INDIAN

BILLS & ACTS

IN

BIOTECHNOLOGY & MICROBIOLOGY

A.B.SOLUNKE

INDIAN

BILLS & ACTS

IN

BIOTECHNOLOGY & MICROBIOLOGY

A.B.SOLUNKE

Shri Govindrao Munghate Arts & Science College, Kurkehda. 441209

www.sgmunghatecollege.in/www.abhaysolunke.info

Contents

BILLS AND ACTS

ACT– A bill which has passed through various legislative steps required and which has become law. A Bill becomes a law.

The bills are discussed in both houses. These bills are brought by the current and ex-members of both houses.

The Acts and Bills in India on various diseases are listed in table below.

Sr. No	Title	Year
	The Prevention And Control Of Infectious and Contagious Diseases in Animals Bill, 2008	
	The Biotechnology Regulatory Authority Of India Bill, 2013	
	Regional Centre for Biotechnology Act, 2016.	
	DNA Technology (Use and Application) Regulation Act, 2019.	
	Children Born of Unmarried Mothers (Determination of Paternity through D.N.A. Test) Act, 1998.	
	The Epidemic Diseases Act, 1897	
	Disaster Management Act 2005	
	Influenza to be an infectious disease	
	The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention And Control) Bill, 2014	
	Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017 (16 of 2017)	
	Maharashtra Gazette on HIV & AIDS Act Acceptance	
	Human Immunodeficiency Virus And Acquired Immune Deficiency Syndrome (Prevention And Control) Act, 2017 (16 Of 2017), Coming Into Force From 10 September, 2018.	
	Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention And Control) Rules, 2018.	
	Vaccination	

The study of bill and its incorporation in syllabus will be helpful for students, researchers, administrators in higher education. It is need of our time to study the bills and to know the processes of their formation and implementation.

CONTAGIOUS DISEASES IN ANIMALS BILL, 2008

AS PASSED BY THE RAJYA SABHA

ON 16TH DECEMBER, 2008

Bill No. CXXVII-C of 2005

THE PREVENTION AND CONTROL OF INFECTIOUS AND CONTAGIOUS DISEASES IN ANIMALS BILL, 2008

(AS PASSED BY THE RAJYA SABHA)

A

BILL

to provide for the prevention, control and eradication of infectious and contagious diseases affecting animals, for prevention of outbreak or spreading of such diseases from one State to another, and to meet the international obligations of India for facilitating import and export of animals and animal products and for matters connected therewith or incidental thereto.

WHEREAS economic losses due to infectious and contagious diseases of animals are enormous in the country with some of these diseases constituting a serious threat to the public;

AND WHEREAS many of such animal diseases can be largely prevented by judicious implementation of vaccination programmes or by taking other appropriate and timely measures on scientific lines;

AND WHEREAS such measures are necessary to facilitate the import and export of animals and animal products and to keep in tune with international practices;

AND WHEREAS it has been realised that the prevention, control and eradication of infectious and contagious diseases of animals from India has to be tackled on a national basis so as to avoid adverse impact of such diseases on the economy of the country and for this purpose harmonise the control procedures and to prevent inter-State transmission of animal diseases;

AND WHEREAS the national level handling has to be done with the active involvement of the State Governments, particularly in regard to the precautionary measures required to be taken within their jurisdiction in respect of certain infectious and contagious diseases and the regulation of movement of animals outside their respective areas by timely adoption of appropriate measures;

AND WHEREAS India is a Member Country of the *Office International Des Epizooties, Paris* and it is necessary to implement the general obligations, decisions and recommendations of the said Organisation and abide by the International Animal Health Code stipulated by the said Organisation;

BE it enacted by Parliament in the Fifty-ninth Year of the Republic of India as follows:—

CHAPTER I

PRELIMINARY

1. Short title, extent and commencement.

(*1*) This Act may be called the Prevention and Control of Infectious and Contagious Diseases in Animals Bill, 2008.

(*2*) It shall come into force on such date as the Central Government may, by notification, appoint; and different dates may be appointed for different States or for different areas therein as well as for different provisions of this Act, and any reference in any such provision of this Act to the commencement of this Act shall be construed in relation to any State or area or provision as a reference to the coming into force of this Act or, as the case may be, of that provision, in such State or area.

2. Definitions

In this Act, unless the context otherwise requires,–
(*a*) "animal" means,–
(*i*) cattle, buffalo, sheep, goat, yak, mithun;
(*ii*) dog, cat, pig, horse, camel, ass, mule, poultry, bees; and
(*iii*) any other animal or bird as the Central Government may, by notification, specify;
(*b*)"Check Post" means any place established as such by the Director to carry out checking of animals for the purpose of this Act;
(*c*)"Competent Officer" means any person or officer of the Government notified as a Competent Officer under section 17;
(*d*)"compulsory vaccination" means vaccination of any animal against any Scheduled disease in respect of which vaccination is made mandatory under the provisions of this Act;
(*e*)"controlled area" means any local area which has been declared as such by the State Government under sub-section (*1*) of section 6;
(*f*)"defective vaccine" means any vaccine which is expired, breach in seal, contaminated, improperly stored, unlabelled or with mutilated label;
(*g*)"Director", in relation to a State, means any officer in charge of the Department of Animal Husbandry or Veterinary Services, or both, notified by the State Government as such for the purpose of this Act;
(*h*) "free area" means any controlled area which has been declared as such under sub-section (*5*) of section 6;
(*i*)"infected animal" means an animal which is infected with any Scheduled disease;
(*j*)"infected area" means an area declared as such under section 20;
(*k*)"notification" means notification published in the Official Gazette;
(*l*)"prescribed" means prescribed by rules made under this Act;
(*m*)"publication" includes propagation of information through the media or newspaper or any other mass media and the means of local communication such as declaration in loud voice and by beating drums in the area;
(*n*)"Quarantine Camp" means any place declared to carry out quarantine of animals and birds for the purpose of this Act;
(*o*)"scheduled disease" means any disease included in the Schedule;
(*p*)"Veterinarian" means a person having a recognized veterinary qualification who, under the law for the time being in force, is allowed to treat animal diseases;
(*q*)"Veterinary Officer" means any officer, appointed as such by the State Government under clause (*b*) of section 3;
(*r*)"Village Officer", in relation to a village, means any person who is authorized or designated as such in accordance with the qualifications prescribed by the State Government.

CHAPTER II
CONTROL OF SCHEDULED DISEASES

3. Appointment of Veterinary Officers.
The State Government may, by notification, appoint—
(*a*) **such number of persons, as it deems proper, to be veterinarians to undertake inspection and specifying the local limits of their respective jurisdiction; and**
(*b*) **such number of Veterinarians, as it deems proper, to be Veterinary Officers, who shall exercise their powers and discharge their duties within the local limits of their jurisdiction as may be specified in the said notification.**
4. Reporting scheduled diseases obligatory.
(*1*) Every owner, or any other person, non-governmental organization, public bodies or the village panchayat in charge, of any animal which he or it has reason to believe to be infective of a scheduled disease shall report the fact to the Village Officer or village panchayat in-charge, who may report the same in writing to the nearest available Veterinarian.

(*2*) The Village Officer shall visit the area falling within his jurisdiction for reporting any outbreak of the disease.
(*3*) Every Veterinarian shall, on receipt of a report under sub-section (*1*), or otherwise, if he has reason to believe that any animal is infected with a scheduled disease, report the matter to the Veterinary Officer.
(*4*) Where in any State there is any occurrence of scheduled disease in relation to any animal, the Director shall send an intimation to the Directors of the States which are in the immediate neighbourhood of the place where there is such occurrence, for taking appropriate preventive measures against the spread of the disease.

5. Duty to segregate infected animals.

(*1*) Every owner or person in charge of an animal, which he has reason to believe is infective of a scheduled disease, shall segregate such animal and have it kept in a place away from all other animals which are healthy, and take all possible steps to prevent the infected animal from coming in contact with any other animal.
(*2*) The owner or other person in charge of, or having control over, the animal referred to in sub-section (*1*) shall confine that animal and prevent it from grazing in a common place or to drink water from any common source including a vessel, pond, lake or river.
(*3*) All other infected animals shall be segregated by the Municipality, Panchayat or other local administration.

6. Notification of controlled areas and free areas.

(*1*) The State Government may, with the object of preventing, controlling or eradicating any scheduled disease, by notification, declare any area to be a controlled area in respect of any scheduled disease affecting any species of animal and any other species that may be susceptible to the disease specified in the said notification.
(*2*) The State Government shall also cause the substance of the notification issued under sub-section (*1*) to be published in a local newspaper in the vernacular language and by declaration in loud voice and by beating drums in the area.
(*3*) Where a notification has been issued under sub-section (*1*), all animals of the species in the controlled area shall be subjected to compulsory vaccination against that disease, and be subjected to such other measures against the disease, in such manner and within such time as the State Government, may, by public notice, direct.
(*4*) The State Government shall make available necessary vaccine and it shall be obligatory on the part of every owner, or the person in charge of an animal which is required to be vaccinated under sub-section (*3*), to get the animal compulsorily vaccinated.
(*5*) Where the State Government is satisfied, on a report received from the Director or otherwise, that, in any controlled area, any of the scheduled diseases affecting any species of animal is no longer prevalent, it may, by notification, declare the area to be a free area in respect of that disease in relation to the particular species of animal.
(*6*) Where a notification has been issued under sub-section (*5*), no animal of the species or of any other susceptible species with regard to which it is a free area shall be allowed to enter the free area unless duly immunized by vaccination against that particular disease.

7. Prohibition of movement of animals from controlled area.

(*1*) Where a notification has been issued under sub-section (*1*) of section 6 declaring any area as a controlled area in relation to any disease affecting any species of animals, no animal belonging to that species shall be moved from the place where it is kept.
(*2*) The Director may, for the purpose of control, prevention or eradication of any scheduled disease, in respect of any area, by order published in the Official Gazette, prohibit the movement of all animals belonging to any species specified therein, from the place where it is kept, to any other place.
(*3*) Nothing contained in sub-sections (*1*) and (*2*) shall be deemed to prohibit–

(*a*)the movement of any animal referred to therein, from the place where it is kept, to the nearest place where it can be got vaccinated, so long as the animal is being moved for the purpose of its immunization by vaccination; or

(*b*) the movement of any such animal, so long as it is accompanied by a valid certificate of vaccination to indicate that the animal is duly immunized against the particular disease and it bears proper mark of such vaccination.

8. Vaccination, marking and issue of vaccination certificate.

(*1*)The vaccine to an animal may be administered by any person competent under the law for the time being in force to administer it, and issue a certificate of administration of vaccination.

(*2*)Where any animal has been vaccinated for any scheduled disease in compliance with the provisions of sub-section (*1*), the person vaccinating the animal shall cause to put a mark by branding, tattooing or ear tagging, or in such other manner as the Director may, by general or special order, direct and the same shall, unless otherwise specified by the Director shall not be removed.

(*3*)The authority issuing a certificate of vaccination shall specify the date of vaccination, dates of manufacture and expiry of the vaccine and the date up to which the vaccination of the animal with the particular vaccine shall be valid.

9. Contents of vaccination certificate.

Every vaccination certificate issued under this Act shall be in such form and shall contain such particulars as may be prescribed by the Central Government.

10. Entry and exit of animals into controlled area and free area.

(*1*)Where any area has been declared as a controlled area under sub-section (*1*) of section 6 in respect of any disease affecting any species of animals, no animal belonging to that species shall be taken out of, or brought into that area save as provided in section 16.

(*2*)The Director may, by notice duly published in the Official Gazette and at least in one daily local newspaper in vernacular language, extend the prohibition contained in sub-section

(*1*) to any other species of animals, if animals belonging to that species are also likely to be infected with that disease.

(*3*)No carrier of goods or animal shall carry any animal from or out of a controlled area, free area or infected area by land, sea or air unless he complies with the provisions of section 16.

(*4*)Nothing contained in sub-sections (*1*) to (*3*) shall apply to the carriage by railway or any animal referred to in those sub-sections through any area which, for the time being, is declared as a controlled area or infected area so long as the animal is not unloaded (for whatsoever purpose or duration) in any place within that area:

Provided that the State Government may, by notification, declare that any species of animal so carried through any local area within the State shall be duly immunized against such scheduled disease, in such manner and within such time as may be specified in that notification and a certificate of vaccination shall be a pre-requisite for the transportation of the animals by the railways through that area:

Provided further that, where any notification as referred to in the first proviso has been issued, it shall be incumbent on the State Government to intimate that fact to the concerned Railway authorities so as to enable them to satisfy themselves about the immunization of the animal before transporting it through the local area of the State.

11. Precautionary measures in relation to controlled areas.

No person shall take out of the controlled area–

(*a*) any animal, alive or dead, which is infected with, or reasonably suspected to have been infected with, any scheduled disease notified under sub-section (*1*) of section 6,

(*b*) any kind of fodder, bedding or other material which has come into contact with any animal infected with such disease or could, in any manner, carry the infection of the notified disease, or

(*c*) the carcass, skin or any other part or product of such animal.

12. Prohibition of markets, fairs, exhibition, etc., in the controlled areas.
No person, organization or institution shall hold any animal market, animal fair, animal exhibition and carry on any other activity which involves grouping or gathering of any species of animals within a controlled area:
Provided that the Competent Officer may, *suo motu* or on application made to him in this behalf, relax the prohibition in relation to any species of animals, in a case where animals belonging to that species are not susceptible to the scheduled disease and are incapable of carrying it, if he is satisfied that in the public interest it is necessary to accord such relaxation.
13. Prohibition of bringing of infected animals into market and other places.
No person shall bring or attempt to bring into market, fair, exhibition or other congregation of animals or to any public place, any animal which is known to be infected with a Scheduled disease.
14. Check Posts and Quarantine Camps.
(*1*)The Director may establish as many Quarantine Camps and Check Posts within the State as may be required–
(*a*)for the detention of animals suffering from any scheduled disease or of animals which have come into contact with or have been kept in the proximity of any such infected animal;
(*b*) for ensuring the prevention of entry into or exit from any controlled area or infected area or free area, of any animal belonging to the species of animals in respect of which a notification, issued under sub-section (*1*) of section 6, or an order issued under sub-section (*2*) of section 7, is in force.
(*2*)Any animal which is required to be detained, inspected, vaccinated, or marked, may be kept in the Quarantine Camp for such period as the Competent Officer may direct.
(*3*) Every animal detained at a Quarantine Camp shall be under the custody of the person in charge of the camp, and shall be vaccinated and marked.
(*4*) The officer in charge of the Quarantine Camp shall, at the time of release of an animal from the station, grant a permit, in such form as may be prescribed by the State Government, to the person taking charge of the animal, and every such person shall be bound to produce the permit whenever required to do so by any Competent Officer.
15. Inspection and detention of animals at Check Posts and Quarantine Camps.
(*1*)Every person in charge of any Check Post or Quarantine Camp shall inspect any animal stopped at the Check Post, or detained therein or at the Quarantine Camp.
(*2*)The manner of inspection and the period of detention of the animal at the Check Post or at the Quarantine Camp for the purpose of inspection or for the administration of compulsory vaccination, the marking of animals and the form and manner in which permit for entry in respect of any animal may be issued, shall be such as may be prescribed by the State Government.
16. Entry and exit of vaccinated animals into controlled and free areas.
Notwithstanding anything contained in section 10, an animal belonging to the species of animals in respect of which an area has been declared as a controlled or free area in relation to any scheduled disease, which has been duly vaccinated against that disease, shall be allowed to enter into or be taken out of the controlled area or free area, or to be taken out of any other place on the production of a certificate to the effect that vaccine against that disease has been administered and a period of not less than twenty-one days has lapsed thereafter.
17. Appointment of Competent Officers.
The State Government may, for the proper implementation of the provisions of this Act, by notification, authorise any person to exercise any power or discharge any duty as a Competent Officer, under this Act, who shall exercise such powers and such duties within the local limits of his jurisdiction as may be specified in the notification.
18. Cleaning and disinfection of carriers.
(*1*) Every common carrier whether a vessel or vehicle shall be cleaned and disinfected immediately before and after the transportation of any animal in that vessel or vehicle, and so also any other place where the animal has been kept in transit.

(*2*)Where any area has been declared as a controlled area or free area in respect of any scheduled disease affecting any species of animal, the Director may, by an order duly published in the Official Gazette and in a local newspaper in the vernacular language, direct the owner of every vehicle in which any animal belonging to that species is carried, to have the vehicle properly cleaned and disinfected.

19. Powers of entry and inspection.

Any Veterinary Officer or other Competent Officer may enter upon and inspect any land or building or place, vessel or vehicle, for the purpose of ensuring compliance of the provisions of this Act or the rules or orders made thereunder, by the persons responsible for such compliance.

CHAPTER III
INFECTED AREAS

20. Declaration of infected areas.

If the Veterinary Officer, upon receipt of a report from a Veterinarian or otherwise, is satisfied that, in any place or premises falling within his jurisdiction, an animal has been infected with any scheduled disease, or that an animal, which he has reason to believe has been so infected, is kept, may, by notification and publication in at least one local newspaper in the vernacular language and by declaration in loud voice and by beating drums, declare such area as he may deem fit (including the place or premises aforesaid) to be an infected area.

21. Effect of declaration of infected areas.

(*1*) Where an area has been declared as an infected area under section 20, all provisions of this Act which are applicable in relation to a controlled area shall *mutatis mutandis* apply thereto as if for the words "controlled area,", the words "infected area" have been substituted.

(*2*)Without prejudice to the generality of the provisions contained in sub-section (*1*), the following further provisions shall apply in relation to an infected area, namely:—

(*a*)in respect of every animal in that area which is infected or reasonably believed to be infected, with any scheduled disease, the owner or other person in charge of the animal, shall forthwith get it treated by a Veterinarian;

(*b*)all articles, which are likely to have come into contact with any animal referred to in clause (*a*), shall be treated or disposed off in such a manner as the Veterinarian may direct;

(*c*)every Veterinarian shall, for the purpose of inspection, have the power to enter any place or premises where any animal is kept or is likely to be kept;

(*d*) the owner or any other person in charge of the animal referred to in clause

(*a*)shall keep the animal in isolation forthwith, and also take such other measures as may be necessary for the prevention, treatment and control of the disease as the Veterinarian may direct.

22. Denotification of infected area.

If the Veterinary Officer, after such enquiry as he may deem fit, is satisfied that there is no longer the threat or danger of any animal being infected with the scheduled disease in any infected area, by notification and publication in a local newspaper in vernacular language, declare that the area is no longer an infected area as aforesaid, whereupon all the restrictions referred to in section 21 shall cease to apply.

CHAPTER IV
INFECTED ANIMALS

23. Segregation, examination and treatment of infected animals.

(*1*)Where the Veterinarian has, on receipt of a report or otherwise, reason to believe that any animal is infected with a scheduled disease, he may, by order in writing, direct the owner or any other person in charge of such animal–

(*a*) to keep it segregated from other apparently healthy animals; or

(*b*) to subject it to such treatment as may be required under the circumstances.

(*2*)Where any action has been taken in pursuance of sub-section (*1*), the Veterinarian shall forthwith give a detailed report of the incidence of the disease to the Veterinary Officer.

(*3*)On receipt of a report from the Veterinarian, the Veterinary Officer shall, as soon as possible, examine that animal as well as any other animal which could have come in contact with it, and for that purpose, submit the animal to such test and medical examination as may be required under the circumstances.

(*4*) If, after such test and examination, the Veterinary Officer is of the opinion that an animal is not infected with any of the scheduled diseases, he shall issue a certificate in writing that the animal is not infected with any such disease.

24. Drawing samples from animals.

(*1*) Where the Veterinary Officer considers it necessary for the purpose of ascertaining whether the animal which is suspected to have been infected with any scheduled disease or susceptible to such infection, is actually infected, or for the purpose of ascertaining the nature of the scheduled disease with which an animal is infected, he may draw such samples, as may be required, from the animal for the purpose of carrying out such investigations as he may deem necessary under the circumstances.

(*2*)The Veterinary Officer or any other Competent Officer shall draw samples from any animal for the purposes of ascertaining whether the animal has been vaccinated against any disease, or whether the vaccination of the animal has been effective in conferring it immunity and have the samples examined, in such manner as he may deem necessary.

25. Resort to euthanasia for infected animals.

If the Veterinary Officer deems it necessary that an animal, which is infected with a scheduled disease, euthanasia has to be resorted to, for preventing the spread of the disease to other animals in the area or to protect public health if the disease is of zoonotic importance, he may, notwithstanding anything contained in any other law for the time being in force, by an order in writing, direct euthanasia of the animal and the carcass disposed of immediately to his satisfaction.

26. Disposal of carcass.

Every person in possession of carcass (or any part thereof) of any animal, which, at the time of its death, was infected with any scheduled disease or was suspected to have been infected, shall dispose it of in such manner as may be prescribed.

27. Powers of Veterinary Officer and Veterinarian to hold postmortem examination.

(*1*)Where the Veterinary Officer or any Veterinarian has reason to believe that the death of an animal has been caused by an infection of any scheduled disease, he may make or cause to be made a post-mortem examination of the animal and for that purpose he may cause the carcass of any such animal to be exhumed where required followed by proper disposal after necessary examination and post-mortem.

(*2*)Every examination and post-mortem referred to in sub-section(*1*) shall be conducted in such manner, and the report of post-mortem shall be in such form, as may be prescribed.

28. Seizure and removal of certain animals.

Where any animal which is infected or suspected to have been infected is found without any person claiming to be its owner, or where a valid order or direction given in relation to any such animal is not promptly complied with by the owner or other person in control of the animal, it shall be open to the Veterinary Officer or any other Competent Officer, to seize the animal and remove it to a place of isolation or segregation, as he may deem proper.

