose of research shall only be allowed in laboratories or inside laboratory area notified by the Ministry of Environment and Forests for this purpose under the Environment (Protection) Act, 1986.
- (3) The ¹[Genetic Engineering Appraisal Committee] shall give directions to the occupier to determine or take measures concerning the discharge of microorganisms/genetically engineered organisms or cells mentioned in the Schedule from the laboratories, hospitals and other areas including prohibition of such discharges and laying down measures to be taken to prevent such discharges.
- (4) Any person operating or using genetically engineered organisms/ microorganisms mentioned in the schedule for scale up or pilot operations shall have to obtain licence issued by the ¹[Genetic Engineering Appraisal Committee] for any such activity. The possessor shall have to apply for licence in prescribed proforma.
- (5) Certain experiments for the purpose of education within the field of gene technology or microorganism may be carried out outside the laboratories and laboratory areas mentioned in sub-rule (2) and will be looked after by the Institutional Biosafety Committee.

8. Production

Production in which genetically engineered organisms or cells or micro-organisms are generated or used shall not be commenced except with the consent of ¹[Genetic Engineering Appraisal Committee] with respect of discharge of genetically engineered organisms or cells into the environment. This shall also apply to production taking place in connection with development, testing and experiments where such production, etc., is not subject to rule 7.

9. Deliberate or unintentional release

¹ Subs. by G.S.R. 613 (E), dated 16-07-2010 (w.e.f. 22.07.2010).

- (1) Deliberate or unintentional release of genetically engineered organisms/hazardous microorganisms or cells, including deliberate release for the purpose of experiment shall not be allowed.

Note: Deliberate release shall mean any intentional transfer of genetically engineered organisms/hazardous, microorganisms or cells to the environment or nature, irrespective of the way in which it is done.

- (2) The ¹[Genetic Engineering Appraisal Committee] may in special cases give approval of deliberate release.

10. Permission and approval for certain substances

Substances and products, which contain genetically engineered organisms or cells or microorganisms shall not be produced, sold, imported or used except with the approval of ¹[Genetic Engineering Appraisal Committee].

11. Permission and approval for foodstuffs

Food stuffs, ingredients in food stuffs and additives including processing and containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with the approval of the ¹[Genetic Engineering Appraisal Committee].

12. Guidelines

- (1) Any person who applies for approval under rules 8-11 shall, as determined by the ¹[Genetic Engineering Appraisal Committee] submit information and make examinations or cause examinations to be made to eradicate the case, including examinations according to specific directions and at specific laboratories. He shall also make available an on-site emergency plan to GEAC before obtaining the approval. If the authority makes examination itself, it may order the applicant to delay the expenses incurred by it in so doing.
- (2) Any person to whom an approval has been granted under rules 8-11 above shall notify the ¹[Genetic Engineering Appraisal Committee] of any change in or addition to the information already submitted.

13. Grant of approval

- (1) In connection with the granting of approval under rules 8 to 11 above, terms and conditions shall be stipulated, including terms and conditions as to the control to be exercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information to the State Biotechnology Coordination Committee or to the District Level Committee.
- (2) All approvals of the ¹[Genetic Engineering Appraisal Committee] shall be for a specific period not exceeding four year at the first instance renewable for 2 years at a time. The ²[Genetic Engineering Appraisal Committee] shall have powers to revoke such approval in the following situations: -
 - (a) If there is any new information as to the harmful effects of the genetically engineered organisms or cells.

¹ Subs. by G.S.R. 613 (E), dated 16-07-2010 (w.e.f. 22.07.2010).

- (b) If the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or
- (c) Noncompliance of any condition stipulated by ¹[Genetic Engineering Appraisal Committee.]

14. Supervision

- (1) The ¹[Genetic Engineering Appraisal Committee] may supervise the implementation of the terms and conditions laid down in connection with the approvals accorded by it.
- (2) The ¹[Genetic Engineering Appraisal Committee] may carry out this supervision through the State Biotechnology Coordination Committee or the State Pollution Control Boards/District Level Committee or through any person authorised in this behalf.