CHAPTER V
ENFORCEMENT AND PENALTIES

29. Enforcement of orders and recovery of expenses.

(*1*) Where by any rule, notification, notice, requisition, order or direction made under this Act, any person is required to take any measure or to do anything—

(*a*) in respect of any animal, carcass of any animal or other thing in his custody or charge, the same shall be promptly complied with by that person;

(*b*)in case of any stray or ownerless animal, carcass of such animal or parts thereof, the same shall be promptly complied with by the municipality or Panchayat, as the case may be, at its cost.

(*2*)If the measures as referred to in sub-section (*1*) are not taken within such time as may be allowed for the purpose, the authority issuing the notice, requisition, order or direction, may cause the measures to be taken at the cost of the person or municipality or Panchayat, as the case may be, who or which was required to take the measures.

(*3*)The costs of any measures taken under sub-section (*2*), shall be recoverable from the person or the municipality or Panchayat, as the case may be, concerned in the manner provided by the Code of Criminal Procedure, 1973, for the recovery of fines imposed by a Court, as if such costs were a fine imposed by a Court.

30. Village Officers, etc., to assist.

All Municipal, Panchayat or Village Officers and all officers of the rural and dairy development, revenue, agriculture, animal husbandry and veterinary departments of the State Government, shall be bound–

(*a*)to give immediate information to the Veterinary Officer and to the Veterinarian having jurisdiction in the area regarding the prevalence of a scheduled disease amongst any animal or species of animals, in the area;

(*b*) to take all necessary measures to prevent the outbreak or spread of any scheduled disease; and

(*c*) to assist the Veterinary Officer and the Veterinarian in the discharge of their duties or in the exercise of their powers under this Act.

31. Penalty for issuing vaccination certificate without authority or administering defective vaccine.

If any person issues a vaccination certificate,–

(*a*) without authority or competence in that behalf, or

(*b*) after administering the vaccine which is known to be defective in any manner, he shall be guilty of an offence punishable with a fine of five thousand rupees or in case of non-payment of fine with imprisonment which may extend to one month, and in the case of any subsequent offence, with fine of ten thousand rupees or with imprisonment which may extend to three months.

32. Penalties.

Any person who contravenes the provisions of this Act or obstructs the Competent Officer in performing his duties shall be guilty of an offence punishable with fine which may extend to one thousand rupees, and in case of failure to pay the penalty with imprisonment for a term which may extend to one month; and in the case of any subsequent offence (whether under the same provision or any other provision of this Act except in case of sections 31 and 33) with a fine of two thousand rupees, or with imprisonment for a term which may extend to two months in case of non-payment of the penalty.

33. Penalty for placing infected animal or carcass in river, etc.

Whoever places or causes or permits to be placed in any river, lake, canal or any other water body, the carcass or any part of the carcass of any animal which at the time of its death was known to be infected, shall be guilty of an offence and, on conviction, be punished, in the case of a first offence with fine of two thousand rupees or with imprisonment of one month in case of non-payment of fine and in the case of subsequent conviction with a fine of five thousand rupees or imprisonment for a term which may extend to three months or with both.

34. Offences by companies.

(*1*) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded and punished accordingly:

Provided that nothing contained in this sub-section shall render such person liable to any punishment provided in this Act, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(*2*)Notwithstanding anything contained in sub-section(*1*), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.–For the purposes of this section,—

(*a*)"company" means anybody corporate and includes a co-operative society registered or deemed to be registered under any law for the time being in force, a firm or other association of individuals; and

(*b*)"director", in relation to a firm, means a partner in the firm.

CHAPTER VI
PRECAUTIONARY MEASURES ON CAUSATIVE ORGANISM, ETC.

35. Prevention of escape of causative organism.

(*1*)In every institution, laboratory or clinic, engaged in the manufacture, testing or research, related to vaccines, sera, diagnostics or chemotherapeutic drugs and aimed at the prevention or treatment of any scheduled disease, adequate precautionary measures shall be taken –

(*a*) to ensure that the causative organism of any scheduled disease does not escape or otherwise get released;

(*b*) to guard against any such escape or release; and

(*c*) to warn and to protect everyone concerned in the event of any escape.

(*2*) Notwithstanding anything contained in any other law for the time being in force, every animal–

(*a*) used for the manufacture, testing or research as referred to sub-section (*1*), or

(*b*)which is likely to carry or transmit any scheduled disease, shall be promptly administered euthanasia and disposed of by the person in charge of or having control of the institution, laboratory or clinic, as the case may be, referred to in that sub-section.

(*3*) Every person who is in charge of or having control of an institution, laboratory or clinic referred to in sub-section (*1*) comply with the provisions of sub-section (*1*) and subsection (*2*); and in the event of non-compliance he shall be guilty of an offence punishable with fine which may extend to twenty thousand rupees or imprisonment for a term which may extend to six months or with both, and in case the establishment is in commercial manufacturing of vaccines or medicine, a temporary suspension of license up to a period of one year may also be imposed.

CHAPTER VII
MISCELLANEOUS

36. Power to delegate.

The State Government may, by notification, delegate to any officer or authority subordinate to it, all or any of the powers conferred on it by or under this Act, except the powers to make rules under sub-section(*2*) of section 42.

37. Officers and authorities to function subject to Government control.

All officers and authorities under this Act shall exercise their powers and discharge their duties conferred or imposed on them by or under this Act, in accordance with such orders, not inconsistent with the provisions of this Act, as the Central Government or the State Government may, from time to time, make.

38. Power to amend the Schedule.

(*1*) The Central Government may, by notification, add to, or omit from the Schedule any animal disease and the said disease shall, as from the date of the notification, be deemed to have been added to, or omitted from, the Schedule.

(*2*)Every notification issued under sub-section (*1*) shall, as soon as may be after it is issued, be laid before each House of Parliament.

39. Power to issue directions.

The Central Government may, with the object of prevention, control and eradication of any infectious or contagious disease of animals, issue such directions to the State Government or other authorities under this Act, from time to time, including directions for furnishing such returns and statistics on Scheduled diseases, and vaccination, as it may deem fit and every such direction shall be complied with.

40. Certain persons to be public servants.

Every Competent Officer, Director and Veterinary Officer, while exercising any power or performing any duty under this Act, shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code.

41. Power to remove difficulties.

(*1*)If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act, as appear to it to be necessary or expedient for removing the difficulty:

Provided that no such order shall be made after the expiry of a period of two years from the date of commencement of this Act.

(*2*)Every order made under this section shall, as soon as may be after it is made, be laid before each House of Parliament.

42. Power of Central Government to make rules.

(*1*)The Central Government may, subject to the condition of previous publication, by notification, make rules for carrying out the provisions of this Act.

(*2*)In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

(*a*) the form of vaccination certificate and the particulars which such certificate shall contain, under section 9;

(*b*) the manner of disposal of carcass, under section 26;

(*c*) the manner of conducting examination and post-mortem under sub-section

(*1*) and the form of report of post-mortem under sub-section (*2*), of section 27;

(*d*) any other manner which may be prescribed or in respect of which rules are required to be made by the Central Government.

43. Power of State Government to make rules.

(*1*)The State Governments may, by notification and with the prior approval of the Central Government, make Rules for carrying out the purposes of this Act.

(*2*)In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:–

(*a*) the form of permit to be granted by the officer in charge of a Quarantine Camp, under sub-section (*4*) of section 14;

(*b*)the manner of inspection and the period of detention of an animal at a Check Post or at a Quarantine Camp for the administration of compulsory vaccination and marking of animals and the form and manner of issue of entry permit, under subsection

(*2*) of section 15;

(*c*) any other matter in respect of which rule is to be or may be made by the State Government.

44. Laying of rules.

(*1*) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not

be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

(*2*)Every rule made by the State Government under this Act shall be laid, as soon as may be, after it is made, before the State Legislature.

45. Repeal and savings.

On the commencement of this Act–

(*i*)The Glanders and Farcy Act, 1899;

(*ii*)The Dourine Act, 1910; and

(*iii*)any other corresponding law of any State, so far as it is inconsistent with the provisions of this Act, shall stand repealed:

Provided that nothing contained in this section shall –

(*a*)affect the previous operation of any such provision of law or anything duly done or suffered thereunder;

(*b*)affect any right, privilege, obligation or liability acquired, accrued or incurred under any such provision of law;

(*c*)affect any penalty, forfeiture or punishment incurred in respect of any offence committed against any such provision of law; or

(*d*)affect any investigation, legal proceeding or remedy in respect of any such right, privilege, obligation, liability, penalty, forfeiture or publishment as aforesaid; and every such investigation, legal proceeding or remedy may be continued, instituted or enforced, and any such penalty, forfeiture and punishment may be imposed, as if the aforesaid provisions of law had continued:

Provided further that, anything done or any action taken under any such provision of law, including any notification, order, notice or receipt issued or declaration made, shall in so far as it is not inconsistent with the provisions of this Act, be deemed to have been done, taken, issued or make under the corresponding provisions of this Act, and shall continue in force accordingly, unless and until superseded by anything done or any action taken under this Act.

THE SCHEDULE

[*See* sections 2 (O) and 38]

(*a*) Multiple species diseases

1. Anthrax. 2. Aujeszky's disease. 3. Bluetongue. 4. Brucellosis. 5. Crimean Congo haemorrhagic fever.6.Echinococcosis/hydatidosis.7.Foot and mouth disesase.8.Heartwater.9.Japanese encephalitis.10. Leptospirosis. 11. New world screwworm *(Cochlimyia hominivorax).* 12. Old world screwworm *(Chrysomya bezziana).* 13. Paratuberculosis. 14. Q fever. 15. Rabies. 16. Rift Valley fever. 17. Rinderpest. 18. Trichinellosis. 19. Tularemia. 20. Vesicular stomatitis. 21. West Nile fever.

(*b*) Cattle diseases

1. Bovine anaplasmosis. 2. Bovine babesiosis. 3. Bovine genital cmpylobacteriosis. 4. Bovine spongiform encephalopathy. 5. Bovine tuberculosis. 6. Bovine viral diarrhoea. 7. Contagious bovine pleuropneumonia. 8. Enzootic bovine leucosis. 9. Haemorrhagic septicaemia. 10. Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis. 11. Lumpy skin disease. 12. Malignant catarrhal fever. 13. Theileriosis. 14. Trichomonosis. 15. Trypanosomosis.

(*c*) Sheep and goat diseases

1. Caprine arthritis/encephalitis. 2. Contagious agalactia. 3. Contagious caprine pleuropneumonia.
4. Enzootic abortion of ewes (ovine chlamydiosis). 5. Maedi-visna. 6. Nairobi sheep disease. 7. Ovine epididymitis (*Brucella ovis*). 8. Peste des petits ruminants. 9. Salmonellosis (S. abortusovis). 10. Scrapie. 11. Sheep pox and goat pox.

(*d*) Equine diseases

1. African horse sickness. 2. Contagious equine metritis. 3. Dourine. 4. Equine encephalomyelitis (Eastern). 5. Equine encephalomyelitis (Western). 6. Equine infectious anaemia. 7. Equine

Influenza. 8. Equine piroplasmosis. 9. Equine rhinopneumonitis. 10. Equine viral arteritis. 11. Glanders. 12. Surra (*Trypanosoma evansi*). 13. Venezuelan equine encephalomyelitis.

(*e*) Swine diseases

1. African swine fever. 2. Classical swine fever. 3. Nipah virus encephalitis. 4. Porcine cysticercosis. 5. Porcine reproductive and respiratory syndrome. 6. Swine vesicular disease. 7. Transmissible gastroenteritis.

(*f*) Avian diseases

1. Avian chlamydiosis. 2. Avian infectious bronchitis. 3. Avian infectious laryngotracheitis. 4. Avian mycoplasmosis (*M. gallisepticum*). 5. Avian mycoplasmosis (*My. synoviae*). 6. Duck virus hepatitis. 7. Fowl cholera. 8. Fowl typhoid. 9. Highly pathogenic avian inflenza and low pathogenic avian influenza in poultry. 10. Infectious bursal disease (Gumboro disease). 11. Marek's disease. 12. Newcastle disease. 13. Pullorum disease. 14. Turkey rhinotracheitis.

(*g*) Cattle diseases

1. Myxomatosis. 2. Rabbit haemorrhagic disease.

(*h*) Bee diseases

1. Acarapisosis of honey bees. 2. American foulbrood of honey bees. 3. European foulbrood of honey bees. 4. Small hive bettle infestation (*Aethina tumida*). 5. *Tropilaelaps* infestation of honey bees. 6. Varroosis of honey bees.

(*i*) Fish diseases

1. Epizootic haematopoietic necrosis. 2. Infectious haematopoietic necrosis. 3. Spring viraemia of carp. 4. Viral haemorrhagic septicaemia. 5. Infectious pancreatic necrosis. 6. Infectious salmon anaemia. 7. Epizootic ulcerative syndrome. 8. Bacterial kidney disease (*Renibacterium salmoninarum*). 9. Gyrodactylosis (*Gyrodactylus salaris*). 10. Red sea bream iridoviral disease.

(*j*) Molluse diseases

1. Infection with *Bonamia ostreae.* 2. Infection with *Bonamia exitiosa.* 3. Infection with *Marteilia refringens.* 4. Infection with *Mikrocytos mackini.* 5. Infection with *Perkinsus marinus.* 6. Infection with *Perkinsus olseni.* 7. Infection with *Xenohaliotis californiensis.*

(*k*) Crustacean diseases

1. Taura syndrome. 2. White spot disease. 3. Yellowhead disease. 4. Tetrahedral baculovirosis (*Baculovirus penaei*). 5. Spherical baculovirosis (*Penaeus monodon*-type baculovirus). 6. Infectious hypodermal and haematopoietic necrosis. 7. Crayfish plague (*Aphanomyces astaci*).

(*l*) Other diseases

1. Camelpox. 2. Leishmaniosis.

RAJYA SABHA

———

A

BILL

to provide for the prevention, control and eradication of infectious and contagious diseases affecting animals, for prevention of outbreak or spreading of such diseases from one State to another, and to meet the international obligations of India for facilitating import and export of animals and animal products and for matters connected therewith or incidental thereto.

———

(*As passed by the Rajya Sabha*)

GMGIPMRND—4439RS(S-5)—16-12-2008.

PREVENTION AND CONTROL OF INFECTIOUS AND CONTAGIOUS DISEASES IN ANIMALS ACT, 2009
ACT NO. 27 OF 2009

THE PREVENTION AND CONTROL OF INFECTIOUS AND CONTAGIOUS DISEASES IN ANIMALS ACT, 2009

ACT NO. 27 OF 2009

[20*th March*, 2009.]

An Act to provide for the prevention, control and eradication of infectious and contagious diseases affecting animals, for prevention of outbreak or spreading of such diseases from one State to another, and to meet the international obligations of India for facilitating import and export of animals and animal products and for matters connected therewith or incidental thereto.

WHEREAS economic losses due to infectious and contagious diseases of animals are enormous in the country with some of these diseases constituting a serious threat to the public;

AND WHEREAS many of such animal diseases can be largely prevented by judicious implementation of vaccination programmes or by taking other appropriate and timely measures on scientific lines;

AND WHEREAS such measures are necessary to facilitate the import and export of animals and animal products and to keep in tune with international practices;

AND WHEREAS it has been realised that the prevention, control and eradication of infectious and contagious diseases of animals from India has to be tackled on a national basis so as to avoid adverse impact of such diseases on the economy of the country and for this purpose harmonise the control procedures and to prevent inter-State transmission of animal diseases;

AND WHEREAS the national level handling has to be done with the active involvement of the State Governments, particularly in regard to the precautionary measures required to be taken within their jurisdiction in respect of certain infectious and contagious diseases and the regulation of movement of animals outside their respective areas by timely adoption of appropriate measures;

AND WHEREAS India is a Member Country of the *Office International Des Epizooties, Paris* and it is necessary to implement the general obligations, decisions and recommendations of the said Organisation and abide by the International Animal Health Code stipulated by the said Organisation;

BE it enacted by Parliament in the Sixtieth Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

1. Short title, extent and commencement.—

(*1*) This Act may be called the Prevention and Control of Infectious and Contagious Diseases in Animals Bill, 2009.

(*2*) It shall come into force on such date1 as the Central Government may, by notification, appoint; and different dates may be appointed for different States or for different areas therein as well as for different provisions of this Act, and any reference in any such provision of this Act to the commencement of this Act shall be construed in relation to any State or area or provision as a reference to the coming into force of this Act or, as the case may be, of that provision, in such State or area.

2. Definitions.—

In this Act, unless the context otherwise requires,—

(*a*) "animal" means,—

(*i*) cattle, buffalo, sheep, goat, yak, mithun;

(*ii*) dog, cat, pig, horse, camel, ass, mule, poultry, bees; and

(*iii*) any other animal or bird as the Central Government may, by notification, specify;

(*b*) "Check Post" means any place established as such by the Director to carry out checking of animals for the purpose of this Act;

(*c*) "Competent Officer" means any person or officer of the Government notified as a Competent Officer under section 17;

(*d*) "compulsory vaccination" means vaccination of any animal against any scheduled disease in respect of which vaccination is made mandatory under the provisions of this Act;

(*e*) "controlled area" means any local area which has been declared as such by the State Government under sub-section (*1*) of section 6;

(*f*) "defective vaccine" means any vaccine which is expired, breach in seal, contaminated, improperly stored, unlabelled or with mutilated label;

(*g*) "Director", in relation to a State, means any officer in charge of the Department of Animal Husbandry or Veterinary Services, or both, notified by the State Government as such for the purpose of this Act;

(*h*) "free area" means any controlled area which has been declared as such under sub-section (*5*) of section 6;
(*i*) "infected animal" means an animal which is infected with any scheduled disease;
(*j*) "infected area" means an area declared as such under section 20;
(*k*) "notification" means notification published in the Official Gazette;
(*l*) "prescribed" means prescribed by rules made under this Act;
(*m*)"publication" includes propagation of information through the media or newspaper or any other mass media and the means of local communication such as declaration in loud voice and by beating drums in the area;
(*n*)"Quarantine Camp" means any place declared to carry out quarantine of animals and birds for the purpose of this Act;
(*o*) "scheduled disease" means any disease included in the Schedule;
(*p*)"Veterinarian" means a person having a recognised veterinary qualification who, under the law for the time being in force, is allowed to treat animal diseases;
(*q*)"Veterinary Officer" means any officer, appointed as such by the State Government under clause (*b*) of section 3;
(*r*)"Village Officer", in relation to a village, means any person who is authorised or designated as such in accordance with the qualifications prescribed by the State Government.

CHAPTER II
CONTROL OF SCHEDULED DISEASES

3. Appointment of Veterinary Officers.—The State Government may, by notification, appoint**—**
(*a*) such number of persons, as it deems proper, to be Veterinarians to undertake inspection and specifying the local limits of their respective jurisdiction; and
(*b*) such number of Veterinarians, as it deems proper, to be Veterinary Officers, who shall exercise their powers and discharge their duties within the local limits of their jurisdiction as may be specified in the said notification.

4.Reporting scheduled diseases obligatory.—(*1*) Every owner, or any other person, non-governmental organisation, public bodies or the village panchayat, in charge of any animal which he or it has reason to believe to be infective of a scheduled disease shall report the fact to the Village Officer or village panchayat in-charge, who may report the same in writing to the nearest available Veterinarian.
(*2*) The Village Officer shall visit the area falling within his jurisdiction for reporting any outbreak of the disease.
(*3*)Every Veterinarian shall, on receipt of a report under sub-section (*1*), or otherwise, if he has reason to believe that any animal is infected with a scheduled disease, report the matter to the Veterinary Officer.
(*4*)Where in any State there is any occurrence of scheduled disease in relation to any animal, the Director shall send an intimation to the Directors of the States which are in the immediate neighbourhood of the place where there is such occurrence, for taking appropriate preventive measures against the spread of the disease.

5. Duty to segregate infected animals.—(*1*) Every owner or person in charge of an animal, which he has reason to believe is infective of a scheduled disease, shall segregate such animal and have it kept in a place away from all other animals which are healthy, and take all possible steps to prevent the infected animal from coming in contact with any other animal.
(*2*)The owner or other person in charge of, or having control over, the animal referred to in sub-section (*1*) shall confine that animal and prevent it from grazing in a common place or to drink water from any common source including a vessel, pond, lake or river.
(*3*)All other infected animals shall be segregated by the Municipality, Panchayat or other local administration.

6.Notification of controlled areas and free areas.—(*1*) The State Government may, with the object of preventing, controlling or eradicating any scheduled disease, by notification, declare any area to be a controlled area in respect of any scheduled disease affecting any species of animal and any other species that may be susceptible to the disease specified in the said notification.
(*2*) The State Government shall also cause the substance of the notification issued under sub-section (*1*) to be published in a local newspaper in the vernacular language and by declaration in loud voice and by beating drums in the area.
(*3*)Where a notification has been issued under sub-section (*1*), all animals of the species in the controlled area shall be subjected to compulsory vaccination against that disease, and be subjected to such other measures

against the disease, in such manner and within such time as the State Government, may, by public notice, direct.

(*4*) The State Government shall make available necessary vaccine and it shall be obligatory on the part of every owner, or the person in charge of an animal which is required to be vaccinated under sub-section (*3*), to get the animal compulsorily vaccinated.

(*5*) Where the State Government is satisfied, on a report received from the Director or otherwise, that, in any controlled area, any of the scheduled diseases affecting any species of animal is no longer prevalent, it may, by notification, declare the area to be a free area in respect of that disease in relation to the particular species of animal.

(*6*) Where a notification has been issued under sub-section (*5*), no animal of the species or of any other susceptible species with regard to which it is a free area shall be allowed to enter the free area unless duly immunized by vaccination against that particular disease.

7. Prohibition of movement of animals from controlled area.—(*1*) Where a notification has been issued under sub-section (*1*) of section 6 declaring any area as a controlled area in relation to any disease affecting any species of animals, no animal belonging to that species shall be moved from the place where it is kept.

(*2*) The Director may, for the purpose of control, prevention or eradication of any scheduled disease, in respect of any area, by order published in the Official Gazette, prohibit the movement of all animals belonging to any species specified therein, from the place where it is kept, to any other place.

(*3*) Nothing contained in sub-sections (*1*) and (*2*) shall be deemed to prohibit**—**

(*a*) the movement of any animal referred to therein, from the place where it is kept, to the nearest place where it can be got vaccinated, so long as the animal is being moved for the purpose of its immunization by vaccination; or

(*b*) the movement of any such animal, so long as it is accompanied by a valid certificate of vaccination to indicate that the animal is duly immunized against the particular disease and it bears proper mark of such vaccination.

8.Vaccination, marking and issue of vaccination certificate.—(*1*) The vaccine to an animal may be administered by any person competent under the law for the time being in force to administer it, and issue a certificate of administration of vaccination.

(*2*) Where any animal has been vaccinated for any scheduled disease in compliance with the provisions of sub-section (*1*), the person vaccinating the animal shall cause to put a mark by branding, tattooing or ear tagging, or in such other manner as the Director may, by general or special order, direct and the same shall, unless otherwise specified by the Director, shall not be removed.

(*3*) The authority issuing a certificate of vaccination shall specify the date of vaccination, dates of manufacture and expiry of the vaccine and the date up to which the vaccination of the animal with the particular vaccine shall be valid.

9.Contents of vaccination certificate.—Every vaccination certificate issued under this Act shall be in such form and shall contain such particulars as may be prescribed by the Central Government.

10.Entry and exit of animals into controlled area and free area.—(*1*) Where any area has been declared as a controlled area under sub-section (*1*) of section 6 in respect of any disease affecting any species of animals, no animal belonging to that species shall be taken out of, or brought into that area save as provided in section 16.

(*2*)The Director may, by notice duly published in the Official Gazette and at least in one daily local newspaper in vernacular language, extend the prohibition contained in sub-section (*1*) to any other species of animals, if animals belonging to that species are also likely to be infected with that disease.

(3) No carrier of goods or animal shall carry any animal from or out of a controlled area, free area or infected area by land, sea or air unless he complies with the provisions of section 16.

(*4*)Nothing contained in sub-sections (*1*) to (*3*) shall apply to the carriage by railway of any animal referred to in those sub-sections through any area which, for the time being, is declared as a controlled area or infected area so long as the animal is not unloaded (for whatsoever purpose or duration) in any place within that area:

Provided that the State Government may, by notification, declare that any species of animal so carried through any local area within the State shall be duly immunized against such scheduled disease, in such manner and within such time as may be specified in that notification and a certificate of vaccination shall be a pre-requisite for the transportation of the animals by the railways through that area:

Provided further that, where any notification as referred to in the first proviso has been issued, it shall be incumbent on the State Government to intimate that fact to the concerned railway authorities so as to enable

them to satisfy themselves about the immunization of the animal before transporting it through the local area of the State.

11.Precautionary measures in relation to controlled areas.—No person shall take out of the controlled area**—**

(*a*) any animal, alive or dead, which is infected with, or reasonably suspected to have been infected with, any scheduled disease notified under sub-section (*1*) of section 6;

(*b*) any kind of fodder, bedding or other material which has come into contact with any animal infected with such disease or could, in any manner, carry the infection of the notified disease; or

(*c*) the carcass, skin or any other part or product of such animal.

12.Prohibition of markets, fairs, exhibition, etc., in the controlled areas.—No person, organisation or institution shall hold any animal market, animal fair, animal exhibition and carry on any other activity which involves grouping or gathering of any species of animals within a controlled area:

Provided that the Competent Officer may, *suo motu* or on application made to him in this behalf, relax the prohibition in relation to any species of animals, in a case where animals belonging to that species are not susceptible to the scheduled disease and are incapable of carrying it, if he is satisfied that in the public interest it is necessary to accord such relaxation.

13.Prohibition of bringing of infected animals into market and other places.—No person shall bring or attempt to bring into market, fair, exhibition or other congregation of animals or to any public place, any animal which is known to be infected with a scheduled disease.

14.Check Posts and Quarantine Camps.—(*1*) The Director may establish as many Quarantine Camps and Check Posts within the State as may be required**—**

(*a*) for the detention of animals suffering from any scheduled disease or of animals which have come into contact with or have been kept in the proximity of any such infected animal;

(*b*) for ensuring the prevention of entry into or exit from any controlled area or infected area or free area, of any animal belonging to the species of animals in respect of which a notification, issued under sub-section (*1*) of section 6, or an order issued under sub-section (*2*) of section 7, is in force.

(*2*) Any animal which is required to be detained, inspected, vaccinated, or marked, may be kept in the Quarantine Camp for such period as the Competent Officer may direct.

(*3*) Every animal detained at a Quarantine Camp shall be under the custody of the person in charge of the camp, and shall be vaccinated and marked.

(*4*) The officer in charge of the Quarantine Camp shall, at the time of release of an animal from the station, grant a permit, in such form as may be prescribed by the State Government, to the person taking charge of the animal, and every such person shall be bound to produce the permit whenever required to do so by any Competent Officer.

15. Inspection and detention of animals at Check Posts and Quarantine Camps.—(*1*) Every person in charge of any Check Post or Quarantine Camp shall inspect any animal stopped at the Check Post, or detained therein or at the Quarantine Camp.

(*2*) The manner of inspection and the period of detention of the animal at the Check Post or at the Quarantine Camp for the purpose of inspection or for the administration of compulsory vaccination, the marking of animals and the form and manner in which permit for entry in respect of any animal may be issued, shall be such as may be prescribed by the State Government.

16. Entry and exit of vaccinated animals into controlled and free areas.—Notwithstanding anything contained in section 10, an animal belonging to the species of animals in respect of which an area has been declared as a controlled or free area in relation to any scheduled disease, which has been duly vaccinated against that disease, shall be allowed to enter into or be taken out of the controlled area or free area, or to be taken out of any other place on the production of a certificate to the effect that vaccine against that disease has been administered and a period of not less than twenty-one days has elapsed thereafter.

17. Appointment of Competent Officers.—The State Government may, for the proper implementation of the provisions of this Act, by notification, authorise any person to exercise any power or discharge any duty as a Competent Officer, under this Act, who shall exercise such powers and such duties within the local limits of his jurisdiction as may be specified in the notification.

18. Cleaning and disinfection of carriers.—(*1*) Every common carrier whether a vessel or vehicle shall be cleaned and disinfected immediately before and after the transportation of any animal in that vessel or vehicle, and so also any other place where the animal has been kept in transit.

2) Where any area has been declared as a controlled area or free area in respect of any scheduled disease affecting any species of animal, the Director may, by an order duly published in the Official Gazette and in a local newspaper in the vernacular language, direct the owner of every vehicle in which any animal belonging to that species is carried, to have the vehicle properly cleaned and disinfected.

19. Powers of entry and inspection.—Any Veterinary Officer or other Competent Officer may enter upon and inspect any land or building or place, vessel or vehicle, for the purpose of ensuring compliance of the provisions of this Act or the rules or orders made thereunder, by the persons responsible for such compliance.

CHAPTER III
INFECTED AREAS

20. Declaration of infected areas.—If the Veterinary Officer, upon receipt of a report from a Veterinarian or otherwise, is satisfied that, in any place or premises falling within his jurisdiction, an animal has been infected with any scheduled disease, or that an animal, which he has reason to believe has been so infected, is kept, may, by notification and publication in at least one local newspaper in the vernacular language and by declaration in loud voice and by beating drums, declare such area as he may deem fit (including the place or premises aforesaid) to be an infected area.

21. Effect of declaration of infected areas.—(*1*) Where an area has been declared as an infected area under section 20, all provisions of this Act which are applicable in relation to a controlled area shall *mutatis mutandis* apply thereto as if for the words "controlled area", the words "infected area" have been substituted.

(*2*) Without prejudice to the generality of the provisions contained in sub-section (*1*), the following further provisions shall apply in relation to an infected area, namely:—

(*a*) in respect of every animal in that area which is infected or reasonably believed to be infected, with any scheduled disease, the owner or other person in charge of the animal, shall forthwith get it treated by a Veterinarian;

(*b*) all articles, which are likely to have come into contact with any animal referred to in clause (*a*), shall be treated or disposed off in such a manner as the Veterinarian may direct;

(*c*) every Veterinarian shall, for the purpose of inspection, have the power to enter any place or premises where any animal is kept or is likely to be kept;

(*d*) the owner or any other person in charge of the animal referred to in clause (*a*) shall keep the animal in isolation forthwith, and also take such other measures as may be necessary for the prevention, treatment and control of the disease as the Veterinarian may direct.

22. Denotification of infected area.—If the Veterinary Officer, after such enquiry as he may deem fit, is satisfied that there is no longer the threat or danger of any animal being infected with the scheduled disease in any infected area, by notification and publication in a local newspaper in vernacular language, declare that the area is no longer an infected area as aforesaid, whereupon all the restrictions referred to in section 21 shall cease to apply.

CHAPTER IV
INFECTED ANIMALS

23. Segregation, examination and treatment of infected animals.—(*1*) Where the Veterinarian has, on receipt of a report or otherwise, reason to believe that any animal is infected with a scheduled disease, he may, by order in writing, direct the owner or any other person in charge of such animal—

(*a*) to keep it segregated from other apparently healthy animals; or

(*b*) to subject it to such treatment as may be required under the circumstances.

(*2*) Where any action has been taken in pursuance of sub-section (*1*), the Veterinarian shall forthwith give a detailed report of the incidence of the disease to the Veterinary Officer.

(*3*) On receipt of a report from the Veterinarian, the Veterinary Officer shall, as soon as possible, examine that animal as well as any other animal which could have come in contact with it, and for that purpose, submit the animal to such test and medical examination as may be required under the circumstances.

(*4*) If, after such test and examination, the Veterinary Officer is of the opinion that an animal is not infected with any of the scheduled diseases, he shall issue a certificate in writing that the animal is not infected with any such disease.

24. Drawing samples from animals.—(*1*) Where the Veterinary Officer considers it necessary for the purpose of ascertaining whether the animal which is suspected to have been infected with any scheduled disease or susceptible to such infection is actually infected, or for the purpose of ascertaining the nature of

the scheduled disease with which an animal is infected, he may draw such samples, as may be required, from the animal for the purpose of carrying out such investigations as he may deem necessary under the circumstances.

(*2*) The Veterinary Officer or any other Competent Officer shall draw samples from any animal for the purposes of ascertaining whether the animal has been vaccinated against any disease, or whether the vaccination of the animal has been effective in conferring it immunity and have the samples examined, in such manner as he may deem necessary.

25. Resort to euthanasia for infected animals.—If the Veterinary Officer deems it necessary that an animal, which is infected with a scheduled disease, euthanasia has to be resorted to, for preventing the spread of the disease to other animals in the area or to protect public health if the disease is of zoonotic importance, he may, notwithstanding anything contained in any other law for the time being in force, by an order in writing, direct euthanasia of the animal and the carcass disposed of immediately to his satisfaction.

26. Disposal of carcass.—Every person in possession of carcass (or any part thereof) of any animal, which, at the time of its death, was infected with any scheduled disease or was suspected to have been infected, shall dispose it of in such manner as may be prescribed.

27. Powers of Veterinary Officer and Veterinarian to hold post-mortem examination.—(*1*) Where the Veterinary Officer or any Veterinarian has reason to believe that the death of an animal has been caused by an infection of any scheduled disease, he may make or cause to be made a post-mortem examination of the animal and for that purpose he may cause the carcass of any such animal to be exhumed where required followed by proper disposal after necessary examination and post-mortem.

(*2*) Every examination and post-mortem referred to in sub-section (*1*) shall be conducted in such manner, and the report of post-mortem shall be in such form, as may be prescribed.

28. Seizure and removal of certain animals.—Where any animal which is infected or suspected to have been infected is found without any person claiming to be its owner, or where a valid order or direction given in relation to any such animal is not promptly complied with by the owner or other person in control of the animal, it shall be open to the Veterinary Officer or any other Competent Officer, to seize the animal and remove it to a place of isolation or segregation, as he may deem proper.

CHAPTER V
ENFORCEMENT AND PENALTIES

29. Enforcement of orders and recovery of expenses.—(*1*) Where by any rule, notification, notice, requisition, order or direction made under this Act, any person is required to take any measure or to do anything**—**

(*a*) in respect of any animal, carcass of any animal or other thing in his custody or charge, the same shall be promptly complied with by that person;

(*b*) in case of any stray or ownerless animal, carcass of such animal or parts thereof, the same shall be promptly complied with by the municipality or Panchayat, as the case may be, at its cost.

(*2*) If the measures as referred to in sub-section (*1*) are not taken within such time as may be allowed for the purpose, the authority issuing the notice, requisition, order or direction, may cause the measures to be taken at the cost of the person or municipality or Panchayat, as the case may be, who or which was required to take the measures.

(*3*) The costs of any measures taken under sub-section (*2*), shall be recoverable from the person or the municipality or Panchayat, as the case may be, concerned in the manner provided by the Code of Criminal Procedure, 1973 (2 of 1974) for the recovery of fines imposed by a Court, as if such costs were a fine imposed by a Court.

30. Village Officers, etc., to assist.—All Municipal, Panchayat or Village Officers and all officers of the rural and dairy development, revenue, agriculture, animal husbandry and veterinary departments of the State Government, shall be bound**—**

(*a*) to give immediate information to the Veterinary Officer and to the Veterinarian having jurisdiction in the area regarding the prevalence of a scheduled disease amongst any animal or species of animals, in the area;

(*b*) to take all necessary measures to prevent the outbreak or spread of any scheduled disease; and

(*c*) to assist the Veterinary Officer and the Veterinarian in the discharge of their duties or in the exercise of their powers under this Act.

31. Penalty for issuing vaccination certificate without authority or administering defective vaccine.—If any person issues a vaccination certificate,**—**

(*a*) without authority or competence in that behalf, or

(*b*) after administering the vaccine which is known to be defective in any manner,
he shall be guilty of an offence punishable with a fine of five thousand rupees or in case of non-payment of fine with imprisonment which may extend to one month, and in the case of any subsequent offence, with fine of ten thousand rupees or with imprisonment which may extend to three months.

32. Penalties.—Any person who contravenes the provisions of this Act or obstructs the Competent Officer in performing his duties shall be guilty of an offence punishable with fine which may extend to one thousand rupees, and in case of failure to pay the penalty with imprisonment for a term which may extend to one month; and in the case of any subsequent offence (whether under the same provision or any other provision of this Act except in case of sections 31 and 33) with a fine of two thousand rupees, or with imprisonment for a term which may extend to two months in case of non-payment of the penalty.

33. Penalty for placing infected animal or carcass in river, etc.—Whoever places or causes or permits to be placed in any river, lake, canal or any other water body, the carcass or any part of the carcass of any animal which at the time of its death was known to be infected, shall be guilty of an offence and, on conviction, be punished, in the case of a first offence with fine of two thousand rupees or with imprisonment of one month in case of non-payment of fine and in the case of subsequent conviction with a fine of five thousand rupees or imprisonment for a term which may extend to three months or with both.

34. Offences by companies.—(*1*) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded and punished accordingly:

Provided that nothing contained in this sub-section shall render such person liable to any punishment provided in this Act, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(*2*) Notwithstanding anything contained in sub-section (*1*), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.—For the purposes of this section,—

(*a*) "company" means any body corporate and includes a co-operative society registered or deemed to be registered under any law for the time being in force, a firm or other association of individuals; and

(*b*) "director", in relation to a firm, means a partner in the firm.

CHAPTER VI
PRECAUTIONARY MEASURES ON CAUSATIVE ORGANISM, ETC.

35. Prevention of escape of causative organism.—(*1*) In every institution, laboratory or clinic, engaged in the manufacture, testing or research, related to vaccines, sera, diagnostics or chemotherapeutic drugs and aimed at the prevention or treatment of any scheduled disease, adequate precautionary measures shall be taken—

(*a*) to ensure that the causative organism of any scheduled disease does not escape or otherwise get released;

(*b*) to guard against any such escape or release; and

(*c*) to warn and to protect everyone concerned in the event of any escape.

(*2*) Notwithstanding anything contained in any other law for the time being in force, every animal—

(*a*) used for the manufacture, testing or research as referred to sub-section (*1*), or

(*b*) which is likely to carry or transmit any scheduled disease,

shall be promptly administered euthanasia and disposed of by the person in charge of or having control of the institution, laboratory or clinic, as the case may be, referred to in that sub-section.

(*3*) Every person who is in charge of or having control of an institution, laboratory or clinic referred to in sub-section (*1*) comply with the provisions of sub-section (*1*) and sub-section (*2*); and in the event of non-compliance he shall be guilty of an offence punishable with fine which may extend to twenty thousand rupees or imprisonment for a term which may extend to six months or with both, and in case the establishment is in commercial manufacturing of vaccines or medicine, a temporary suspension of licence up to a period of one year may also be imposed.

CHAPTER VII
MISCELLANEOUS

36. Power to delegate.—The State Government may, by notification, delegate to any officer or authority subordinate to it, all or any of the powers conferred on it by or under this Act, except the powers to make rules under sub-section (*2*) of section 42.

37. Officers and authorities to function subject to Government control.—All officers and authorities under this Act shall exercise their powers and discharge their duties conferred or imposed on them by or under this Act, in accordance with such orders, not inconsistent with the provisions of this Act, as the Central Government or the State Government may, from time to time, make.

38. Power to amend the Schedule.—(*1*) The Central Government may, by notification, add to, or omit from the Schedule any animal disease and the said disease shall, as from the date of the notification, be deemed to have been added to, or omitted from, the Schedule.

(*2*) Every notification issued under sub-section (*1*) shall, as soon as may be after it is issued, be laid before each House of Parliament.

39. Power to issue directions.—The Central Government may, with the object of prevention, control and eradication of any infectious or contagious disease of animals, issue such directions to the State Government or other authorities under this Act, from time to time, including directions for furnishing such returns and statistics on scheduled diseases, and vaccination, as it may deem fit and every such direction shall be complied with.

40. Certain persons to be public servants.—Every Competent Officer, Director and Veterinary Officer, while exercising any power or performing any duty under this Act, shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860).

41. Power to remove difficulties.—(*1*) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act, as appear to it to be necessary or expedient for removing the difficulty:

Provided that no such order shall be made after the expiry of a period of two years from the date of commencement of this Act.

(*2*) Every order made under this section shall, as soon as may be after it is made, be laid before each House of Parliament.

42. Power of Central Government to make rules.—(*1*) The Central Government may, subject to the condition of previous publication, by notification, make rules for carrying out the provisions of this Act.

(*2*) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

(*a*) the form of vaccination certificate and the particulars which such certificate shall contain, under section 9;

(*b*) the manner of disposal of carcass, under section 26;

(*c*) the manner of conducting examination and post-mortem under sub-section (*1*) and the form of report of post-mortem under sub-section (*2*) of section 27;

(*d*) any other matter which may be prescribed or in respect of which rules are required to be made by the Central Government.

43. Power of State Government to make rules.—(*1*) The State Government may, by notification and with the prior approval of the Central Government, make rules for carrying out the purposes of this Act.

(*2*) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

(*a*) the form of permit to be granted by the officer in charge of a Quarantine Camp, under sub-section (*4*) of section 14;

(*b*) the manner of inspection and the period of detention of an animal at a Check Post or at a Quarantine Camp for the administration of compulsory vaccination and marking of animals and the form and manner of issue of entry permit, under sub-section (*2*) of section 15;

(*c*) any other matter in respect of which rule is to be or may be made by the State Government.

44. Laying of rules.—(*1*) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may

be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

(*2*) Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before the State Legislature.

45. Repeal and savings.—On the commencement of this Act**—**

(*i*) The Glanders and Farcy Act, 1899 (13 of 1899);

(*ii*) The Dourine Act, 1910 (5 of 1910); and

(*iii*) any other corresponding law of any State, so far as it is inconsistent with the provisions of this Act,

shall stand repealed:

Provided that nothing contained in this section shall**—**

(*a*) affect the previous operation of any such provision of law or anything duly done or suffered thereunder;

(*b*) affect any right, privilege, obligation or liability acquired, accrued or incurred under any such provision of law;

(*c*) affect any penalty, forfeiture or punishment incurred in respect of any offence committed against any such provision of law; or

(*d*) affect any investigation, legal proceeding or remedy in respect of any such right, privilege, obligation, liability, penalty, forfeiture or punishment as aforesaid; and every such investigation, legal proceeding or remedy may be continued, instituted or enforced, and any such penalty, forfeiture and punishment may be imposed, as if the aforesaid provisions of law had continued:

Provided further that, anything done or any action taken under any such provision of law, including any notification, order, notice or receipt issued or declaration made, shall in so far as it is not inconsistent with the provisions of this Act, be deemed to have been done, taken, issued or made under the corresponding provisions of this Act, and shall continue in force accordingly, unless and until superseded by anything done or any action taken under this Act.