15. Penalties

- (1) If an order is not complied with, the District Level Committee or State Biotechnology Co-ordination Committee may take measures at the expense of the person who is responsible.
- (2) In case where immediate intervention is required in order to prevent any damage to the environment, nature or health, the District Level Committee or State Biotechnology Coordination Committee may take the necessary steps without issuing any order or notice. The expenses incurred for this purpose will be repayable by the person responsible for such damage.
- (3) The State Biotechnology Co-ordination Committee/District Level Committee may take samples for a more detailed examination of organisms and cells.
- (4) The State Biotechnology Co-ordination Committee/District Level Committee shall be competent to ask for assistance from any other government authority to carry out its instructions.

16. Responsibility to notify interruptions or accidents

- (1) Any person who under rule 7-11 is responsible for conditions or arrangements shall immediately notify the District Level Committee/State Biotechnology Co- ordination Committee and the state medical officer of any interruption of operations or accidents that may lead to discharges of genetically engineered organisms or cells which may be harmful to the environment, nature or health or involve any danger thereto.
- (2) Any notice given under sub-rule (1) above shall not lessen the duty of the person who is responsible to try effectively to minimise or prevent the effects of interruptions of operations or accidents.

17. Preparation off-site emergency plan by the DLC

- (1) It shall be the duty of the DLC to prepare an off-site emergency plan detailing how emergencies relating to a possible major accident at a site will be dealt with and in preparing the plan, the DLC shall consult the occupier and such other person as it may deem necessary.

¹ Subs. by G.S.R. 613 (E), dated 16-07-2010 (w.e.f.22-7-2010).

- (2) For the purpose of enabling the DLC- to prepare. the emergency plan required under sub-rule (1), the occupier shall provide the DLC with such information relating to the handling of hazardous microorganisms/ genetically engineered organisms under his control as the DLC may required including the nature, extent and likely off-site affects of a possible major accident and the DLC shall provide the occupier with any information from the off-site emergency plan which relates to his duties under rule 16.

18. Inspections and informations regarding finance

- (1) The State Biotechnology Co-ordination Committee or the ¹[Genetic Engineering Appraisal Committee] /the DLC or any person with special knowledge duly authorised by the State Biotechnology Co-ordination Committee or the ¹[Genetic Engineering Appraisal Committee] or the DLC where it is deemed necessary, at any time on due production of identity be admitted to public as well as to private promises and localities for the purpose of carrying out supervision.
- (2) Any person who is responsible for activities subject to rules 7-11 above shall at the request of District Level Committee or State Biotechnology Coordination Committee or the GEAC submit all such information including information relating to financial conditions and accounts, as is essential to the authority's administration under these rules He shall also allow supervision or inspection by the authorities or persons indicated in sub-rule (1).
- (3) The ¹[Genetic Engineering Appraisal Committee] may fix fees to cover, in whole or in part, the expenses incurred by the authorities in connection with approvals, examinations, supervisions and control.

19. Appeal

- (l) Any person aggrieved by a decision made by ¹[Genetic Engineering Appraisal Committee] /State Biotechnology Co-ordination Committee in pursuance of these rules may within thirty days from the date on which the decision is communicated to him, prefer an appeal to such authority as may be appointed by Ministry of Environment and Forests provided that the appellate authority may entertain the appeal after the expiry of the said period of thirty days if such authority is satisfied that the appellants was prevented by sufficient cause from filing the appeal in time.

20. Exemption

The Ministry of Environment and Forests shall, wherever necessary, exempt an occupier handling a particular microorganism/genetically engineered organism from rule 7-11.

¹ Subs. by G.S.R. 613 (E), dated 16-07-2010 (w.e.f.22-7-2010).