THE SCHEDULE

[*See* sections 2 (O) and 38]

(*a*) Multiple species diseases

1. Anthrax. 2. Aujeszky's disease. 3. Bluetongue. 4. Brucellosis. 5. Crimean Congo haemorrhagic fever.6.Echinococcosis/hydatidosis.7.Foot and mouth disesase.8.Heartwater.9.Japanese encephalitis.10. Leptospirosis. 11. New world screwworm *(Cochlimyia hominivorax).* 12. Old world screwworm *(Chrysomya bezziana).* 13. Paratuberculosis. 14. Q fever. 15. Rabies. 16. Rift Valley fever. 17. Rinderpest. 18. Trichinellosis. 19. Tularemia. 20. Vesicular stomatitis. 21. West Nile fever.

(*b*) Cattle diseases

1. Bovine anaplasmosis. 2. Bovine babesiosis. 3. Bovine genital cmpylobacteriosis. 4. Bovine spongiform encephalopathy. 5. Bovine tuberculosis. 6. Bovine viral diarrhoea. 7. Contagious bovine pleuropneumonia. 8. Enzootic bovine leucosis. 9. Haemorrhagic septicaemia. 10. Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis. 11. Lumpy skin disease. 12. Malignant catarrhal fever. 13. Theileriosis. 14. Trichomonosis. 15. Trypanosomosis.

(*c*) Sheep and goat diseases

1. Caprine arthritis/encephalitis. 2. Contagious agalactia. 3. Contagious caprine pleuropneumonia. 4. Enzootic abortion of ewes (ovine chlamydiosis). 5. Maedi-visna. 6. Nairobi sheep disease. 7. Ovine epididymitis (*Brucella ovis*). 8. Peste des petits ruminants. 9. Salmonellosis (S. abortusovis). 10. Scrapie. 11. Sheep pox and goat pox.

(*d*) Equine diseases

1. African horse sickness. 2. Contagious equine metritis. 3. Dourine. 4. Equine encephalomyelitis (Eastern). 5. Equine encephalomyelitis (Western). 6. Equine infectious anaemia. 7. Equine Influenza. 8. Equine piroplasmosis. 9. Equine rhinopneumonitis. 10. Equine viral arteritis. 11. Glanders. 12. Surra (*Trypanosoma evansi*). 13. Venezuelan equine encephalomyelitis.

(*e*) Swine diseases

1. African swine fever. 2. Classical swine fever. 3. Nipah virus encephalitis. 4. Porcine cysticercosis. 5. Porcine reproductive and respiratory syndrome. 6. Swine vesicular disease. 7. Transmissible gastroenteritis.

(*f*) Avian diseases

1. Avian chlamydiosis. 2. Avian infectious bronchitis. 3. Avian infectious laryngotracheitis. 4. Avian mycoplasmosis (*M. gallisepticum*). 5. Avian mycoplasmosis (*My. synoviae*). 6. Duck virus hepatitis. 7. Fowl cholera. 8. Fowl typhoid. 9. Highly pathogenic avian inflenza and low pathogenic avian influenza in poultry. 10. Infectious bursal disease (Gumboro disease). 11. Marek's disease. 12. Newcastle disease. 13. Pullorum disease. 14. Turkey rhinotracheitis.

(*g*) Cattle diseases

1. Myxomatosis. 2. Rabbit haemorrhagic disease.

(*h*) Bee diseases

1. Acarapisosis of honey bees. 2. American foulbrood of honey bees. 3. European foulbrood of honey bees. 4. Small hive bettle infestation (*Aethina tumida*). 5. *Tropilaelaps* infestation of honey bees. 6. Varroosis of honey bees.

(*i*) Fish diseases

1. Epizootic haematopoietic necrosis. 2. Infectious haematopoietic necrosis. 3. Spring viraemia of carp. 4. Viral haemorrhagic septicaemia. 5. Infectious pancreatic necrosis. 6. Infectious salmon anaemia. 7. Epizootic ulcerative syndrome. 8. Bacterial kidney disease (*Renibacterium salmoninarum*). 9. Gyrodactylosis (*Gyrodactylus salaris*). 10. Red sea bream iridoviral disease.

(*j*) Molluse diseases

1. Infection with *Bonamia ostreae.* 2. Infection with *Bonamia exitiosa.* 3. Infection with *Marteilia refringens.* 4. Infection with *Mikrocytos mackini.* 5. Infection with *Perkinsus marinus.* 6. Infection with *Perkinsus olseni.* 7. Infection with *Xenohaliotis californiensis.*

(*k*) Crustacean diseases

1. Taura syndrome. 2. White spot disease. 3. Yellowhead disease. 4. Tetrahedral baculovirosis (*Baculovirus penaei*). 5. Spherical baculovirosis (*Penaeus monodon*-type baculovirus). 6. Infectious hypodermal and haematopoietic necrosis. 7. Crayfish plague (*Aphanomyces astaci*).

(*l*) Other diseases

1. Camelpox. 2. Leishmaniosis.

BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA BILL, 2013

AS INTRODUCED IN LOK SABHA

Bill No. 57 of 2013

THE BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA BILL, 2013

A

BILL

to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and provide for establishment of the Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology and for matters connected therewith or incidental thereto.

WHEREAS the modern biotechnology offers opportunities to address important needs related to agriculture, health, food production and environment;

AND WHEREAS India is a party to the United Nations Convention on Biological Diversity signed at Rio de Janeiro on the 5th day of June, 1992 which came into force on the 29th December, 1993; and Cartagena Protocol on Biosafety to the Convention which was adopted in Montreal on the 29th September, 2000 and came into force on the 11th September, 2003;

AND WHEREAS the aforesaid Convention and the Protocol provide that each Contracting Party shall, as far as possible and as appropriate, establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from modern biotechnology;

AND WHEREAS the Protocol provides that the Parties to the Protocol shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account the risks involved to human health;

AND WHEREAS it is considered necessary to take measures for the safe and responsible use of biotechnology for safeguarding the health and safety of the people of India and to protect the environment and consolidate regulatory policies, rules and services under statutory and autonomous regulatory authority and also to strengthen the implementation of the aforesaid Convention and Protocol.

BE it enacted by Parliament in the Sixty-fourth Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

1. Short title, extent and commencement.

(*1*) This Act may be called the Biotechnology Regulatory Authority of India Act, 2013.

(*2*) It extends to the whole of India.

(*3*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint; and different dates may be appointed for different provisions of this Act and any reference in any provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.

(*4*) Any reference in this Act to a law which is not in force in the State of Jammu and Kashmir shall in relation to that State be construed as a reference to the corresponding law, if any, in that State.

2. Declaration as to expediency of control by Union.

It is hereby declared that it is expedient in the public interest that the Union should take under its control the regulation of organisms, products and processes of modern biotechnology industry.

3. Definitions.

In this Act, unless the context otherwise requires,—

(*a*)"animal clones" means animals derived through somatic cell nuclear transfer techniques excluding humans;

(*b*)"Appellate Tribunal" means the Biotechnology Regulatory Appellate Tribunal established under section 44;

(*c*)"Authority" means the Biotechnology Regulatory Authority of India established under sub-section (*1*) of section 4;
(*d*) "biotechnology" means modern biotechnology as defined under clause (*r*);
(*e*) "Chairperson" means the Chairperson of the Authority appointed under section 5;
(*f*)"Chief Regulatory Officer" means the head of a Division of the Authority under sub-section (*3*) of section 21;
(*g*)"clinical trial" means systematic study of any new organism or product specified in Schedule I in human for the purpose of generating data for discovering or verifying its clinical, pharmacological (including pharmacodynamic and pharmacokinetic) biological, or, adverse effects with the objective of determining safety, efficacy or tolerance of that organism or product;
(*h*) "confidential commercial information" means,—
(*i*) a trade secret or any other information which has a commercial or other value which would be, or could reasonably be expected to be, destroyed or diminished if such information was disclosed; or
(*ii*)such other information which relates to lawful commercial or financial affairs of a person, organisation or undertaking dealing with organisms or products specified under Part I or Part II or Part III of Schedule I which, if disclosed, could adversely affect such person, organisation or undertaking;
(*i*)"conjugation" means the union of gametes or unicellular organisms during fertilisation;
(*j*)"containment" means measures and protocols applied to limit contact of genetically engineered organisms or products with the environment external to the containment facility;
(*k*)"containment facility" means an enclosed structure with walls, floor and ceiling, or an area within such building, where containment is in accordance with the physical and operational requirements specified and regulated under clause (*d*) of sub-section (*2*) of section 18;
(*l*)"environment" shall have the meaning assigned to it in clause (*a*) of section 2 of the Environment (Protection) Act, 1986;
(*m*)"environmental release" means the use of genetically engineered organisms into the environment outside of any containment;
(*n*)"field trials" means a field experiment of growing a genetically engineered organism in the environment under specified terms and conditions which are intended to mitigate the establishment and spread of the organism;
(*o*)"import" means to bring into India the organisms and products of modern biotechnology by land, sea or air;
(*p*)"manufacture" means and includes the preparation, compounding, propagation, processing, or fabrication of any organism or product regulated under this Act;
(*q*)"Member" means a whole-time Member or part-time Member of the Authority appointed under section 5 and includes the Chairperson;
(*r*)"modern biotechnology" means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection but does not include tissue culture of unmodified plant cells; animal cell culture of unmodified gametes; and natural processes such as conjugation, transduction, transformation; polyploidy induction; and mutation breeding;
(*s*)"Monitoring Officer" means a person appointed as such under sub-section (*1*) of section 38;
(*t*)"mutation breeding" means a process which involves the use of ionizing radiation or chemical mutagenesis to induce mutations in the genome;
(*u*)"notification" means a notification published in the Official Gazette and the expression "notify" shall be construed accordingly;

(*v*)"organism" means any genetically engineered organism or living modified organism or genetically modified organism excluding humans, which is a product of modern biotechnology;
(*w*) "polyploidy induction" means the induction of a cell to have more than twice the basic or haploid number of chromosomes;
(*x*) "premises" means a building or structure or part of a building or structure or land;
(*y*) "prescribed" means prescribed by rules made by the Central Government under this Act;
(*z*) "regulations" means regulations made by the Authority under this Act;
(*za*) "Schedule" means Schedules I and II to this Act;
(*zb*)"State Government in relation to a Union territory" means the Administrator of that Union territory appointed by the President under article 239 of the Constitution;
(*zc*)"transduction" means natural transfer by means of a viral vector of a deoxyribonucleic acid sequence from one cell to another;
(*zd*)"transformation" means any reference to the natural transfer of genetic material from the donor to the recipient;
(*ze*)"University Grants Commission" means the University Grants Commission established under section 4 of the University Grants Commission Act, 1956;
(*zf*)"use" means authorisation of an organism or product regulated under this Act as safe for its intended purpose and such authorisation shall be subject to all other laws for the time being in force and rules and regulations made thereunder.

CHAPTER II
BIOTECHNOLOGY REGULATORY AUTHORITY OF INDIA

4. Establishment of Biotechnology Regulatory Authority of India.

(*1*) **The Central Government shall, by notification, establish an Authority to be known as the Biotechnology Regulatory Authority of India to exercise the powers conferred on it and to perform the functions assigned to it under this Act.**

(*2*) The Authority shall be a body corporate, by the name aforesaid, having perpetual succession and a common seal with power to acquire, hold and dispose of properties, both movable and immovable, and to contract, and shall, by the said name, sue or be sued.
(*3*) The head office of the Authority shall be in the National Capital Region.
(*4*) The Authority may, with the prior approval of the Central Government, establish its offices at any other place in India.

5. Composition of Authority.

The Authority shall consist of a Chairperson and two whole-time Members and two part-time Members to be appointed by the Central Government.

6. Qualifications for appointment of Chairperson and Members.

(*1*) The Chairperson of the Authority shall be a person of ability, integrity and outstanding scientific calibre with a doctorate degree or equivalent degree in the field of biological sciences or a postgraduate degree in medical sciences from a university recognized by the University Grants Commission or a university or institute established by law for the time being in force, and having not less than twenty years experience in a leadership role in a scientific organisation, scientific institution or scientific agency, or similar organisation or institution or agency, out of which at least five years should be as head of the organisation or institution or agency or unit or division, as the case may be.
(2)A Member, shall be a person of ability, integrity and outstanding scientific caliber with a doctorate degree or equivalent degree in the field of biological sciences or a postgraduate degree in medical sciences from a university recognised by the University Grants Commission or a university or institute established by law for the time being in force, and having not less than fifteen years experience in a leadership role in a scientific organisation, scientific institution or scientific agency or unit or division:

Provided that the Central Government shall, while appointing the Members, ensure that one such Member has requisite knowledge and experience in the fields of molecular biology, health care, agriculture or environment biotechnology and areas connected therewith respectively.

(*3*)The Chairperson and whole-time Members of the Authority shall be appointed on the recommendation of the Selection Committee constituted under sub-section (*1*) of section 7.

(*4*)The Chairperson or the whole-time Member of the Authority shall not hold any other office during the period of holding his office as such.

(*5*)The Central Government shall, within a period of two months from the date of occurrence of any vacancy in the office of the Chairperson or Member, by reason of death, resignation or removal of the Chairperson or a Member and six months before the superannuation or completion of the term of office of the Chairperson or a Member, make a reference to the Selection Committee constituted under section 7 for filling up of such vacancy.

7. Selection Committee for selection of Chairperson and Members.

(*1*)The Central Government shall, for the purpose of selection of the Chairperson and Members, constitute a Selection Committee consisting of—

(*a*) Cabinet Secretary – Chairperson of the Selection Committee;

(*b*)Secretary-in-charge of the Ministry or Department of the Central Government dealing with health research–Member;

(*c*)Secretary-in-charge of the Ministry or Department of the Central Government dealing with Agriculture–Member;

(*d*)Secretary-in-charge of the Ministry or Department of the Central Government dealing with Biotechnology–Member;

(*e*)Secretary-in-charge of the Ministry or Department of the Central Government dealing with Environment–Member;.

(*f*)Secretary-in-charge of the Ministry or Department of the Central Government dealing with Personnel–Member;

(*g*) two eminent biotechnologists to be nominated by the Central Government— Members.

(*2*)A scientist not below the rank of Grade 'G' in the Department of Biotechnology in the Ministry of Science and Technology shall be the convenor of the meetings of the Selection Committee.

(*3*)The Selection Committee shall finalise the selection of the Chairperson and Members of the Authority within two months from the date on which the reference is made to it under sub-section (*5*) of section 6.

(*4*)The Selection Committee shall recommend a panel of two names for every vacancy referred to it.

(*5*)Before recommending any person for appointment as a Chairperson or a Member of the Authority, the Selection Committee shall satisfy itself that such person does not have any financial or other conflict of interest, which is likely to affect prejudicially his functions as Chairperson or Member, as the case may be.

(*6*)No appointment of the Chairperson or Member of the Authority shall be invalid merely by reason of any vacancy in the Selection Committee.

(*7*)Subject to the provisions of sub-sections (*1*) to (*6*), the Selection Committee may regulate its own procedure.

8. Functions of Chairperson.

(*1*) The Chairperson shall have powers of general superintendence and direction in the conduct of the affairs of the Authority (including all its decisions, risk assessment units Environment Apprisal Panel and Product Ruling Committees) and he shall, in addition to presiding over the meetings of the Authority, and without prejudice to any of the provisions of this Act, exercise and discharge such powers and functions of the Authority as may be prescribed.

(*2*) The Chairperson shall be responsible for—

(*a*) the day-to-day administration of the Authority;

(*b*) implementing the work programmes and the decisions of the Authority;

(*c*)the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority;
(*d*)submission of the annual report of the Authority in the form and manner as specified under section 74.
(*3*)Without prejudice to the provisions contained in sub-sections (*1*) and (*2*), the Chairperson shall be the chief executive of the Authority and shall exercise such powers and discharge such functions as chief executive of the Authority as may be prescribed.
(*4*) The Chairperson, or whole-time Member or an officer of the Authority if so authorised by the Chairperson, shall approve all financial expenditures of the Authority.

9. Term of office and other conditions of service of Chairperson and Members.

(*1*) The Chairperson and other Members shall hold office for a term of three years from the date on which they enter upon their offices, and shall be eligible for re-appointment for a further period of three years:
Provided that the Chairperson or a Member shall not hold office as such after he has attained the age of sixty-five years.
(*2*)The Chairperson and every Member shall, before entering upon his office make and subscribe, to an oath of office and of secrecy, in such form and in such manner and before such authority as may be prescribed.
(*3*) Any person holding any office (whether as an employee or an officer or a director or managing director or secretary or manager or in any other capacity) under the Central Government or State Government or in a company (including a Government Company referred to in section 617 of the Companies Act, 1956) or in any other institution, organisation, society or University or Board, shall, on his selection as the Chairperson or a whole-time Member, be required to seek retirement or resign from the services of such Central or State Government or company or institution or organisation or society or University or Board, as the case may be, before accepting the employment as the Chairperson or whole-time Member.
(*4*)**The salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and whole-time Members and allowances payable to part-time Members shall be such as may be prescribed:**
Provided that the salary, allowances and other terms and conditions of service of the Chairperson or a whole-time Member shall not be varied to his disadvantage after his appointment.
(*5*) Notwithstanding anything contained in sub-section (*1*), the Chairperson or a Member may—
(*a*) relinquish his office by giving in writing to the Central Government a notice of not less than three months; or
(*b*) be removed from his office in accordance with the provisions of section 11.

10. Restriction on Chairperson or Members on employment after cessation of office.

(*1*) The Chairperson or a Member, ceasing to hold office as such, shall not—
(*a*)for a period of two years from the date on which they cease to hold office, accept any employment in, or connected with the management or administration of, any person which has been associated with or granted authorisation for research, transport or import of organisms or products or manufacture or use of organisms and products under this Act:
Provided that nothing contained in this section shall apply to any employment under the Central Government or a State Government or local authority or in any statutory authority or any corporation established by or under any Central, State or Provincial Act or a Government company as defined in section 617 of the Companies Act, 1956; or
(*b*) act for, or on behalf of, any person or organisation in connection with any specific proceeding or transaction or negotiation or a case to which the Authority is a party and with respect to which the Chairperson or such Member before cessation of his office had acted for, or provided advice to, the Authority; or

(*c*)give advice to any person (including his client, business associate or employer) using information which was obtained in his capacity as the Chairperson or a Member and being not available or cannot be made available to the public; or

(*d*)for a period of two years from his last day in office, enter into a contract of service with, or accept an appointment to a board of directors of, or accept an offer of employment with, an entity with which he had direct and significant official dealings during his term of office as such without the due approval of the Central Government.

(*2*)The Chairperson and Members shall not communicate or reveal to any person any matter which has been brought under his consideration or known to him while acting as such.

11. Removal of Chairperson and Members.

(*1*) Notwithstanding anything contained in sub-section (*5*) of section 9, the Central Government may, by order, remove from office, the Chairperson or any Member, if he —

(*a*) has been adjudged an insolvent; or

(*b*) has been convicted of an offence which, in the opinion of the Central Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable of acting as Chairperson or Member; or

(*d*) has acquired such financial or other interests as is likely to affect prejudicially his functions; or

(*e*) has so abused his position as to render his continuance in office prejudicial to the public interest.

(*2*)The Chairperson or any Member shall not be removed under clauses (*d*) and (*e*) of sub-section (*1*) unless he has been given a reasonable opportunity of being heard in the matter.

12. Meetings of Authority.

(*1*)The Authority shall meet at such times and places, and observe such rules of procedure in regard to the transaction of business at its meetings (including quorum at such meeting) as may be specified by regulations.

(*2*)The Chairperson, if for any reason, is unable to attend a meeting of the Authority, the senior-most Member shall preside at the meeting.

(*3*) All questions which come up before any meeting of the Authority shall be decided by a majority of votes of the Members present and voting, and in the event of an equality of votes, the Chairperson or in his absence, the Member presiding, shall have a second or casting vote.

13. Vacancies, etc., not to invalidate proceedings of Authority.

No act or proceeding of the Authority shall be invalidated merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the Authority; or

(*b*) any defect in the appointment of a person as a Member of the Authority; or

(*c*) any irregularity in the procedure of the Authority not affecting the merits of the case.

14. Chief Regulatory Officers and other employees of Authority.

(*1*)The Authority may appoint, such number of, Chief Regulatory Officers and other officers and such other employees as it considers necessary for the efficient discharge of its functions and exercise of its powers under this Act.

(*2*)**The salaries, allowances and pensions payable to, and other terms and conditions of service of, the Chief Regulatory Officers and other officers and employees of the Authority, shall be such as may be prescribed.**

CHAPTER III

INTER-MINISTERIAL GOVERNING BOARD AND BIOTECHNOLOGY ADVISORY COUNCIL

15. Constitution of Inter-Ministerial Governing Board.

(*1*) The Central Government shall, by notification, constitute an Inter-Ministerial Governing Board to promote Inter-Ministerial or Departmental co-operation required for effective discharge of functions and performance of the Authority for the purposes of this Act.

(*2*)The Inter-Ministerial Governing Board shall consist of members representing following Ministries, Departments, Councils, Directorate, authorities and officers of the Central Government or under its control or established under the Central Acts, namely:—
(*a*) the Ministry of Commerce and Industry;
(*b*) the Ministry of Food Processing Industries;
(*c*) the Ministry of Environment and Forests;
(*d*) the Ministry of Health and Family Welfare;
(*e*) the Ministry of External Affairs;
(*f*) the Department of Agriculture and Co-operation, Ministry of Agriculture;
(*g*) the Department of Animal Husbandry, Dairying and Fisheries, Ministry of Agriculture;
(*h*) the Department of Biotechnology, Ministry of Science and Technology;
(*i*) the Department of Science and Technology, Ministry of Science and Technology;
(*j*)the Indian Council of Agricultural Research, Ministry of Agriculture, being society registered under the Societies Registration Act, 1860;
(*k*) the Indian Council of Medical Research, Ministry of Health and Family Welfare, being society registered under the Societies Registration Act, 1860;
(*l*)the Council of Scientific and Industrial Research, Ministry of Science and Technology, being society registered under the Societies Registration Act, 1860;
(*m*) the office of the Drug Controller General of India or office of any other authority regulating the manufacture or sale of drugs;
(*n*) the Directorate of Plant Protection, Quarantine and Storage, Ministry of Agriculture;
(*o*)the Food Safety and Standards Authority of India established under the Food Safety and Standards Act, 2006;
(*p*) the Biotechnology Regulatory Authority of India, established under this Act;
(*q*) such other officer of the Central Government as may be specified, by notification, by the Central Government.
(*3*)No Ministries, Departments, Councils, Directorate, authorities and offices referred to in clauses (*a*) to (*q*) of sub-section (*2*) shall nominate any person below the rank of an Additional Secretary to the Government of India or equivalent rank to represent such Ministries, Departments, Councils, Directorate, authorities and offices in the Inter-Ministerial Governing Board.
(*4*)The Secretary, in the Department of Science and Technology, Ministry of Science and Technology shall be the Chairperson of the Inter-Ministerial Governing Board.
(*5*) One of the Members of the Authority, as may be nominated by the Chairperson of the Authority, shall be the convenor of meetings of the Inter-Ministerial Governing Board.
(*6*)The functions of the Inter-Ministerial Governing Board shall be to ensure coordination amongst various Ministries, Departments, Councils, Directorate, authorities and offices on the matters of discharge of duties and performance of the functions of the Authority and regulatory policy, standards and protocols relating to organisms and products of modern biotechnology and discharge such other functions as may be prescribed.
(*7*)The expenses for attending the meetings of the Inter-Ministerial Governing Board (including travel expenses or any other allowances) shall be borne by the respective Ministries, Departments, Councils, Directorate, authorities and offices whom they represent under clauses (*a*) to (*q*) of sub-section(*2*).

16. Constitution of Biotechnology Advisory Council.

(*1*) The Central Government shall, by notification, constitute a Biotechnology Advisory Council to render strategic advice to the Authority on the matters relating to developments in modern biotechnology and their implications in India.
(*2*)The Biotechnology Advisory Council shall consist of a Presiding Officer and members not exceeding fifteen comprising from the following, namely:—
(*a*) Chairperson of the Authority – Presiding Officer;

(*b*) plant scientist (from public or private sector);
(*c*) animal or veterinary scientist (from public or private sector);
(*d*) industrial or environmental scientist (from public or private sector);
(*e*) medical or pharmaceutical scientist (from public or private sector);
(*f*) nutritionist or community health specialist;
(*g*) representative from consumer affairs organisation;
(*h*) representative from farmer organisation;
(*i*) economist;
(*j*) ethicist;
(*k*) legal expert;
(*l*) any other person not falling under clauses (*a*) to (*k*).
(*3*) The members of Biotechnology Advisory Council referred to in clauses (*b*) to (*l*) shall be appointed, on the recommendations of the Inter-Ministerial Governing Board, by the Central Government in such manner as may be prescribed so as to secure the highest standards of competence, relevant expertise, and the broadest possible geographic representation within the country.
(*4*) One of the Members of the Authority, as may be nominated by the Chairperson of the Authority, shall be the convenor of the meetings of the Biotechnology Advisory Council.
(*5*) The members of the Biotechnology Advisory Council shall hold office as such for a term of three years from the date on which they enter upon their office and shall be eligible for re-appointment for a further period of three years.
(*6*) The functions of the Biotechnology Advisory Council shall be to advise the Authority on the relevant practices on the matters relating to modern biotechnology and its products, their uses, safety and effects and discharge such other functions, as may be prescribed.
(*7*) The expenses for attending the meetings of the Biotechnology Advisory Council (including travel expenses and sitting fee) or any other allowances incurred by the members shall be borne by the Authority.

17. Meetings of Inter-Ministerial Governing Board and Biotechnology Advisory Council.

The Inter-Ministerial Governing Board and the Biotechnology Advisory Council shall meet at such times and places, and shall observe such procedures in regard to the transaction of business at their meetings (including the quorum), as may be prescribed.

CHAPTER IV
FUNCTIONS AND POWERS OF AUTHORITY

18. Functions and powers of Authority.

(*1*) It shall be the duty of the Authority to regulate the research, transport, import, manufacture and use of organisms and products as specified in Schedule I so as to ensure the safety to human health, animal health and the environment.
(*2*)Without prejudice to the provisions of sub-section (*1*), the Authority may by regulations specify measures to regulate,—
(*a*) the import of organisms and products specified under Parts I and III of Schedule I;
(*b*) the import of organisms and products for research and development specified under Part II of Schedule I;
(*c*) the transport of organisms and products specified under Parts I, II and III of Schedule I;
(*d*) the containment of organisms and products specified under Parts I, II and III of Schedule I;
(*e*) the research including field trials of organisms specified under Parts I and III of Schedule I;
(*f*) the research including pre-clinical evaluation of organisms and products specified under Part II of Schedule I;
(*g*)the environmental release of organisms and products specified under Parts I, II and III of Schedule I;

(*h*)the procedures and standards to be followed by the laboratories or research institutions notified under section 41 or by other laboratories or research institutions for undertaking research on organisms and products specified under Parts I, II and III of Schedule I;
(*i*) all processes and other new products of modern biotechnology;
(*j*) the amounts of fees and other charges to be levied under this Act; and
(*k*) any other measures necessary for the purpose of giving effect to the purposes of this Act.
(*3*) Without prejudice to the provisions contained in sub-sections (*1*) and (*2*), the Authority shall,—
(*a*)provide scientific advice and technical support to the Central Government and State Governments in matters of framing the policy and rules in areas which have a direct or indirect bearing on the safety of products and processes regulated under this Act;
(*b*)provide technical support to the agencies in India which deal with international activities related to establishing and implementing policies which have impact on the regulation of modern biotechnology;
(*c*)monitor, review and analyse national and international policies which may affect priorities in relation to the modern biotechnology sector;
(*d*)develop and implement guidelines for safety assessment methodologies for products and processes regulated under this Act;
(*e*)monitor and forward information relating to the safety of modern biotechnology products and processes regulated under this Act to the Central Government and State Governments;
(*f*)provide scientific and technical advice and assistance to the Central Government and State Governments regarding risk management procedures with regard to the safety of modern biotechnology products and processes regulated under this Act;
(*g*)establish a network of organisations to facilitate scientific co-operation, the exchange of information, the development and implementation of projects, the exchange of expertise and best practices followed in areas relating to modern biotechnology under this Act;
(*h*) ensure that the process and criteria for safety assessment and decision making in relation to modern biotechnology become accessible and understandable;
(*i*)inform the public of all applications for field trials and all regulatory decisions made by the Authority under this Act;
(*j*)organise workshops, conferences and such other programmes to inform the public about the mandate, programmes and policies of the Authority;
(*k*)commit to a process of continual quality improvement and professional development in all programmes, policies and activities of the Authority to ensure that the scientific and management capacity within the Authority remain up to date and consistent with best practices adopted internationally;
(*l*)provide training opportunities to State-level personnel and other stakeholders, who are entrusted with responsibilities related to the regulation of organisms and products of modern biotechnology;
(*m*)serve as the nodal agency for co-ordination for work on standards and guidance related to regulation of organisms and products of modern biotechnology, with the international, governmental and non-governmental organisations;
(*n*) promote consistency between international technical standards and technical standards in India related to regulation of organisms and products of modern biotechnology while ensuring that the level of protection adopted in India is not reduced;
(*o*)discharge in case, it considers so necessary, any other functions in relation to organisms, products and processes of modern biotechnology.

19. Powers of Authority to call for information, conduct investigations, etc.

(*1*) Where the Authority considers it expedient so to do, it may, by order in writing,—
(*a*) call upon any person, who had submitted application under sub-section (*1*) of section 24 or under sub-section (*1*) of section 27 or who has been granted authorisation under sub-section (*1*) of

section 24, or under sub-section (*1*) of section 27, or from any person engaged in activities relating to modern biotechnology, at any time to furnish in writing such information or explanation relating to its affairs as the Authority may require; or

(*b*) appoint one or more persons to make an inquiry in relation to the affairs of any person referred to in clause (*a*); and

(*c*) direct any of its officers or employees to inspect the books of account or other documents of any person referred to in clause (*a*).

(*2*) Where any inquiry in relation to the affairs of any person referred to in clause (*a*) of sub-section (*1*) has been undertaken under that sub-section,—

(*a*) every director, manager, secretary or other officer, if such person referred to in clause (*a*) of sub-section (*1*) is a company; or

(*b*) every partner, manager, secretary or other officer, if such person referred to in clause (*a*) of sub-section (*1*) is a firm; or

(*c*) every other person or body of persons who has had dealings in the course of business with any of the persons mentioned in clauses(*a*) and (*b*) of sub-section(*1*), shall be bound to produce before the Authority making the inquiry, all such books of account or other documents in his custody or power relating to, or having a bearing on the subject-matter of such inquiry and also to furnish to the Authority with any such statement or information relating thereto, as the case may be, required of him within such time as may be specified.

(*3*) Every person referred to in clause (*a*) of sub-section(*1*) shall maintain such books of account or other documents as may be prescribed.

20. Power of Authority to issue directions.

The Authority shall have the power to issue such directions to any person referred to in clause (*a*) of sub-section(*1*) of section 19 as it may consider necessary for proper safety of products or processes of modern biotechnology or which may be necessary for proper discharge of its functions or exercise of its powers under this Act.

CHAPTER V
DIVISIONS, UNITS AND PRODUCT RULINGS COMMITTEE OF AUTHORITY

21. Regulatory Divisions of Authority.

(*1*) The Authority shall have at least three Regulatory Divisions, namely:—

(*i*)a division, dealing with agriculture, forests and fisheries, and, responsible for regulating in accordance with the provisions of this Act, and rules and regulations made thereunder, the organisms and products as specified in Part I of Schedule I;

(*ii*)a division dealing with human health and veterinary and responsible for regulating in accordance with the provisions of this Act, and the rules and regulations made thereunder, the organisms and products as specified in Part II of Schedule I; and

(*iii*)a division dealing with industrial and environmental applications and responsible for regulating in accordance with the provisions of this Act, and the rules and regulations made thereunder, the organisms and products as specified in Part III of Schedule I.

(*2*)Without prejudice to the provisions contained in sub-section (*1*), the Authority may establish such other divisions as may be necessary, from time to time, to discharge its functions under the Act.

(*3*) Each division of the Authority, referred to in sub-sections (*1*) and (*2*), shall be headed by a Chief Regulatory Officer, who shall be a scientist of outstanding scientific calibre with a doctorate degree in biological or post graduate degree in Medicine or equivalent degree from a university recognised by the University Grants Commission or a university or institute established under any law for the time being in force, in a scientific discipline relevant to the Division and has not less than fifteen years experience in relevant discipline and other qualifications as may be specified by regulations.

(*4*)The duties and functions of the Chief Regulatory Officer shall be such as may be specified by regulations.

(*5*)Every Chief Regulatory Officer shall, before entering upon his office, make and subscribe to an oath of office and of secrecy in such form and in such manner and before such authority as may be prescribed.
(*6*)Every Chief Regulatory Officer shall be appointed on whole-time basis and not take up any employment, business or profession while acting as such and not communicate or reveal to any person or persons any matter which has been brought under his consideration or known to him while acting as such.
(*7*) Any Chief Regulatory Officer, ceasing to hold office, in the Authority, shall not—
(*a*) act for, or on behalf of, any person or organisation in connection with any specific proceeding, transaction, negotiation or case to which the Authority is a party and with respect to which such Chief Regulatory Officer had acted for, or provided advice to, the Authority;
(*b*)render advice to his client, business associate or employer using information which was obtained in his capacity as a Chief Regulatory Officer and the same is not available to the public;
(*c*)for a period of two years from his last day in office, enter into a contract of service with, or accept an appointment to a board of directors of, or accept an offer of employment with, an entity with which he had direct and significant official dealings during his term of office without the prior approval of the Authority.
(*8*)Each regulatory division shall maintain a roster of qualified scientific experts in such manner as may be specified by regulations.

22. Risk Assessment Unit.

The Authority shall constitute a Risk Assessment Unit comprising of scientific officers possessing such qualifications, as may be specified by regulations, and to undertake science-based safety assessments in such manner as may be specified by regulations.

23. Other Units.

(*1*)The Authority shall constitute an Enforcement Unit consisting of Monitoring Officers appointed under sub-section(*1*) of section 38, for enforcing the decisions of the Authority in such manner as may be specified by regulations.
(*2*) Without prejudice to the provisions contained in sub-section (*1*), the Authority may establish such other units, as may be necessary from time to time, to discharge its functions.

24. Procedure by Risk Assessment Unit for research, transport or import of organisms or products.

(*1)*Every person shall obtain authorisation under sub-section (*3*), for the purpose of the research, transport or import of organisms and products as specified in Parts I, II and III of Schedule I, and submit for the said purpose an application to the Authority, in such form and manner, along with such fee and accompanied by such documents and information, as may be specified by regulations.
(*2*)On receipt of the application under sub-section (*1*) for the purpose of the research, transport or import of organisms and products as specified in Parts I, II and III of Schedule I, the Authority shall forward the application to the Risk Assessment Unit which shall undertake a science-based evaluation of the application and submit a clear assessment as to the safety of the proposed research, transport or import of such organisms or products to the Authority.
(*3*)The Authority shall, on receipt of the clear assessment under sub-section (*2*), as to the safety of research, transport or import of organisms and products, referred to in sub-section (*1*), consider all other relevant matters, in addition to the assessment submitted to it, and —
(*a*)if it is of the opinion that the proposed research, transport or import of such organism or product referred to in sub-section(*1*) is safe, it may, in writing, authorise, with or without conditions, such research, transport or import of organisms and products, as the case may be;
(*b*)if it is of the opinion that the proposed research, transport or import of organism and product is not safe to human health, animal health or the environment, it may, in writing, refuse to grant authorisation for the research, transport or import, as the case may be;

(*c*)if the Authority has reasonable grounds to believe that the applicant may not comply with the conditions which may be imposed under clause (*a*) in respect of the authorisation for the research, transport or import referred to in sub-section (*1*), it may in writing refuse to grant authorisation for the research, transport or import, as the case may be.

(*4*) Where the Authority refuses to grant authorisation, referred to in clause (*c*) of sub-section (*3*), it shall record the reasons for such refusal and shall furnish a copy thereof to the applicant.

(*5*)The decisions of the Authority taken under sub-section (*3*) shall be communicated in writing to the applicant and be made available to public, within ten working days of the decision being taken by it.

(*6*)The Authority, may, by notice given in writing to the applicant, may suspend or cancel the authorisation,—

(*a*)if it is of the opinion that any condition of the authorisation has been violated; or (*b*) the authorisation was obtained improperly; or

(*c*) any new risks have emerged for continuation of the activity.

25. Product Rulings Committee.

(*1*) The Authority shall constitute a Product Rulings Committee, in such manner as may be specified by the regulations, for the purpose of making recommendations to the Authority for manufacture or use of organisms and products specified under Part I, Part II and Part III of Schedule I.

(*2*) The Product Rulings Committee referred to in sub-section (*1*) shall consists of —

(*a*) one of the Member of the Authority to be nominated by the Chairperson—

Presiding Officer;

(*b*) all the Chief Regulatory Officers of their Regulatory Divisions — *ex officio* members;

(*c*) one representative from the Central Drugs Standard Control Organisation to be nominated by the Ministry of Health of the Central Government—member;

(*d*)at least three and not exceeding five members, whose names appear as qualified scientific experts in the roster of experts maintained under sub-section (*8*) of section 21, to be appointed by the Authority — members:

Provided that one of the experts shall be nominated by the Ministry of Environment and Forests of the Central Government from the roster of experts prepared for this purpose by the Authority in consultation with that Ministry.

(*3*)The Chief Regulatory Officer dealing with the organisms and products specified under Part I, Part II or Part III of Schedule I shall be the convenor of the Product Rulings Committee constituted for making recommendations for the manufacture or use of the same organisms or products dealt by the said Chief Regulatory Officer.

(*4*)The fee and allowances payable to the qualified scientific experts in the roster of experts maintained under sub-section (*8*) of section 21, shall be such as may be specified by regulations.

(*5*)The Product Rulings Committee shall meet at least once in every three weeks or within such period as may be decided by the Authority.

(*6*) The Product Rulings Committee shall observe such procedures in regard to the transaction of business at their meetings, including the quorum, as may be specified by the regulations.

26. Environment Appraisal Panel or application of law relating to protection of environment.

(*1*)The Authority shall constitute, in consultation with the Union Ministry of Environment and Forests, a panel to be known as the Environment Appraisal Panel, consisting of—

(*a*)a chairperson to be nominated by the Ministry of Environment and Forests of the Central Government;

(*b*) such members not exceeding five; and

(*c*)a Member-Secretary to be nominated in the Ministry of Environment and Forests of the Central Government, having such qualifications and experience as may be prescribed.

(*2*)The Environment Appraisal Panel may regulate its own procedure for the purpose of conducting its meeting (including quorum) and making recommendations under sub-section (*1*).

(*3*)The Environment Appraisal Panel shall make recommendations on environmental safety of organisms and products on such matter covered under section 6 and procedure under section 8 of the Environment (Protection) Act, 1986 as may be referred to it by the Authority under sub-section (*4*) of section 27.

27. Procedure for grant of authorization for manufacture or use of organisms and products.

(*1)* Every person shall obtain authorisation under clause (*a*) of sub-section (*6*),

for the purpose of manufacture or use, of organisms and products specified in Parts I, II [except products covered under drug as defined under clause (*b*) of section 3 of the Drugs and Cosmetics Act, 1940] and III of Schedule I, and submit for the said purpose an application in the form and manner, along with such fees and accompanied by such documents and information as may be specified by regulations.

(*2*)On receipt of the application under sub-section (*1*) for the manufacture or use of organisms and products specified under Parts I, II [except products covered under drug as defined under clause (*b*) of section 3 of the Drugs and Cosmetics Act, 1940] and III of Schedule I, the Authority shall forward the application to the Risk Assessment Unit which shall undertake a science-based evaluation of the application and submit its risk assessment report as to the safety of the proposed manufacture and use of organisms or products to the Authority.

(*3*)The Authority, on receipt of the risk assessment report under sub-section (*2*), as to the safety for manufacture or use of organisms and products, shall forward the risk assessment report of the Risk Assessment Unit to the Product Rulings Committee for giving its recommendations thereon, as to the safety of organisms and products.

(*4*)The Authority shall obtain the opinion of the Environmental Appraisal Panel in case of organisms and products having environmental impact as may be referred by the Authority:

Provided that in case of difference of opinion between the Environmental Appraisal Panel and the Authority, the Authority shall pass an order giving its reason in this regard.

(*5*) Without prejudice to the provisions contained in sub-sections (*1*), (*2*), (*3*) and (*4*), the Authority shall obtain the objections or suggestions from the public in case of organisms and products.

(*6*)The Authority, on receipt of the recommendations under sub-section (*3*), as to the safety for manufacture or use of organisms and products, shall consider all other relevant matters, in addition to the risk assessment report submitted to it by the Risk Assessment Unit and—

(*a*) if it is of the opinion that the proposed manufacture or use of organisms and products is safe it may, in writing authorise, with or without conditions, such manufacture or use of organisms and products, as the case may be;

(*b*) if it is of the opinion that the proposed manufacture or use of organisms and products is not safe to human health or animal health or the environment, it may, in writing refuse to grant authorisation for the manufacture or use of organisms and products, as the case may be;

(*c*)if the Authority has reasonable grounds to believe that the person may not comply with the conditions which may be imposed under clause (*a*) in respect of the authorisation, it may in writing refuse to grant authorisation for the manufacture or use of organisms and products, as the case may be.

(*7*)Where the Authority refuses to grant authorisation referred to in clause (*c*) of sub-section (*6*), it shall record the reasons for such decision and furnish a copy thereof to the applicant.

(*8*) The decisions of the Authority taken under clause (*a*) or clause (*b*) or clause (*c*) of sub-section (*6*) shall be communicated in writing to the applicant and be made available to public, within ten working days of the decision being taken by it.

(*9*)The Authority may, by notice given in writing to the applicant, suspend or cancel the authorisation—

(*a*) if it is of the opinion that any condition of the authorisation has been violated; or

(*b*) the authorisation was obtained improperly; or

(*c*) any new risks have emerged for continuation of the activity.

(*10*)The Authority may develop a prompt and effective product recall system of organisms and products in circumstances as specified.

28. Disclosure of confidential commercial information.

(*1*) In case an application to be submitted under sub-section (*1*) of section 24 or sub-section (*1*) of section 27 requires the disclosure of confidential commercial information, such information shall, notwithstanding anything contained in the Right to Information Act, 2005, be retained as confidential by the Authority and not be disclosed to any other party.

(*2*)If the Authority is satisfied that the public interest outweighs the disclosure of confidential commercial information or such disclosure shall not cause harm to any person, it may refuse to retain that information as confidential commercial information.

29. Scientific Advisory Panels and Roster of Experts.

The Authority may constitute one or more Scientific Advisory Panels, from the roster of experts referred to in sub-section(*8*) of section 21 in such manner as may be specified by the regulations, to provide scientific advice, information and recommendations to the Authority under this Act on biotechnology issues which may, result from regulatory actions of the Authority, and, would have an impact on the safety of human health, animal health and the environment.

30. Seeking advice from Scientific Advisory Panels and roster of experts.

The Authority may, for the purpose of obtaining scientific advice and technical support on any issue relating to modern biotechnology, without prejudice to the other provisions of this Act, may seek advice from any member of the Scientific Advisory Panel referred to in section 29 in such manner as may be specified by the regulations.