A. **ANIMAL AND HUMAN PATHOGENS**

SCHEDULE

BACTERIAL

Risk Group II

- *Acinetobacter calcoaceticus*
- *Actinobacillus* all species except *A. mallei*, which in Risk Group III *Acromonoas hydrophila*
- *Arizona hinshawii*-all serotypes
- *Bacillus anthracis*
- *Bordetella*-all species
- *Borrelia recurrentis* *B. vincenti*
- *Campylobacter fetus*
- *Campylobacter jejuni*
- *Chalarmydia psittaci*
- *Cheamydia trachomatis*
- *Clostridium hauvoci*, *Cl. Difficile* *Cl. fallax*, *Cl. haemolyticum* *Cl. histolyticum*, *Cl. novyi*, (*Cl. perfringes*), *Cl. speticum*, *Cl. sordeili*
- *Cornylobacterium diptheriae*, *C. equi*, *C. haemolyticum*, *C. pseudo tuberculosis*, *pyogenes*, *C. renale*
- *Diplococcus (Streptococcus) pneumoniae*
- *Edwardsiella tarda*
- *Erysipelothrix insidiosa*
- *Escherichia Coli*-all enteropathogenic serotypes enterotaxigenic *Haemophilus ducrevi*, *H. influenzae*, *H. pneumoniae*
- *Herellea vaginicola*
- *Klebsiella*- all species and all serotypes
- *Legionella pneumophila*
- *Letionella*
- *Leptospira interrogans* all serotypes reported in India
- *Listeria*, all species
- *Mima polymorpha*
- *Moraxella*-All species
- *Mycobacteria*-all species including *Mycobacterium avium*
- *M. bovis* *M. tuberculosis*, *M. lepreae*
- *Mycoplasma*-all species except *M. mycoides* and *M. angalactiae*
- *Neisseric gonorrhoea*, *N. meningitis*
- *Pasteurella* all species except those listed in Risk Group III
- *Salmonella*-all species and all serotypes

- Shigella all species and all serotypes
- Shpachrophorus necrophorus
- Staphylococcus aureus
- Straptobacillus moniformis
- Streptococcus pneumoniae
- Streptococcus pyogenes, S. equi
- Streptomyces madurae, s. pelleteri, s. somaliensis
- Treponema carateum, T. palidum and T. pertenu
- Vibrio foctus, V. comma including biotype EI Tor and
- V. parahemolyticus.
- Vibrio cholerae

Risk Group III:

- Actinobacillus mallei
- Bartonella-all species
- Brucella all species
- Clostridium botulium, Cl. tetani
- Francisella tularensis
- Mycobacterium avium, M. bovis, M. tuberculosis, m. leprae
- Paseturella multocida type B ("buffalo" and other foreign virulent strains) Pseudomonas
pseudomallai
- Yersinia pestis

FUNGAL

Risk Group II

- Actinomycetes (including Nocardia Sp, Actinomyces species and Arachina prpinica)
- Aspergilus fumigatus
- Blastomyces dermatitis
- Cryptococcus neoformans C. fersiminosos
- Epidermophyton madurella, microsporon
- Paracoccidiodes brasiliensis
- Sporothrix
- Trichoderma
- Trichophyton

Risk Group III

- Coccidioaes immitis Histoplasma capulatum
- Histoplasma capsulalum var duboissl

PARASITIC

Risk Group II

- Entamoeba histolytica
- Leishmania species
- Naegleria gruberia
- Plasmodium theileri, P. babesia P. falciparum
- Plasmodium babesia
- Schistosoma
- Toxoplasma gondii
- Toxocara canis
- Trichinella spiralis
- Trichomonas
- Trypanosoma cruzi

Risk Group III

- Schistosoma mansoni

VIRAL RICKETTSIAL AND CHLAMYDIAL

Risk Group II

- Adenoviruses-Human, all types
- Avian leukosis
- Cache Valley virus
- CELO (avian adenovirus)
- Cosackie A and B viruses
- Corona viruses
- Cytomegalo viruses
- Dengue virus, when used for transmission experiments
- Echo viruses-all types
- Encephalomyocarditis virus (EMC)
- Flanders virus
- Hart Past virus
- Hepatitis-associated antigen material-hepatitis A and B viruses, non A and non B
- HDV
- Herpes viruses-except herpes virus simiae (monkey B virus) which is in Risk Group IV.
- Infections Bovine Rhinotracheitis virus (IBR).
- Infections Bursal diseases of poultry and Infectious Bronchitis
- Infections Laryngotracheitis (ILT)
- Influenza virus-all types, except A/PR8/34 which in Risk Group I

- Langat virus Leucosis Complex
- Lymphogranuloma venereum agent
- Mark's Disease virus
- Measles virus Mumps virus
- Newcastle disease virus (other than licenced strain for vaccine use)
- Parainfluenza viruses-all types except parainfluenza virus 3, SF4 strain, which is in Risk Group I
- Polio viruses-all types wild and attenuated
- Poxvirus-all types except Mastrim, monkey pox, sheep pox and white pox, which depending on experiments are in Risk Group III or IV.
- Rabies virus-all strains except rabies stret virus, which should be classified in Risk Group III when inoculated into carnivores
- Reoviruses-all types
- Respiratory syncital virus
- Rhinoviruses-all types
- Rinderpest (other than vaccine strain in use)
- Rubella virus
- Stimian viroes-all types except herpeavirus simae (Monkey Virus) which is in Risk Group IV.
- Simian virus 40
- Ad 7 SV 40 (defective)
- Sindbis virus
- Tensaw virus
- Turlock virus
- Vaccinia virus
- Varicella virus
- Vole rickettsia
- Yellow fever virus, 17 D vaccine strain