31. Authentication of decisions or orders, etc.

All orders and decisions of the Authority shall be authenticated by the signature of the Chairperson or any other officer of the Authority so authorised by the Chairperson.

32. Delegation.

The Authority may, by general or special order in writing, delegate to the Chairperson or any member or any officer of the Authority subject to such conditions or limitations, if any, as may be specified in the order, such of its powers and functions (except the power to make regulations under section 83) as it may consider necessary.

CHAPTER VI
PROVISIONS RELATING TO IMPORT OF ORGANISMS AND PRODUCTS AS SPECIFIED IN SCHEDULE I

33. Application of law relating to customs and powers of Customs officers.

(*1*)The law for the time being in force relating to the customs and goods, the import of which is prohibited under the Customs Act, 1962 or any other law for the time being in force shall, subject to the provisions of section 27 of this Act, apply in respect of organisms and products specified under Part I, Part II [except products covered under drug as defined under clause (*b*) of section 3 of the Drugs and Cosmetics Act, 1940] and Part III of Schedule I, the import of which requires the authorisation by the Authority under Chapter V, and officers of Customs and officers empowered under the Customs Act, 1962 or any other law for the time being in force, to perform the duties imposed thereby on a Commissioner of Customs and other officers of Customs, shall have the same powers in respect of such organisms and products as they have for the time being in respect of such goods as aforesaid.

(*2*)Without prejudice to the provisions of sub-section (*1*), the Commissioner of Customs or any officer of the Government authorised by the Central Government in this behalf, may detain any imported package which he suspects to contain any organisms and products specified under Part I, Part II and Part III of Schedule I and the import of which requires the approval of the Authority under Chapter V, and shall forthwith report such detention to the Authority, and, if necessary, forward, with the approval of the Authority, the package or sample of any suspected organisms and products found therein to the laboratory notified or research institution accredited under this Act.

CHAPTER VII
FIELD TRIALS OR CLINICAL TRIAL

34. Field trials or clinical trials.

(*1*) No person shall conduct field trials in respect of any organisms or products specified in Part I and Part III of Schedule I:

Provided that the Authority may having regard to the development of modern biotechnology permit field trials in respect to any organisms or products specified in Part I and Part III of Schedule I with such safeguards as it may consider necessary and which may be specified by the regulations.

(*2*) The Authority may evaluate and recommend clinical trials of organisms and products specified in Part II of Schedule I on the application forwarded by the Central Drugs Standard Control Organisation under the provisions of the Drugs and Cosmetics Act, 1940 and the rules and regulations made thereunder.

Explanation.—For the removal of doubts, it is hereby declared that the Authority shall not grant any permission or authorisation to conduct any clinical trial in respect of organisms and products specified in Part II of Schedule I but nothing shall prevent the Authority to authorise any trial in laboratory or in containment for pre-clinical testing preceding the clinical trial.

CHAPTER VIII
STATE BIOTECHNOLOGY REGULATORY ADVISORY COMMITTEE

35. State Biotechnology Regulatory Advisory Committee.

(*1*)Every State Government shall, for the purposes of discharging its functions under sub-section (*6*),constitute a committee to be called as the "…….. (Name of the State) Biotechnology Regulatory Advisory Committee".

(*2*) Every State Biotechnology Regulatory Advisory Committee shall consist of,—

(*a*)a representative not below the rank of Director from the Ministry or Department dealing with health;

(*b*)a representative not below the rank of Director from the Ministry or Department dealing with environment;

(*c*)a representative not below the rank of Director from the Ministry or Department dealing with agriculture;

(*d*)a representative not below the rank of Director from the Ministry or Department dealing with Industry;

(*e*)two members, having technical expertise in healthcare and allied fields, agriculture and allied fields or environmental or industrial sciences and allied fields, to be nominated by the Authority;

(*f*) two other members, having adequate knowledge of, and experience in, the field of biotechnology to be nominated by the Secretary or Commissioner or head referred to in sub-section (*3*), as the case may be, who presides over the State Biotechnology Regulatory Advisory Committees referred to in that sub-section.

(*3*)Every State Biotechnology Regulatory Advisory Committee shall be convened by the Secretary or head or Commissioner of State Department of Biotechnology or Biotechnology Commission, as the case may be, where no State Department of Biotechnology or Biotechnology Commission exists, by the Secretary or head of the State Department of Science and Technology.

(*4*) The Secretary or head or Commissioner referred to in sub-section (*3*) shall preside over the meetings of the State Biotechnology Regulatory Advisory Committee.

(*5*)The State Biotechnology Regulatory Advisory Committee shall observe such procedures in regard to transaction of business at its meetings (including the quorum and the intervals at which the meeting may be held) and pay such fee and allowances to its members as may be specified by the State Government.

(*6*) The functions of a State Biotechnology Regulatory Advisory Committee shall be to,—

(*a*)act as the nodal agency for inter-action between the State Government and the Authority in respect of matters related to the regulation of modern biotechnology under this Act and the rules and regulations made thereunder;
(*b*)facilitate inter-departmental co-ordination within the State for regulation of modern biotechnology;
(*c*) identify state-specific needs related to the regulation of modern biotechnology and apprise the same to the Authority;
(*d*)collaborate with the Authority for undertaking capacity building and information sharing activities relating to biotechnology within the State;
(*e*)ensure that information relating to activities and programmes of the Authority are made available to the public in a transparent and accessible manner within the State.
(*7*)**The Authority shall provide technical or financial assistance or such other assistance as it may consider necessary, for the establishment of the State Biotechnology Regulatory Advisory Committee and discharge of its functions, in such manner as may be prescribed.**
(*8*) Every State Biotechnology Regulatory Advisory Committee shall prepare and publish an annual report and make the same available to the State, the Authority and the public.

36. Convening of meetings of State Biotechnology Regulatory Advisory Committees.

The Chairperson of the Authority shall convene an annual meeting of State Biotechnology Regulatory Advisory Committees of all the States, in such manner as may be specified by the regulations, with a view to identify priority issues and activities which the State Governments may include in their programmes and operations related to the regulation of modern biotechnology.

CHAPTER IX
ENFORCEMENT OF PROVISIONS OF ACT

37. Authority responsible for enforcement of Act.

The Authority shall be responsible for enforcement of the provisions of this Act and regulations made thereunder.

38. Monitoring Officers.

(*1*)The Authority may, by notification, appoint such number of persons, including the officers of the Authority, any State Governments or any other authority, as Monitoring Officers in its Enforcement Unit referred to in sub-section (*1*) of section 23, as it may deem fit, for the purpose of exercising powers or performing functions under this Act.
(*2*)The persons appointed as Monitoring Officers, under sub-section (*1*), shall possess such qualifications and experience relating to modern biotechnology as may be specified by the regulations.
(*3*)The Authority shall establish such mechanisms, in consultation with the concerned State Governments, State Biotechnology Regulatory Advisory Committees or any other authority, as may be considered necessary to facilitate enforcement of the provisions of this Act, the rules and regulations made thereunder.

39. Functions of Monitoring Officers.

(*1*) Every Monitoring Officer shall undertake such activities, as may be directed by the Authority, to ensure compliance with the provisions of this Act and the rules and regulations made thereunder and such activities include,—
(*a*) enforcement of the regulations made under sub-section (*2*) of section 18 under this Act; and
(*b*)enforcement of compliance of refusal of authorisation under clause (*c*) of sub-section (*6)* of section 27.
(*2*)In exercising the powers or performing the functions as a Monitoring Officer, the Monitoring Officer shall comply with such directions of the Authority, as it may issue to such Monitoring Officers.

40. Powers of Monitoring Officers.

(*1*) The Monitoring Officer may, for the purpose of discharging his functions under this Act, and if so authorised by the Authority, –
(*a*) enter and inspect any premises where products and processes regulated under this Act may be found;
(*b*) inspect, examine, take measurements of, or conduct tests on, or take samples of, anything on the premises which relates to products and processes regulated under this Act;
(*c*) take photographs, make video or audio recordings of the premises or anything on the premises on which products and processes regulated under this Act have been found;
(*d*) inspect any book, record or document on the premises referred to in clause (*a*);
(*e*) take to the premises referred to in clause (*a*), such equipment and materials as the Monitoring Officer may require for the purpose of exercising his powers and discharging his functions in relation to products or processes regulated under this Act.
(*2*) The Monitoring Officer shall, in exercising the powers of entry upon, and inspection of any place under this section, follow, as far as may be, the provisions of the Code of Criminal Procedure, 1973 relating to the search or inspection of a place by a police officer executing a search warrant under that Code.
(*3*) A Monitoring Officer shall not enter any premises except with the consent of the occupant of the premises or under the authority of a warrant.
Explanation.— For the purpose of sub-section (*3*) "warrant" means a warrant issued by the Judicial Magistrate of the first class or the Metropolitan Magistrate, as the case may be, within whose jurisdiction the place, where the warrant is to be executed, is situated.

CHAPTER X
NOTIFICATION OF LABORATORIES

41. Notification of accredited laboratories and research institutions.
The Authority may, notify, for the purposes of this Act, such laboratories or research institutions which have been accredited by such agencies as may be specified by the regulations:
Provided that the Authority may, if it considers so necessary, having regard to emerging nature of modern biotechnology and facilities and equipment available in laboratories, (other than accredited laboratories) may, notify for the purposes of this Act, such laboratories or research institutions which had not been accredited by such agencies, as laboratories or research institutions for the purposes of this Act.

42. Designation of certain organization or agency as auditor.
(*1*) The Authority may designate one or more organisations or agencies as an auditor for the purpose of auditing notified laboratories and research institutions to ensure compliance with activities, relating to safety of modern biotechnology, as may be specified by regulations.
(*2*) An organisation or agency shall not be qualified for designation as auditor under sub-section (*1*), unless such organisation or agency fulfills such criteria as may be specified by regulations.
(*3*) Every person authorised by an organisation or agency referred to in sub-section (*1*) shall, for the purpose of auditing laboratories and research institutions notified under section 41, have a right on all working days to access such notified laboratories and research institutions in respect of which such organisation or agency had been designated as an auditor and be entitled to require from the officers of such notified laboratories and research institutions, such information or document as the auditor may consider necessary for the performance of his duties as an auditor.
(*4*) The auditor referred to in sub-section (*1*) shall, within such time as may be specified by the Authority, make a report in writing to the Authority, including therein the specific areas or issues or standards or procedures, directed by it to be audited, as may be specified by it in this regard.

CHAPTER XI
BIOTECHNOLOGY REGULATORY APPELLATE TRIBUNAL

43. Appeal to Appellate Tribunal.

(*1*) Any person aggrieved by a decision or order or directions of the Authority under this Act, may, within a period of thirty days from the date on which the decision or order or direction is communicated to him, file an appeal to the Biotechnology Regulatory Appellate Tribunal.
(*2*) Every such appeal shall be preferred in such form and manner along with such fees and contain such particulars as may be prescribed.

44. Establishment of Appellate Tribunal.

The Central Government shall, by notification, establish with effect from such date as may be specified therein, an Appellate Tribunal to be known as the Biotechnology Regulatory Appellate Tribunal to exercise the jurisdiction, powers and authority conferred on such Tribunal by or under this Act.

45. Composition of Appellate Tribunal.

(*1*) The Appellate Tribunal shall consist of—
(a) a full-time Chairperson;
(*b*) part-time expert Members not exceeding five, as the Central Government may notify.
(*2*) The Chairperson of the Appellate Tribunal may, if considered necessary, direct any one or more person having specialised knowledge and experience in a particular case before the Appellate Tribunal to assist the Appellate Tribunal in that case.
(*3*) The Appellate Tribunal shall sit at such place or places, as the Central Government may, by notification, specify.
(*4*) The Central Government may, in consultation with the Chairperson of the Appellate Tribunal, make rules regulating generally the practices and procedure of the Appellate Tribunal including —
(a) rules as to the persons who would be entitled to appear before the Appellate Tribunal;
(*b*) rules as to the procedure for hearing appeals and other matters pertaining to the appeals;
(*c*) the minimum number of members who would hear the applications and appeals in respect of any class or classes of appeals.

46. Qualifications for appointment of Chairperson and part-time expert Members.

(*1*) A person shall not be qualified for appointment as the Chairperson of the Appellate Tribunal unless he is, or has been, a Judge of the Supreme Court of India or the Chief Justice of a High Court.
(*2*) A person shall not be qualified for appointment as part-time expert Member, unless he is a person who is an eminent scientist in the field of biological sciences or biotechnology related to healthcare or agriculture or environmental or industrial activities and possesses an experience of at least twenty years in the field, or who has held the post in the Central Government or a State Government dealing with biological sciences or biotechnology related to healthcare or agriculture or environmental or industrial activities equivalent to the Joint Secretary to the Government of India for at least three years and possesses special knowledge in the field.
(*3*) The Chairperson and part-time expert Members of the Appellate Tribunal shall not hold any other office during their tenure as such.

47. Appointment of Chairperson and part time expert Members.

(*1*) Subject to the provisions of sub-sections (*2*) and (*3*), the Chairperson and part-time expert Members of the Appellate Tribunal shall be appointed by the Central Government.
(*2*) The Chairperson shall be appointed by the Central Government in consultation with the Chief Justice of India.
(*3*) The part-time expert Members of the Appellate Tribunal shall be appointed on the recommendations of such Selection Committee and in such manner as may be prescribed.

48. Term of office and other conditions of service of Chairperson and part-time expert Members.

The Chairperson and part time expert Members of the Appellate Tribunal shall hold office as such for a term of three years from the date on which they enter upon their office, but shall not be eligible for re-appointment:
Provided that no Chairperson shall hold office as such after he has attained the age of seventy years:

Provided further that no part-time expert Member shall hold office after he has attained the age of sixty-five years.

49. Resignation.

The Chairperson or part-time expert Member of the Appellate Tribunal may, by notice in writing under their hand addressed to the Central Government, resign from their office.

50. Salaries, allowances and other terms and conditions of service.

The salaries and allowances payable to, and the other terms and conditions of service (including pension, gratuity and other retirement benefits) of, the Chairperson and allowances and fee payable to part-time expert Members of the Appellate Tribunal shall be such as may be prescribed:

Provided that neither the salary and allowances nor the other terms and conditions of service of the Chairperson shall be varied to their disadvantage after his appointment.

51. Restriction on Chairperson or Members on employment after cessation of office.

The Chairperson or a Member of the Appellate Tribunal, ceasing to hold office as such, shall not —

(*a*) for a period of one year from the date on which they cease to hold office, accept any employment in, or connected with the management or administration of, any person which has been a party to a proceeding before the Appellate Tribunal under this Act:

Provided that nothing contained in this section shall apply to any employment under the Central Government or a State Government or local authority or in any statutory authority or any corporation established by or under any Central, State or Provincial Act or a Government company as defined in section 617 of the Companies Act, 1956;

(*b*) act, for or on behalf of any person or organisation in connection with any specific proceeding, transaction, negotiation or a case to which the Authority is a party or whose matter had been before such Chairperson or Member.

(*c*)give advice to any person (including his client, business associate or employer) using information which was obtained in his capacity as the Chairperson or a Member and being not available or cannot be made available to the public.

(*d*)for a period of two years from his last day in office, enter into a contract of service with, or accept an appointment to a board of directors of, or accept an offer of employment with, an entity with which he had direct and significant official dealings during his term of office or whose matter had been before such Chairperson or Member as such without the approval of the Central Government.

52. Removal and suspension of Chairperson and part-time expert Member.

(*1*) The Central Government may, in consultation with the Chief Justice of India, remove from office of the Chairperson of the Appellate Tribunal, who,—

(*a*) has been adjudged an insolvent; or

(*b*) has been convicted of an offence which, in the opinion of the Central Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable; or

(*d*) has acquired such financial or other interest as is likely to affect prejudicially his functions; or

(*e*) has so abused his position as to render his continuance in office prejudicial to the public interest.

(*2*)The Chairperson shall not be removed from his office except by an order made by the Central Government, after an inquiry made by a Judge of the Supreme Court in which such Chairperson has been informed of the charges against him and given a reasonable opportunity of being heard in respect of those charges.

(*3*)The Central Government may suspend from office the Chairperson in respect of whom a reference of conducting an inquiry has been made to the Judge of the Supreme Court under sub-section (*2*), until the Central Government passes an order on receipt of the report of inquiry made by the Judge of the Supreme Court on such reference.

(*4*) The Central Government may, by rules, regulate the procedure for inquiry referred to in sub-section (*2*).
(*5*) The part-time expert Member may be removed from his office by an order of the Central Government on the grounds specified in sub-section (*1*):
Provided that the part-time expert Member shall not be removed unless he has been given an opportunity of being heard in the matter.

53. To act as Chairperson of Appellate Tribunal or to discharge his functions in certain circumstances.

In the event of the occurrence of any vacancy in the office of the Chairperson of the Appellate Tribunal, by reason of his death, resignation or otherwise, such part-time expert Member of the Appellate Tribunal, as the Central Government may, by notification, authorise in this behalf, shall act as the Chairperson until the date on which a new Chairperson is appointed in accordance with the provisions of this Act.

54. Staff of Appellate Tribunal.

(*1*) The Central Government shall determine the nature and categories of the officers and other employees required to assist the Appellate Tribunal in the discharge of its functions.
(*2*) The recruitment of the officers and other employees of the Appellate Tribunal shall be made by the Chairperson in such manner as may be prescribed.
(*3*) The officers and other employees of the Appellate Tribunal shall discharge their functions under the general superintendence of the Chairperson of the Appellate Tribunal.
(*4*) **The salaries and allowances payable to, and the other terms and conditions of service of, the officers and other employees of the Appellate Tribunal shall be such as may be prescribed.**

55. Financial and administrative powers of Chairperson.

The Chairperson of the Appellate Tribunal shall exercise such financial and administrative powers as may be vested in him under the rules made by the Central Government:
Provided that the Chairperson shall have the authority to delegate such of his financial and administrative powers, as he may think fit, to any part-time expert Member or officer of the Appellate Tribunal subject to the condition that the Member or such officer, while exercising such delegated power, continues to act under the direction, control and supervision of the Chairperson.

56. Appellate Tribunal to settle disputes.

(*1*)The Appellate Tribunal shall have the jurisdiction over all civil cases where a substantial question relating to modern biotechnology is involved and such question arises out of the safety and use of organisms, products and processes specified under Part I or Part II or Part III of Schedule I and hear appeals from the decisions or orders of the Authority.
(*2*) The Appellate Tribunal shall hear the appeals referred to in sub-section (*1*) and dispose of such appeals and pass order thereon.
(*3*) No application for deciding substantial question relating to modern biotechnology under this section shall be entertained by the Appellate Tribunal unless it is made within a period of two years from the date on which the cause of action for such question first arose:
Provided that the Appellate Tribunal may, if it is satisfied that the applicant was prevented by sufficient cause from filing the application within the said period, allow it to be filed within a further period not exceeding sixty days.
(*4*) The application, or as the case may be, the appeal filed before the Appellate Tribunal under sub-section (*1*) or sub-section(*3*) shall be dealt with by it as expeditiously as possible and endeavour shall be made by it to dispose of the application, or, as the case may be, the appeal, finally within six months from the date of filing of the application, or as the case may be, the appeal, after providing the parties concerned an opportunity to be heard.

57. Procedure and powers of Appellate Tribunal.

(*1*)The Appellate Tribunal shall not be bound by the procedure laid down by the Code of Civil Procedure, 1908 but shall be guided by the principles of natural justice.
(*2*) Subject to the provisions of this Act, the Appellate Tribunal shall have power to regulate its own procedure.
(*3*)The Appellate Tribunal shall also not be bound by the rules of evidence contained in the Indian Evidence Act, 1872.
(*4*)The Appellate Tribunal shall have, for the purposes of discharging its functions under this Act, the same powers as are vested in a civil court under the Code of Civil Procedure, 1908, while trying a suit, in respect of the following matters, namely:—
(*a*) summoning and enforcing the attendance of any person and examining him on oath;
(*b*) requiring the discovery and production of documents;
(*c*) receiving evidence on affidavits;
(*d*)subject to the provisions of sections 123 and 124 of the Indian Evidence Act, 1872, requisitioning any public record or document or copy of such record or document from any office;
(*e*) issuing commissions for the examination of witnesses or documents;
(*f*) reviewing its decision;
(*g*) dismissing an application for default or deciding it *ex parte*;
(*h*) setting aside any order of dismissal of any application for default or any order passed by it *ex parte*;
(*i*)pass an interim order (including granting an injunction or stay) after providing the parties concerned an opportunity of being heard, on any application made or appeal filed under this Act;
(*j*) any other matter which may be prescribed.
(*5*) All proceedings before the Appellate Tribunal shall be deemed to be judicial proceedings within the meaning of sections 193, 219 and 228 for the purposes of section 196 of the Indian Penal Code, and the Appellate Tribunal shall be deemed to be a civil court for the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973.

58. Decision to be taken by majority.

The decision of the Appellate Tribunal by majority of members shall be binding.

59. Cost.

While disposing of an application or an appeal under this Act, the Appellate Tribunal shall have power to make such order as to costs as it may consider necessary.

60. Execution of award or order of Appellate Tribunal.

An award or order or decision of the Appellate Tribunal under this Act shall be executable by the Appellate Tribunal as a decree of a civil court, and for this purpose, the Appellate Tribunal shall have all the powers of a civil court.