Risk Group III

- African House Sickness (attenuated strain except animal passage) Alastrim, monkey pox and whitepox, when used into vitro
- Arboviruses-All strains except those in Risk Group II and IV
- Blue tongue virus (only serotypes reported in India)
- Ebola fever Virus
- Epstiein-Barr virus
- Feline Leukemia
- Feline sarcoma

- Foot and Mouth Disease virus (all serotypes and subtypes)
- Gibbon Ape Lymphosarcoma
- herpesvirus ateles
- herpevirus saimiri
- herpes Simplex 2
- HIV-1 & HIV-2 and strains of SIV
- Infectious Equine Anaemia
- Lymphocytic choriomeningitis virus (LCM)
- Monkey pox, when used in vitro
- Non-defective Adeno-2 SV-40 hybrids
- Pseudotuberculosis-ornithosis-trachoma group of agents
- Pseudorabies virus
- Rabies street virus, when used in inoculations of carnivores
- Rickettsia-all species except *Vole rickettsia* and *Coxiella burnetii* when used for vector transmission or animal inoculation experiments
- Sheep pox (field strain)
- Swine Fever virus
- Vesicular stomatitis virus
- Woolly monkey Fibrosarcoma
- Yaba pox virus

Risk Group IV

- Alastrim, monkeypox, whitepox, when used for transmission or animal inoculation experiments
- Hemorrhagic fever agents, including Crimean hemorrhagic fever (Congo) Korean hemorrhagic fever and others as yet undefined
- Herpesvirus simiae (monkey B virus)
- Tick-borne encephalitis virus complex, including-Russian Spring Summer Encephalitis, Kyasanur Forest Disease, Omsk hemorrhagic fever and Central European encephalitis viruses

SPECIAL CATEGORY

BACTERIAL

- Contagious Equine Metritis (*H. equinilis*) Pestis-petit de ruminantium

VIRAL RICKETTSIAL AND CHLAMYDIAL:

- African Horse Sickness virus (serotypes not reported in Indian and challenge strains)
- African Swine Fever
- Bat rabies virus

- Blue tongue virus (serotypes not reported in India)
- Exoitic FMD virus types and sub-types
- Junin and Machupo viruses
- Lassa virus
- Marburg virus
- Murrey valley encephalitis virus
- Rift Valley Fever virus
- Smallpox virus-Archival storage and propagation Swine Vesicular Disease
- Veneseulan equine encephalitis virus epidemic strains
- Western Equine encephalitis virus
- Yellow fever virus-Wild strain
- Other Arboviruses causing eizootics and so far not recorded in India.

B: PLANT PESTS

Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, bacteria, fungi, protozoa, other parasitic plants or reproductive parts thereof: viruses or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants are considered plant pests.

Organisms belonging to all lower Taxa contained within the group listed are also included.

1. Viruses

All viruses

All bacteria, fungal, algal, plant, insect and neumatode viruses; special care should be taken for-

- (i) Gemini viruses,
- (ii) Calulimo viruses,
- (iii) Nuclear Polyhedrosis viruses,
- (iv) Grandulosis viruses, and
- (v) Cytoplasmic polyhedrosis viruses

2. Bacteria

Family Pseudomonadaceae

Genus Pseudomonas
Genus Xanthomonas
Genus Azotobacter

Family Rhizobiaceae

Genus Rhizobium/Azorhizobium
Genus Bradyrhizobium
Genus Agrobacterium
Genus Phyllobacterium
Genus Erwinia
Genus Enterobacter
Genus Klebsiella

Family Spiroplasmaceae

Genus Azospirillum
Genus Acqaspirillum
Genus Occeonospirillum
Family Sreplomycetaceae
Genus Streplomyces
Genus Nocardia

Family Actinomycetaceae

Genus Actinomyces

Coryneform Group

Genus Clavibacter
Genus Arthrobacter
Genus Curtobacterium
Genus Bdellovibro

Family Rickettsiaceae

Rickettsial like organisms associated with insect diseases
Gram-negative phloem-limited bacteria associated with plant diseases
Gram-negative xylem-limited bacteria associated with plant diseases
Cynobacteria-all members of blue-green algae
Mollicutes
Family Spiroplasmataceae
Mycoplasma-like organisms associated with plant diseases
Mycoplasma-like organisms associated with insect diseases

Algae

Family Chloophyceae
Family Euglenophyceae
Family Pyrophyceae
Family Chrysophyceae
Family Phacophyceae
Family Rhodophyceae

Fungi

Family Plasmodiophoraceae
Family Chytridiaceae
Family Oldipopsidaceae
Family Synchytriaceae
Family Catenariaceae
Family Coelomomycetaceae
Family Saprologniaceae
Family Zoopagaceae
Family Albuginaceae
Family Peronosporaceae
Family Pythiaceae
Family Mucoraceae
Family Choanephoraceae
Family Mortierellaceae
Family Endogonaceae
Family Synephalastraceae
Family Dimargaritaceae
Family Kickxellaceae

Family Saksenaaceae
Family Entomophthoraceae
Family Ecerinaceae
Family Taphrinaceae
Family Endomycetaceae
Family Saccharomycetacea
Family Eutotiaceae
Family Gymnoascaceae
Family Aseophaeriaceae
Family Onygenaceae
Family Microascaceae
Family Protomycetaceae
Family Elsinoeaceae
Family Myriaginaceae
Family Dothidiaceae
Family Chaetothyriaceae
Family Pharmulariaceae
Family Phillipsiaceae
Family Gysteriaceae
Family Pleosporaceae
Family Melanomataceae
Family Ophiostomataceae
Family Aseosphaeriaceae
Family Erysiphaceae
Family Meliolaceae
Family Xylariaceae
Family Diaporthaceae
Family Hypoeraceae
Family Clavicipitaceae
Family Phacidiaceae
Family Ascocorticiaceae
Family Hemiphacidiaceae
Family Dermataceae
Family Sclerotiniaceae
Family Cyttariaceae
Family Helosiaceae
Family Sarocostomataceae
Family Sarcoscyphaceae
Family Auriculariaceae
Family Ceratobasidiaceae
Family Corticiaceae
Family Hymenochaetaceae
Family Echiodontiaceae
Family Eistuliniaceae
Family Clavariaceae
Family Polyporaceae
Family Tricholomataceae
Family Ustilaginaceae
Family Sporobolomycetaceae
Family Uredinaceae
Family Agaricaceae
Family Graphiolaceae

Family Pucciniaceae
Family Melampsoraceae
Family Gandodermataceae
Family Laboniaceae
Family Sphaeropsidaceae
Family Mclabconiaceae
Family Tuberculariaceae
Family Dermatiaceae
Family Moniliaceae
Family Aganomucetaceae

Parasitic Weeds

Family Balanophoraceae-parasitic species
Family Cuscutaceae-parasitic species
Family Thydonoraceae-parasitic species
Family Lauraceae-parasitic species Genus Cassytha
Family Lennoaceae-parasitic species
Family Loranthaceae-parasitic species
Family Myzodendraceae-parasitic species
Family Olacaceae-parasitic species
Family Orobanchaceae-parasitic species
Family Rafflesiaceae-parasitic species
Family Santalaceae-parasitic species
Family Scrophulariaceae-parasitic species

Protozoa

Genus Phytonomas
And all Protozoa associated with insect pest

Nematodes

Family Anguinidae
Family Belonolaimidae
Family calosiididae
Family Cariconematidae
Family dolichodoridae
Family Fergussiidae
Family hemicycliophoridae
Family Heteroderidae
Family Hoplolaimidae
Family Mclodogynidae
Family Neotylenchidae
Family Nothotylenchidae
Family Paratylenchidae
Family Pratylenchidae
Family Tylenchidae
Family Tylenchulidae
Family Aphelenchoidae
Family Longidoridae
Family Trichodoridae

Mollusca

Super family Planorbacca
Super family Achatinacca
Super family Arionacca
Super family Limacacca
Super family Helicacea
Super family Veronicellacea