61. Appeal to Supreme Court.

(*1*) Notwithstanding anything contained in the Code of Civil Procedure, 1908 or in any other law for the time being force, an appeal shall lie against any order, (not being an interlocutory order) of the Appellate Tribunal to the Supreme Court on one or more of the grounds specified in section 100 of that Code.
(*2*) No appeal shall lie against any decision or order made by the Appellate Tribunal with the consent of the parties.
(*3*) Every appeal under this section shall be preferred within a period of ninety days from the date of the decision or order appealed against:
Provided that the Supreme Court may entertain the appeal after the expiry of the said period of ninety days, if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

CHAPTER XII
OFFENCES AND PENALTIES

62. Punishment for false information.

If a person, in connection with a requirement or direction under this Act, provides any information or produces any document that the person knows is false or misleading, he shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.

63. Punishment for conduct of unapproved field trial.

(*1*) Whoever, himself or by any other person on his behalf, conducts field trials with organisms or products specified in Part I or Part III of Schedule I, in contravention of section 34 shall be punished with imprisonment for a term which shall not be less than six months but which may extend to one year and with fine which may extend to two lakh rupees.

(*2*) Whoever, having been convicted of an offence under sub-section(*1*), is again convicted of an offence under that sub-section, shall be punished with imprisonment for a term which shall not be less than two years but which may extend to four years and with fine which may extend to four lakh rupees.

64. Punishment for obstructing or impersonating an officer of Authority.

If a person, without reasonable excuse, resists, obstructs, or attempts to obstruct, impersonate, threaten, intimidate or assault an officer of the Authority or any person assigned to discharge any function under this Act, or in exercising his functions under this Act, he shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.

65. Punishment in relation to audit report.

If any auditor's report is made, which is false or otherwise than in conformity with the specific areas or issues or standards or procedures directed to be audited by the Authority under sub-section(*4*) of section 42, the auditor concerned and the person, if any, other than the auditor who signs the report or signs or authenticates the document, shall, if the default is willful, be punishable with imprisonment which may extend to three years or with fine which may extend to five thousand rupees or with both.

66. General provisions relating to offences and fine.

If any person contravenes or attempts to contravene or abets the contravention of the provisions of this Act or of any rules or regulations made thereunder, for which no punishment is provided elsewhere in this Act, he shall be punishable with imprisonment for a term which may extend to two years and also with fine which may extend to ten lakh rupees.

67. Offences by companies.

(*1*)Where an offence under this Act has been committed by a company, every person who at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act, if he proves that the offence was committed without his knowledge or that he has exercised all due diligence to prevent the commission of such offence.

(*2*)Notwithstanding anything contained in sub-section (*1*), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to, any neglect on the part of any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

Explanation.—For the purposes of this section,—

(*a*)"company" means anybody corporate and includes a firm or other association of individuals; and

(*b*) "director", in relation to a firm, means a partner in the firm.

68. Offences by society, trust or university.

(*1*)Where an offence under this Act has been committed by a society or trust or university, every person who at the time the offence was committed was in charge of, and was responsible to, the society or trust or university for the conduct of the business of the society or trust or university, as well as the society or trust or university, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act, if he proves that the offence was committed without his knowledge or that he has exercised all due diligence to prevent the commission of such offence.

(*2*)Notwithstanding anything contained in sub-section(*1*), where an offence under this Act has been committed by a society or trust or university and it is proved that the offence has been committed with the consent or connivance of, or is attributable to, any neglect on the part of any governors, vice-chancellor, directors, committee, trustees, registrar or other officer, such governors, vice-chancellor, directors, committee, trustees, registrar or other officer shall also be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

69. Offences by Government Departments.

(*1*)Where an offence under this Act has been committed by any Department of Government, the Head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(*2*)Notwithstanding anything contained in sub-section(*1*), where an offence under this Act has been committed by a Department of Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the Head of the Department, such officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

70. Cognizance of offences.

(*1*)No court shall take cognizance of any offence punishable under this Act or the rules or regulations made thereunder save on a complaint made by the Authority or any officer or person authorised by it.

(*2*) No court inferior to that of a Chief Metropolitan Magistrate or a Chief Judicial Magistrate shall try any offence punishable under this Act.

CHAPTER XIII
FINANCE, ACCOUNTS, AUDITS AND REPORTS

71. Grants by Central Government.

The Central Government may, after due appropriation made by Parliament by law in this behalf, make to the Authority, grants of such sums of money as the Central Government may think fit for being utilised for the purposes of this Act.

72. Other fees and revenue.

The fees or revenue collected by the Authority shall be credited to the Consolidated Fund of India and the entire amount so credited may, after due appropriation made by Parliament by law in this behalf, be transfered to the Authority.

73. Budget, accounts and audit.

(*1*)The Authority shall prepare a budget, maintain proper accounts and other relevant records and prepare an annual statement of accounts in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor- General of India.

(*2*)The accounts of the Authority shall be audited by the Comptroller and Auditor-General of India at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Authority to the Comptroller and Auditor-General of India.

(*3*) The Comptroller and Auditor-General of India and any person appointed by him in connection with the audit of the accounts of the Authority under this Act shall have the same rights and

privileges and authority in connection with such audit as the Comptroller and Auditor-General of India generally has in connection with the audit of Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers, and to inspect any of the offices of the Authority.

(*4*) The accounts of the Authority, as certified by the Comptroller and Auditor-General of India or any other person appointed by him in this behalf, together with the audit report thereon shall be forwarded annually to the Central Government by the Authority and the Central Government shall cause the audit report to be laid, as soon as may be after it is received, before each House of Parliament.

74. Annual report.

(*1*) The Authority shall prepare once in every year, in such form and at such time as may be prescribed by the Central Government, an annual report giving,—

(*a*) a description of all the activities of the Authority for the previous year;

(*b*) the annual accounts for the previous year; and

(*c*) the programmes of work for the coming year.

(*2*) A copy of the report received under sub-section (*1*) shall be laid, as soon as may be after it is received, before each House of Parliament.

CHAPTER XIV
MISCELLANEOUS

75. Power of Central Government to issue directions.

(*1*) Without prejudice to the foregoing provisions of this Act, the Authority shall, in exercise of its powers or the performance of its functions under this Act, be bound by such directions on question of policy, other than those relating to technical and administrative matters, as the Central Government may give in writing to it from time to time:

Provided that the Authority shall, as far as practicable, be given an opportunity to express its views before any direction is given under this sub-section.

(*2*)The decision of the Central Government, whether a question is one of policy or not, shall be final.

76. Power of Central Government to supersede Authority.

(*1*) If, at any time the Central Government is of the opinion,—

(*a*) that, on account of circumstances beyond the control of the Authority, it is unable to discharge the functions or perform the duties imposed on it by or under the provisions of this Act; or

(*b*)that the Authority has persistently defaulted in complying with any direction given by the Central Government under this Act or in the discharge of the functions or performance of the duties imposed on it by or under the provisions of this Act and as a result of such default the financial position of the Authority or the administration of the Authority has suffered; or

(*c*)that circumstances exist which render it necessary in the public interest so to do, the Central Government may, by notification, supersede the Authority for such period, not exceeding six months, as may be specified in the notification and appoint a person or persons as the President may direct to exercise powers and discharge functions under this Act:

Provided that before issuing any such notification, the Central Government shall give a reasonable opportunity to the Authority to make representations against the proposed supersession and shall consider the representations, if any, of the Authority.

(*2*) Upon the publication of a notification under sub-section(*1*) superseding the Authority,—

(*a*) the Chairperson and other members shall, as from the date of supersession, vacate their offices as such;

(*b*)all the powers, functions and duties which may, by or under the provisions of this Act, be exercised or discharged by or on behalf of the Authority shall, until the Authority is reconstituted under sub-section(*3*), be exercised and discharged by the person or persons referred to in sub-section(*1*); and

(*c*)all properties owned or controlled by the Authority shall, until the Authority is reconstituted under sub-section (*3*), vest in the Central Government.

(*3*)On or before the expiration of the period of supersession specified in the notification issued under sub-section (*1*), the Central Government shall reconstitute the Authority by a fresh appointment of its Chairperson and other members and in such case any person who had vacated his office under clause(*a*) of sub-section(*2*) shall not be deemed to be disqualified for re-appointment.

(*4*)The Central Government shall cause a copy of the notification issued under sub-section (*1*) and a full report of any action taken under this section and the circumstances leading to such action to be laid before each House of Parliament at the earliest.

77. Bar of jurisdiction.

No civil court shall have jurisdiction in respect of any matter which the Appellate Tribunal is empowered by or under this Act to determine and no injunction shall be granted by any court or other authority in respect of any action taken or to be taken in pursuance of any power conferred by or under this Act.

78. Members and staff of Authority to be public servants.

The Chairperson, Members, Chief Regulatory Officers, other officers and other employees of the Authority shall be deemed, when acting or purporting to act in pursuance of any of the provisions of this Act, to be public servants within the meaning of section 21 of the Indian Penal Code.

79. Protection of action taken in good faith.

No suit, prosecution or other legal proceedings shall lie against the Central Government, the Authority and other bodies constituted under this Act or any officer of the Central Government, or any Member, Chief Regulatory Officers and other officers or other employees of such Authority and bodies or any other officer acting under this Act for anything which is in good faith done or intended to be done under this Act or the rules or regulations made thereunder.

80. Provisions of this Act not to apply to the Drugs and Cosmetics Act, 1940 and the Food Safety and Standards Act, 2006.

Nothing contained in this Act shall apply to the clinical trials of drug as defined under clause (*b*) of section 3 of the Drugs and Cosmetics Act, 1940 or food or food additive or any material or thing which is covered under the Food Safety and Standards Act, 2006.

81. Act to have overriding effect.

Save as otherwise provided, the provisions of this Act shall have effect, notwithstanding anything inconsistent therewith contained in any other law for the time being in force or in any instrument having effect by virtue of any law other than this Act.

82. Power to make rules.

(*1*)The Central Government may, by notification in the Official Gazette, make rules for carrying out the provisions of this Act.

(*2*)In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

(*a*)powers and functions of the Authority which may be exercised and discharged by the Chairperson under sub-section(*1*) of section 8;

(*b*) powers and functions which may be exercised and discharged by the Chairperson as the chief executive of the Authority under sub-section (*3*) of section 8;

(*c*) the form and the manner in which, and the authority before whom, the oath of office and of secrecy to be subscribed by the Chairperson and every Member under sub-section (*2*) of section 9;

(*d*) the salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and Members under sub-section (*4*) of section 9;

(*e*)the salaries, allowances and pensions payable to, and other conditions of service of the Chief Regulatory Officers, other officers and employees of the Authority, under sub-section (*2*) of section14;

(*f*) the other functions of the Inter-Ministerial Governing Board under subsection (*6*) of section 15;
(*g*) the manner in which members of the Biotechnology Advisory Council referred to in clauses(*b*) to (*l*) of sub-section(*2*) of section 16 shall be appointed under sub-section (*3*) of that section;
(*h*) the other functions of the Biotechnology Advisory Council to be specified under sub-section(*6*) of section 16;
(*i*) the times and places at which the meetings of the Inter-Ministerial Governing Board and the Biotechnology Advisory Council to be held and procedures to be observed in regard to the transaction of business at its meetings, (including the quorum) under section 17;
(*j*) the books of account and other documents which the persons referred to in clause(*a*) of sub-section (*1*) of section 19 shall maintain under sub-section(*3*) of that section;
(*k*) the form and manner in which and the authority before whom the oath of office and of secrecy to be subscribed by every Chief Regulatory Officer under sub-section(*5*) of section 21;
(*l*) the members of the Environment Appraisal Panel, their qualifications and experience under sub-section (*1*) of section 26;
(*m*) the manner in which the Authority shall provide technical or financial assistance or such other assistance as may be necessary, for the establishment of State Biotechnology Regulatory Advisory Committee, and, discharge of its functions, under sub-section(*7*) of section 35;
(*n*) the form and manner in which, and the fees along with which, the appeal shall be preferred and the particulars which such appeal shall contain, under sub-section(*2*) of section 43;
(*o*) the rules regulating generally the practices and procedure of the Appellate Tribunal in respect of matters specified under clauses (*a*) to (*c*) of sub-section (*4*) of section 45;
(*p*)the manner in which the part-time expert Members of the Appellate Tribunal on the recommendations of the Selection Committee shall be appointed under sub-section(*3*) of section 47;
(*q*) the salaries and allowances payable to, and the other terms and conditions of service (including pension, gratuity and other retirement benefits) of, the Chairperson and allowance and fee payable to part-time expert Member of the Appellate Tribunal under section 50;
(*r*) the procedure for inquiry, for removal of the Chairperson of the Appellate Tribunal, under sub-section(*4*) of section 52;
(*s*) the manner in which the recruitment of the officers and other employees of the Appellate Tribunal shall be made under sub-section(*2*) of section 54;
(*t*)the salaries and allowances and other terms and conditions of service of the officers and employees of the Appellate Tribunal under sub-section (*4*) of section 54;
(*u*) the financial and administrative powers of the Chairperson of the Appellate Tribunal as may be vested in him under section 55;
(*v*)such other matters in respect of which the Appellate Tribunal shall have power, for the purposes of discharging its functions under this Act, under clause (*j*) of sub-section(*4*) of section 57;
(*w*)the form in which the Authority shall prepare a budget, maintain proper accounts and other relevant records and prepare an annual statement of accounts under sub-section(*1*) of section 73;
(*x*)the form in which and time at which the Authority shall prepare an annual report under sub-section(*1*) of section 74;
(*y*) any other matter which is required to be, or may be, specified by rules or in respect of which provision is to be made by rules.

83. Power to make regulations.

(*1*) The Authority may, by notification, make regulations in consistent with this Act and the rules made thereunder to carry out the purposes of this Act.
(*2*) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for all or any of the following matters, namely:—

(*a*)the times and places of meetings of the Authority and the rules of procedure to be observed by the Authority in regard to the transaction of business at its meetings (including quorum at such meeting) under sub-section(*1*) of section 12;
(*b*)measures to regulate the research, transport, import, manufacture and use of organisms and products referred to in clauses (*a*) to (*k*) of sub-section(*2*) of section 18;
(*c*) the other qualifications of the Chief Regulatory Officer under sub-section(*3*) of section 21;
(*d*) the duties and functions of the Chief Regulatory Officer under sub-section(*4*) of section 21;
(*e*)the manner of maintenance of roster of qualified scientific experts in each regulatory division under sub-section(*8*) of section 21;
(*f*)the qualifications of the scientific officers of the Risk Assessment Unit and the manner of undertaking science based safety assessment under section 22;
(*g*) the manner of constitution of Enforcement Unit for enforcing the decision of the Authority under sub-section(*1*) of section 23;
(*h*) the form and manner for submission of application for the purpose of obtaining authorisation for research, transport or import of organisms and products, the fee payable therewith and the documents and information to be accompanied with such applications under sub-section(*1*) of section 24;
(*i*) the manner of constitution of a Product Rulings Committee under sub-section (*1*) of section 25;
(*j*) the fee and allowances payable to the qualified scientific experts in the roaster of experts under sub-section(*4*) of section 25;
(*k*) the procedure to be observed by the Product Rulings Committee in regard to transaction of business at the meetings, including the quorum, under sub-section(*6*) of section 25;
(*l*) the form and manner for submission of application for the purpose of obtaining authorisation for the manufacture or use of organisms and products, the fee payable therewith and the documents and information to be accompanied with such applications under sub-section(*1*) of section 27;
(*m*) the manner of constitution of one or more Scientific Advisory Panels under section 29;
(*n*) the manner of seeking advise from any Member of Scientific Advisory Panel from the roster of experts under section 30;
(*o*) the safeguards subject to which the Authority may permit clinical trials or field trials of organisms and products under section 34;
(*p*) the manner of convening by the Chairperson of the Authority, the annual meeting of a State Biotechnology Regulatory Advisory Committee under section 36;
(*q*) the qualifications and experience of Monitoring Officers under sub-section(*2*) of section 38;
(*r*) the agencies which may accredit the laboratories or research institutions under section 41;
(*s*) the organisations or the agencies to be designated by the Authority, and the activities relating to safety of modern biotechnology, the compliance of, which shall be ensured for the purposes of auditing notified laboratories or research institutions under sub-section(*1*) of section 42;
(*t*) the criteria which an organisation or agency shall fulfil, to be designated as auditor, under sub-section(*2*) of section 42;
(*u*) any other matter which is required to be, or may be, specified by regulations or in respect of which provision is to be made by regulations.

84. Power to amend Schedule I.

The Central Government, after consultation with the Authority and after giving, by notification in the Official Gazette, not less than three months' notice of its intention to do so, may, by like notification, add to or otherwise amend the Schedule I of this Act for the purposes of this Act and thereupon the said Schedule shall be deemed to be amended accordingly.

85. Rules, regulations and notifications to be laid before Parliament.

Every rule and every regulation made under this Act and every notification issued under section 84, shall be laid, as soon as may be after it is made, or issued, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or

more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or notification or both Houses agree that the rule or regulation or notification should not be made or issued, the rule or regulation or notification shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation or notification.

86. Application of other laws not barred.

The provisions of this Act shall be in addition to, and not in derogation of, any other law for the time being in force.

87. Amendment of certain enactments and savings.

(*1*)The enactments specified in Parts I and II of the Schedule II to this Act shall be amended in the manner specified therein and such amendments shall take effect from such date as the Central Government may, by notification, specify and such amendments shall not affect—

(*a*)the previous operations of the enactment under repeal or anything duly done or suffered thereunder; or

(*b*)any right, privilege, obligation or liability acquired, accrued or incurred under any of the enactment or orders; or

(*c*)any penalty, forfeiture or punishment incurred in respect of any offences committed against the enactment; or

(*d*)any investigation or remedy in respect of any such penalty, forfeiture or punishment, and any such investigation, legal proceedings or remedy may be instituted, continued or enforced and any such penalty, forfeiture or punishment may be imposed, as if this Act had not been passed.

(*2*)If there is any other law for the time being in force in any State corresponding to this Act, the same shall upon the commencement of this Act, stand repealed and in such case, the provisions of section 6 of the General Clauses Act, 1897 shall apply as if such provisions of the State law had been repealed.

(*3*)Notwithstanding the repeal of enactment specified under sub-section(*2*), the licenses issued under any such enactment or order, which are in force on the date of commencement of this Act, shall continue to be in force till the date of their expiry for all purposes, as if they had been issued under the provisions of this Act or the rules made thereunder.

88. Power to remove difficulties.

(*1*)If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order, published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as may appear to be necessary for removing the difficulty:

Provided that no order shall be made under this section after the expiry of two years from the date of commencement of this Act.

(*2*) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

SCHEDULE I

(*See* section 18)

PART I

1. Organisms and products mentioned under sub-paragraphs (*a*) to (*d*) of this Part which shall be regulated by the Authority**—**

(*a*) any genetically engineered plant, animal, micro-organism, virus or other animate organism that may have application in agriculture, fisheries (including aquaculture), forestry or food production;

(*b*) any genetically engineered plant, animal, micro-organism, virus or other animate organism used as food;

(*c*) any animal clones that may have application in agriculture, fisheries or food production;

(*d*) genetically modified or engineered food and foods containing such ingredients.

PART II

2. Organisms and products mentioned under sub-paragraphs (*a*) to (*j*) of this Part which shall be regulated by the Authority—

(*a*) recombinant proteins and combinations thereof;

(*b*) DNA vaccines intended to induce or increase an antigen specific immune response for prophylactic or therapeutic immunization, regardless of the composition or method of manufacture;

(*c*) vaccines for use in humans or animals that contain living genetically engineered organisms;

(*d*) cellular products, including products composed of human, bacterial or animal cells (such as pancreatic islet cells for transplantation), or from physical parts of those cells (such as whole cells, cell fragments, or other components intended for use as preventative or therapeutic vaccines);

(*e*) recombinant gene therapy products including nucleic acids, viruses, or genetically engineered micro-organisms that mediate their effect by transcription and/or translation of the transferred genetic material, and/or by integrating into the host genome and cells may be modified in these ways *ex vivo* for subsequent administration to the recipient, or altered *in vivo* by gene therapy products administered directly to the recipient;

(*f*) transgenic blood or plasma derived products;

(*g*) stem cell based products;

(*h*) RNA interference (RNAi) based products;

(*i*) products of synthetic biology for human or animal use;

(*j*) any products that include as a component of a product from categories(*a*) to (*i*) above.

PART III

3. Organisms and products mentioned under this Part which shall be regulated by the Authority.

Any genetically engineered plant, animal, micro-organism, virus or other animate organism that may be released into the environment, excluding the provisions of Parts I and II of this Schedule, or have application in industrial production or manufacturing processes.

SCHEDULE II

(*See* section 87)

PART I

AMENDMENTS TO THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

After section 37, the following section shall be inserted, namely:—

"37A. Nothing contained in this Act shall apply to the genetically modified or engineered organisms or any matter or thing connected with it to which are covered under the Biotechnology Regulatory Authority of India Act, 2013.".

PART II

AMENDMENTS TO THE FOOD SAFETY AND STANDARDS ACT, 2006

(34 OF 2006)

1. In section 3, in sub-section(*1*), in clause (*j*), after the proviso, the following *Explanation* shall be substituted, namely:—

'*Explanation.*— For the purposes of this clause "genetically modified or engineered food or food containing such ingredients" means food and food ingredients composed of, or containing, or produced from but not containing genetically modified or engineered organism obtained through modern biotechnology and approved to be safe for human consumption by the Biotechnology Regulatory Authority of India under the provisions of the Biotechnology Regulatory Authority of India Act, 2013.'.

2. In section 13, in sub-section(*3*), clause (*c*) shall be omitted.

3. In section 22, in the *Explanation*, for clause(*2*) the following clause shall be substituted, namely:—

'(*2*) "Genetically modified or engineered food or food containing such ingredients" means food and food ingredients composed of, or containing, or produced from but not containing, genetically modified or engineered organism obtained through modern biotechnology and approved to be safe for human consumption by the Biotechnology Regulatory Authority of India under the provisions of the Biotechnology Regulatory Authority of India Act, 2013.'.