Arthropoda

Super family Ascoidea
Super family Dermanyssoidea
Super family Erjophyoidea
Super family Tetranychoidea
Super family Tetranychoidea
Super family Eupododca
Super family Tydcoidea
Super family Erythraenoidca
Super family Trombidioidea
Super family Hydryphantoidea
Super family Tarasonemoidea
Super family Pyemotoioidea
Super family Hcmisaracoptoidea
Super family Acaroidea
Order Polydesmida
Family Sminthoridao
Family Forficulidzo
Order Isptera
Order Thysanoptera
Family Acredidea
Family Gryllidae
Family Gryllacridiedae
Family Gryllotalpidae
Family Phasmatidao
Family Ronalcidao
Family Tettigoniidao
Family Tatragedidao
Family Thaumastocoridae
Super family Piesmatoidea
Super family Lygacoidea
Super family Idiostoloidea
Super family Careoidea
Super family Penatomoidea
Super family Pyrrhoeomidea
Super family Tingoidea
Super family Miroidea
Order Homoplara
Family Anobiidae
Family Apionidae
Family Anthrididae
Family Bostrichidae
Family Brentidae
Family Bruchidae

Family Buprestodae
Family Byturidae
Family Cantharidae
Family Carabidae
Family Ceambicidae
Family Chrysomelidae
Family Coccinellidae
Family Curculionidae
Family Dermestidae
Family Elateridae
Family Hydrophilidae
Family Lyctidae
Family Meloidae
Family Moredellidae
Family Platypodiidae
Family Scarabaeldae
Family Scolytidae
Family Selbytidae
Order Lepidoptera
Family Agromyidae
Family Anthomidae
Family Cecidomidae
Family Chioropidae
Family Ephydriidae
Family Lonchacidae
Family Muscidae
Family Otitidae
Family Syrphidae
Family Tephritidae
Family Tipulidae
Family Apidae
Family Caphidae
Family Chalcidae
Family Cynipidae
Family Eurytomidae
Family formisidae
Family Psilidae
Family Sircidae
Family Tenthredinidae
Family Torymidae
Family Xyloioipidae and

Also unclassified organism and/or organisms whose classification is unknown, and all other organisms associated with plant and insect disease.

**DELEGATION OF POWERS TO THE SEED ANALYST UNDER SECTION 14 OF THE
ENVIRONMENT (PROTECTION) ACT, 1986**

MINISTRY OF ENVIRONMENT AND FORESTS

NOTIFICATION

New Delhi, the 1st September, 2006

G.S.R.589(E).- In exercise of the powers conferred by Section 23 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby delegates the power vested in it under Section 14 of the said Act to the Seed Analyst, notified under Section 12 of the Seeds Act, 1966 (54 of 1966) to use the signed document purporting to be reported of Genetically modified crop as evidence of the facts stated therein in any proceedings conferred under the Environment (Protection) Act, 1986 subject to the condition the Central Government may revoke such delegation of powers if in the opinion of the Central Government such a course of action is necessary in public interest.

[F.No.10/40/2003-CS]

Desh Deepak Verma, Jt. Secy.

Note: Principal Notification published in the Gazette of India vide Notification No.G.S.R.1198(E), dated 12.11.1986 and subsequently amended vide S.O.152(E), dated 10.2.1988, S.O.289(E), dated 14.4.1988, S.O.488(E), dated 17.5.1988, S.O.881(E), dated 22.9.1988, S.O.408(E), dated 6.6.1989, S.O.479(E), dated 25.7.1999, S.O.157(E), dated 27.2.1996, S.O.730(E), dated 10.7.2002.

**EXEMPTIONS TO THE OCCUPIER HANDLING A PARTICULAR MICROORGANISM/
GENETICALLY ENGINEERED ORGANISM**

MINISTRY OF ENVIRONMENT AND FORESTS

NOTIFICATION

New Delhi, the 20th September, 2006.

G.S.R.616(E).- Whereas the Ministry of Environment and Forests has notified the rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganism/ Genetically Engineered Organisms or Cells Rules, 1989 hereinafter referred to as Rules vide No.GSR1037(E), dated 5th December, 1989.

And Whereas rule 20 of the rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganism/Genetically Engineered Organism or Cells Rules, 1989 empowers the Ministry of Environment and Forests to exempt an occupier handling a particular microorganism/genetically engineered organism from the application of the provisions of Rules 7 to 11 (both inclusive).

Now, therefore, in pursuance of rule 20 of the rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms /Genetically Engineered Organisms or Cells Rules, 1989, the Central Government hereby consider it necessary that the manufacture and/or importer of recombinant pharmaceuticals falling in the following categories may be exempted from the provisions of rules 7 to 10 (both inclusive) of the above said Rules with effect from the date of publication of this notification in the official gazette.

- (a) Indigenous product development, manufacture and marketing of pharmaceutical products derived from organisms, falling under Risk Group I and Group II as specified in the Recombinant DNA Safety Guidelines, 1990.
- (b) Import and marketing of products derived from Living Modified Organisms (*LMOs*) as Drugs and Pharmaceuticals in bulk and/or finished formulations where the end product being imported is not a Living Modified Organisms.

[F.No.12/7/2004-CS]
DESH DEEPAK VERMA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide number GSR 1037(E), dated 5.12.1989, which came into force vide notification SO 677(E), dated 13th September, 1993 and amended vide notification GSR 493(E), dated 14th July, 2005.

**EXEMPTIONS TO THE OCCUPIER OF THE PROCESSED FOOD DERIVED FROM
LIVING MODIFIED ORGANISMS****MINISTRY OF ENVIRONMENT AND FORESTS****NOTIFICATION**

New Delhi, the 23rd August, 2007

S.O.1519(E).- Whereas, the Central Government with a view to protecting the environment, nature and health in connection with the application of gene technology and micro-organisms, has notified the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms/Genetically engineered organisms or Cells Rules, 1989 (hereinafter referred to as the said Rules) vide number G.S.R.1037(E), dated the 5th December, 1989.

And, whereas, rule 20 of the said Rules empowers the Ministry of Environment and Forests to exempt an occupier handling a particular microorganism/Genetically engineered organisms from the application of the provisions of rule 7 to 11 of the said Rules.

And, whereas, the Ministry of Environment and Forests consider it necessary that the occupier or processed food derived from living modified organisms specified in column (1) of the Table below may be exempted from the provisions of the rule specified in column (2) of the said Table;

Now, therefore, in pursuance of rule 20 of the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms/Genetically engineered organisms or Cells Rules, 1989, the Ministry of Environment and Forests, hereby exempts the occupier of the processed food derived from living modified organisms specified in the Table with effect from the date of publication of this notification in the Official Gazette, namely: -

TABLE

Processed food items derived from living modified organisms (1)	Rule from which exempted (2)
Food stuffs, ingredients in food stuffs and additives Including processing aids derived from living Modified Organisms where the end product is not a Living Modified Organisms.	Rule 11

[F.No.13/16/2007-CS-III]

A. K. Goyal, Jt. Secy.

Note: - The Manufacture, Use, Import, Export and Storage of Hazardous microorganisms/ Genetically engineered organisms or Cells Rules, 1989 were published in the Gazette of India, Extraordinary, vide number G.S.R.1037(E), dated the 5th December, 1989, which came into force vide notification S.O.677(E), dated the 13th September, 1993 and were subsequently amended vide notification numbers G.S.R.493(E), dated the 14th July, 2005 and G.S.R.616(E), dated the 20th September, 2006.

MINISTRY OF ENVIRONMENT AND FORESTS

NOTIFICATION

New Delhi, the 25th February, 2008

S.O.411(E).- Notification No.S.O.1519(E), dated 23rd August, 2007 is kept in abeyance for a period of six months i.e. up to 30th September, 2008 or until issue of further notification by the Ministry of Health and Family Welfare regarding regulation of GM processed foods by the Food Safety and Standards Authority, whichever is earlier.

[F.No.13/16/2007-CS-II]

A. K. Goyal, Jt. Secy.

Note: The Manufacture, Use, Import, Export and Storage of Hazardous microorganisms/Genetically engineered organisms or Cells Rules, 1989 were published in the Gazette of India, Extraordinary, vide number G.S.R.1037(E), dated the 5th December, 1989, which came into force vide notification S.O.667(E), dated the 13th September, 1993, and subsequently were amended vide notification numbers G.S.R.493(E), dated 14th July, 2005, G.S.R.616(E), dated the 20th September, 2006 and No.S.O.519(E), dated 23.8.2007