4. After section 98, the following section shall be inserted, namely:—

"98A. Nothing contained in this Act shall apply to the genetically modified or engineered organisms or any matter or thing connected with it to which are covered under the Biotechnology Regulatory Authority of India Act, 2013.".

STATEMENT OF OBJECTS AND REASONS

Modern biotechnology is recognised globally as a rapidly advancing science wherein advanced molecular techniques and processes are employed to develop useful products, processes and services in areas of agriculture, human and animal healthcare, environment management and industry. There are large number of biotech products already in the market and many more of such products are in the pipeline *viz.* therapeutic biotech drugs; vaccines; genetically modified crops with resistance to pests and diseases, drought and salinity and with enhanced nutritional factors. Biotechnology industry in India has been growing at an average annual rate of twenty to thirty per cent. during the last five years and its turnover during 2011-12 exceeded Rs. 20,440.00 crores approximately. The potential of biotechnology with respect to food security, public health, employment generation, intellectual wealth creation, expanding entrepreneurial opportunities and augmenting industrial growth warrants a focused approach towards innovation, regulation and commercialisation.

2. There are public concerns in respect of organisms and products derived from modern biotechnology on human, animal and environmental safety. Various countries have developed regulatory mechanisms to ensure safe and responsible use of biotechnology organisms and products. In India, activities and processes involving the genetically engineered organisms and products thereof, are at present, broadly regulated under the rules titled as ''Rules for Manufacture, Use/Import/Export and Storage of hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989'' notified under the Environment (Protection) Act, 1986 and the guidelines published by the Department of Biotechnology in the Ministry of Science and Technology.

3. Subsequent to making of aforesaid rules and publication of guidelines biotechnology regulatory system in India has experienced a number of challenges. The Task Force on the Application of Agriculture Biotechnology constituted by the Ministry of Agriculture in 2003 recommended the establishment of an ''autonomous, statutory and professionally-led National Biotechnology Regulatory Authority'' for generating the necessary public, political, professional and commercial confidence in the science-based regulatory mechanism. Subsequently, the other Task Force constituted by Ministry of Environment and Forests in 2004 on recombinant pharma also supported the establishment of the Biotechnology Regulatory Authority.

4. India is a party to the United Nations Convention on Biological Diversity signed at Rio de Janeiro on the 5th day of June, 1992 which came into force on the 29th December, 1993; and Cartagena Protocol on Biosafety to the Convention which was adopted in Montreal on the 29th September, 2000 and came into force on the 11th September, 2003.

5. In order to implement the recommendations of the aforesaid Task Forces, and to give effect to certain provisions of the aforesaid Convention and Protocol, it has been decided to establish an independent statutory regulator to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology so as to keep pace in regulatory measures with the rapid technology advancement in the field of modern biotechnology and at the same time ensure safety to human and animal health and the environment.

6. The proposed statutory independent regulator that is the Biotechnology Regulatory Authority of India (BRAI) would be a nodal agency of the Government of India to ensure comprehensive safety assessment of organisms and products of modern biotechnology.

Commercialisation of biotechnology products in agriculture and healthcare would be subject to all other laws whether Central or State, for the time being in force and the rules and regulations made thereunder. The organisational plan of the Authority also provides collaborative arrangements, co-ordination and mechanisms with other existing regulatory agencies. The Biotechnology Regulatory Authority of India proposed to be established under the proposed legislation would regulate the trials preceding the clinical trials in the health sector and present mechanism for regulating clinical trials would continue.

7. The Biotechnology Regulatory Authority of India Bill, 2013, *inter alia,* provides for the following, namely:—

(a) establishment of the Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology;

(b) constitution of Inter-Ministerial Governing Board to oversee the performance of the Authority;

(c) constitution of Biotechnology Advisory Council to render strategic advice to the Authority on the matters relating to developments in modern biotechnology and their implications in India;

(d) providing for Regulatory Divisions of the Authority dealing with agriculture, forest and fisheries, human health and veterinary products and industrial and environmental applications for implementation of safety assessment procedures and processes;

(e) constitution of Risk Assessment Unit comprising of scientific officers, product rulings committee and environmental appraisal panel for elaborate risk assessment process involving scientific experts and representatives of concerned Ministries including a special public review system for evaluation of applications before final approvals;

(f) constitution of the State Biotechnology Regulatory Advisory Committee to act as nodal agency between the State Government and the Authority in respect of matters related to the regulation of modern biotechnology;

(g) provides for notification by the Authority of accredited laboratories and research institutions by the Authority for the purposes of proposed legislation;

(h) provides for Biotechnology Regulatory Appellate Tribunal consisting of full-time Chairperson who has been a Judge of the Supreme Court of India or a Chief Justice of a High Court and part-time expert members not exceeding five to hear the appeals against the decision or order or direction of the Authority;

(i) provides for offences and penalties for contravening the provisions of the proposed legislation;

(j) empower the Central Government to supersede the Authority in certain circumstances.

8. The notes on clauses explain in detail various provisions in the Bill.

9. The Bill seeks to achieve the above objectives.

NEW DELHI; S. JAIPAL REDDY

The 11*th March*, 2013.

Notes on clauses

Clause 1.—This clause provides for short title, extent and commencement. It provides that the proposed legislation will extend to whole of India. It further provides that any reference made in the proposed legislation, to a law which is not in force in the State of Jammu and Kashmir, shall in relation to that State be construed as a reference to the corresponding law, if any, in that State. It is also proposed to empower the Central Government to bring it into force on such date as it may appoint by notification in the Official Gazette and the Central Government may notify different dates for different provisions of the proposed legislation.

Clause 2.—This clause makes the Declaration as to expediency of control by Union. It proposes to declare that it is expedient in the public interest that the Union should take under its control the regulation of organisms, products and processes of modern biotechnology industry.

Clause 3.—This clause seeks to define certain expressions used in the proposed legislation. These definitions *inter alia,* include "animal clones", "Biotechnology", "clinical trial", "conjugation", "environmental release", "modern biotechnology", "mutation breeding", "organism", "polyploidy induction", "transduction", "use", etc.

Clause 4.—This clause provides for the establishment of Biotechnology Regulatory Authority of India which shall be a body corporate and having its headquarters in the National Capital Region. It further provides for establishing branch offices at any other place in India with prior approval of the Central Government.

Clause 5.—This clause contains provision for composition of Authority. It provides that the Authority shall consist of a Chairperson, two whole-time members and two part-time members to be appointed by the Central Government.

Clause 6.—This clause provides for qualifications for appointment of Chairperson and Members. It provides that the Chairperson of the Authority shall be a person of ability, integrity and outstanding scientific calibre with a doctorate degree or equivalent degree in the field of biological sciences or a postgraduate degree in medical sciences from a university recognised by the University Grants Commission or a university or institute established by law for the time being in force, and having not less than twenty years' experience in a leadership role in a scientific organisation, scientific institution or scientific agency, or similar organisation or institution or agency, out of which at least five years should be as head of the organisation or institution or agency or unit or division.

It further provides that a Member, shall be a person of ability, integrity and outstanding scientific calibre with a doctorate degree or equivalent degree in the field of biological sciences or a postgraduate degree in medical sciences from a university recognised by the University Grants Commission or established by law for the time being in force, and having not less than fifteen years' experience in a leadership role in a scientific organisation, scientific institution or scientific agency or unit or division and the Central Government shall, while appointing the Members, ensure that one such Member has requisite knowledge and experience in the fields of molecular biology, health care, agriculture and environment biotechnology and areas connected therewith respectively.

It further provides that the Chairperson and Members of the Authority shall be appointed on the recommendation of the Selection Committee constituted under sub-clause (*1*) of clause 7 and the Chairperson or the whole-time Member of the Authority shall not hold any other office during the period of holding his office as such.

It also provides that the Central Government shall, within a period of two months from the date of occurrence of any vacancy in the office of the Chairperson or Member, by reason of death, resignation or removal of the Chairperson or a Member and six months before the superannuation or completion of the term of office of the Chairperson or a Member, make a reference to the Selection Committee constituted under clause 7 for filling up of such vacancy.

Clause 7.—This clause provides for constitution of Selection Committee for selection of Chairperson and Members. It provides that the Central Government shall, for the purpose of selection of the Chairperson and Members, constitute a Selection Committee consisting of Cabinet Secretary as Chairperson of the Selection Committee; Secretaries-in-charge of each Ministry or the Department of the Central Government dealing with health research, Agriculture, Bio-technology, Environment, Personnel and two eminent biotechnologists nominated by the Central Government as its Members.

It further provides that a scientist not below the rank of Grade 'G' in the Department of Biotechnology in the Ministry of Science and Technology as convenor of the meetings of the Selection Committee.

It further provides that the Selection Committee shall finalise the selection of the Chairperson and Members of the Authority within two months from the date on which the reference is made to it under sub-clause (*5*) of clause 6 and the Selection Committee shall recommend a panel of two names for every vacancy referred to it.

It further provides that before recommending any person for appointment as a Chairperson or a Member of the Authority, the Selection Committee shall satisfy itself that such person does not have any financial or other conflict of interest, which is likely to affect prejudicially his functions as Chairperson or Member and also provides that no appointment of the Chairperson or Member of the Authority shall be invalid merely by reason of any vacancy in the Selection Committee.

Clause 8.—This clause lays down the functions of the Chairperson. It provides that the Chairperson shall be the Chief Executive of the Authority and empowered to exercise all powers and do all acts and things to be exercised or done by the Authority. Various responsibilities of the Chairperson *inter alia* include day to day administration of the authority, implementing work programmes and decisions, preparing the statement of revenue and expenditure, approving financial expenditure and submission of the annual report of the Authority.

Clause 9.—This clause provides for the term of office and other conditions of service of Chairperson and Members. It provides that the Chairperson and other Members shall hold office for a term of three years from the date on which they enter upon their offices, and shall be eligible for re-appointment for a further period of three years and provides that the Chairperson or a Member shall not hold office as such after he has attained the age of sixty-five years.

It further provides that the Chairperson and every Member shall, before entering upon their office make and subscribe, to an oath of office and of secrecy, in such form and in such manner and before such authority as may be prescribed.

It further provides that any person holding any office (whether as an employee or an officer or a director or managing director or secretary or manager or in any other capacity) under the Central Government or State Government or in a company (including a Government Company referred to in section 617 of the Companies Act, 1956) or in any other institution, organisation, society or University or Board, shall, on his selection as the Chairperson or a whole-time Member, be required to seek retirement or resign from the services of such Central or State Government or company or institution or organisation or society or University or Board, as the case may be, before accepting the employment as the Chairperson or whole time Member.

It further provides that the salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and whole-time Members and allowances payable to part-time Members shall be such as may be prescribed by the Central Government but neither the salary and allowances nor the other terms and conditions of service of the Chairperson or a whole-time Member shall be varied to their disadvantage after their appointment.

It also provide that the Chairperson or Member may relinquish their office by giving in writing to the Central Government a notice of not less than three months or be removed from their office in accordance with the provisions of clause 11.

Clause 10.—This clause lays down restriction on Chairperson or Members on employment after cessation of office. It lays down that the Chairperson or a Member, ceasing to hold office as such, shall not, for a period of two years from the date on which they cease to hold office, accept any employment in, or connected with management or administration of, any person which has been associated with or granted authorisation for research, transport or import of organisms or products or manufacture or use of organisms and products under the proposed legislation.

It further lays down that nothing contained in this clause shall apply to, any employment under the Central Government or a State Government or local authority or in any Statutory authority or any corporation established by or under any Central, State or Provincial Act or a Government company as defined in section 617 of the Companies Act, 1956; act, for or on behalf of any person or organisation in connection with any specific proceeding or transaction or negotiation or a case to which the Authority is a party and with respect to which the Chairperson or such Member before cessation of their office had acted for, or provided advice to, the Authority; or, give advice to any person (including his client, business associate or employer) using information which was obtained in their capacity as the Chairperson or a Member and being not available or cannot be made

available to the public; or, for a period of two years from their last day in office, enter into a contract of service with, accept an appointment to a board of directors of, or accept an offer of employment with, an entity with which they had direct and significant official dealings during their term of office as such without the due approval of the Central Government.

It also lays down that the Chairperson and Members shall not communicate or reveal to any person any matter which has been brought under their consideration or known to them while acting as such.

Clause 11.—This clause contains the provisions relating to the removal of the Chairperson or a Member. It provides that the Central Government may, by order, remove from office, the Chairperson or a Member, in case he has been adjudged as insolvent, convicted of an offence or involved in moral turpitude or has become physically or mentally incapable or acquired financial or other interest likely to affect prejudicially his functions or abused his position prejudicially to the public. It also provides for giving a reasonable opportunity to Chairperson or Member before his removal.

Clause 12.—This clause provides for the procedures for meetings of the Authority. It provides for an alternate senior-most Member to preside at the meetings in case the Chairperson is unable to attend a meeting of the Authority. It makes provision for decisions to be made in the meeting of Authority by a majority vote of the Members present and voting. In the event of an equality of votes, the Chairperson or in his absence, the person presiding, shall have a second or casting vote. The Authority would observe such rules of procedure in regard to transaction of business which may be provided in the rules made by the Central Government.

Clause 13.—This clause provides that vacancies, etc., in the Authority will not invalidate proceedings of Authority. It provides that proceedings of the Authority shall not be invalidated merely because of reasons such as any vacancy in, or any defect in the constitution of the Authority or appointment of a person as a Member of the Authority or any irregularity in the procedure of the Authority not affecting the merits of the case.

Clause 14.—This clause contains provisions for Chief Regulatory Officers and other employees of the Authority. It provides for appointment of Chief Regulatory Officers, other officers and employees by the Authority. It further provides that the salaries, allowances, pensions, conditions of services of the Chief Regulatory Officers and other officers and employees of the Authority shall be provided by the rules made by the Central Government.

Clause 15.—This clause provides for constitution of Inter-Ministerial Governing Board. It provides that the Central Government shall, by notification, constitute an Inter-Ministerial Governing Board to promote Inter-Ministerial or Departmental co-operation required for the effective discharge of functions and performance of the Authority for the purposes of the proposed legislation. It further provides for composition of Inter-Ministerial Governing Board which would *inter alia* consist of concerned (a) Ministries and Departments of the Central Government, (b) research bodies such as Indian Council of Agricultural Research (ICAR), Indian Council of Medical Research (ICMR) and Council of Scientific and Industrial Research (CSIR), (c) other regulatory authorities such as the Drug Controller General of India; the Directorate of Plant Protection, Quarantine and Storage; the Food Safety and Standards Authority; and the Biotechnology Regulatory Authority of India. It further provides that no person below the rank of Additional Secretary to the Government of India or equivalent rank shall be appointed as a Member of the Inter-Ministerial Governing Board. It also provides that the Secretary, Department of Science and Technology shall be the Chairperson and one of the Members of the Authority shall be the convener of the Inter-Ministerial Governing Board.

Clause 16.—This clause provides for constitution of the Biotechnology Advisory Council. It provides that the Central Government shall, by notification, constitute a Biotechnology Advisory Council to render strategic advice to the Authority on the matters relating to developments in modern biotechnology and their implications in India. It provides that the Biotechnology Advisory Council shall consist of a Presiding Officer and members not exceeding fifteen representing, *inter alia,* the

scientific experts in various disciplines from public and private sectors, consumer affairs organisations, farmers organisations, economist, ethicist, and legal experts. It further seeks to provide that members to the Biotechnology Advisory Council shall be appointed on the recommendations of the Inter-Ministerial Governing Board according to specific criteria such as expertise, knowledge, and experience, so as to secure the highest standards of competence, relevant expertise, and the broadest possible geographic representation within the country. It further provides that the Chairperson of the Authority would be the Presiding Officer of the Biotechnology Advisory Council and one of the Members of the Authority shall be the convener and appointment of the members shall be for a term of three years with eligibility for re-appointment for a further period of three years.

It also provides that the expenses for attending the meetings of the Biotechnology Advisory Council (including travel expenses and sitting fee) or any other allowances incurred by the members would be borne by the Authority.

Clause 17.—This clause deals with the provisions of meetings of Inter-Ministerial Governing Board and Biotechnology Advisory Council. It provides that the Inter-Ministerial Governing Board and the Biotechnology Advisory Council shall meet at such times and places, and shall observe such procedures in regard to the transaction of business at their meetings, (including the quorum), as may be prescribed by rules.

Clause 18.—This clause provides for the functions and powers of Authority. It *inter alia* provides that it shall be the duty of the Authority to regulate the research, transport, import, manufacture and use of organisms and products as specified in Schedule I so as to ensure the safety to human health, animal health and the environment. It further provides that the Authority shall provide scientific advice and technical support to the Central Government and State Governments in matters of framing the policy, develop and implement guidelines for safety assessment, establish a network of organisations to facilitate scientific co-operation, organise workshops and training programmes for State level personnel and other stakeholders, inform the public of all applications for field trials and all regulatory decisions made by the Authority, etc.

It also provides for the Authority to serve as a nodal agency for coordination of work on standards and guidance related to regulation of organisms and products of modern biotechnology and to promote consistency with international technical standards.

Clause 19.—This clause provides for the powers of the Authority to call for information, conduct investigation, etc. It, *inter alia,* states that where the Authority considers it expedient so to do, it may by order in writing call upon any person, who had submitted application under sub-section (*1*) of section 24 or under sub-section (*1*) of section 27 or who has been granted authorisation under sub-section (*1*) of section 24, or under sub-section (*1*) of section 27, or from any person engaged in activities relating to modern biotechnology, at any time to furnish in writing such information or explanation relating to its affairs as the Authority may require or appoint one or more persons to make an inquiry in relation to the affairs of any person, etc.

Clause 20.—This clause empowers the Authority to issue directions. It provides that the Authority shall have the power to issue directions to any person referred to in clause (*a*) of sub-clause (*1*) of clause 19 for proper safety of products or processes of modern biotechnology or which may be necessary for proper discharge of its functions or exercise of its powers under the proposed legislation.

Clause 21.—This clause relates to Regulatory Divisions of the Authority. It provides that the Authority shall have at least three Regulatory Divisions of the Authority with each division dealing with, (*i*) Agriculture, Forest and Fisheries; (*ii*) Human Health and Veterinary; and (*iii*) Industrial and Environmental Applications. It further provides that each division shall be headed by a Chief Regulatory Officer, who shall be a scientist of outstanding scientific caliber in relevant discipline. It further provides that the Chief Regulatory Officer shall not enter into a contract of service with, accept an appointment to a board of directors of, or accept an offer of employment with, an entity

with which he had direct and significant official dealings during his term of office without the due approval of the Central Government for a period of two years from his last day in office. This clause also provides for maintaining a roster of qualified scientific experts in such manner as may be specified by regulations.

Clause 22.—This clause seeks for constitution of Risk Assessment Unit. It provides that the Authority shall constitute a Risk Assessment Unit comprising of scientific officers possessing such qualifications, and to undertake science-based safety assessments in such manner, as may be specified by regulations.

Clause 23.—This clause provides for constitution of other Units by the Authority. It provides for constitution of an Enforcement Unit consisting of Monitoring Officers for enforcing the decisions of the Authority. It also provides for setting up of such other units as may be necessary from time to time.

Clause 24.—This clause provides for the procedure by Risk Assessment Unit for research, transport, or import of organisms or products. Sub-clause (*1*) of this clause provides that every person shall obtain authorisation under sub-clause (*3*) for other purpose of research, transport or import of organisms and products as specified in Schedule I and submit for the said purpose an application to the Authority. Sub-clause (*2*) of this clause provides that on receipt of the application under sub-section (*1*), the Authority shall forward the application to the Risk Assessment Unit for science-based evaluation of the application and submit a clear assessment as to the safety of the proposed research, transport or import of such organisms or products to the Authority for giving authorisation with or without conditions. It further empowers the Authority to suspend or cancel the authorisation if it is of the opinion that any condition of the authorisation has been violated, or the authorisation was obtained improperly or any new risks have emerged for continuation of the activity.

Clause 25.—This clause, *inter alia*, provides for the constitution of a Product Rulings Committee. It provides for constitution of a Product Rulings Committee for the purpose of making recommendations for manufacture or use of organisms and products as specified in Schedule I to the proposed legislation. It further provides that the Product Rulings Committee shall be comprised of (*i*) one of the Members nominated by the Authority as its Chairperson (*ii*) all the Chief Regulatory Officers of the Regulatory Divisions (*iii*) one representative from the Central Drugs Standards Control Organisation to be nominated by the Ministry of Health; and (*iv*) at least three and not exceeding five experts to be appointed by the Authority, whose names appear as qualified scientific experts in the roster of experts maintained under sub-clause (*8*) of clause 21. It further provides for meetings of the Product Rulings Committee at least once in every three weeks.

Clause 26.—This clause provides for constitution of Environment Appraisal Panel or application of law relating to protection of environment. It provides that the Authority shall constitute, in consultation with the Union Ministry of Environment and Forests, a panel to be known as the Environment Appraisal Panel, consisting of a Chairperson to be nominated by Ministry of Environment and Forests; other members not exceeding five and a Member Secretary to be nominated by the Ministry of Environment and Forests having such qualifications and experience as may be prescribed. It further provides that the said Appraisal Panel would regulate its own procedure for the purpose of conducting its meeting (including quorum) and making recommendations relating to environmental safety of organisms and products as may be referred to it by the Authority.

Clause 27.—This clause lays down the procedure for grant of authorisation for manufacture or use of organisms and products. It provides that every person shall obtain authorisation for the purpose of manufacture or use of organisms and products specified in Parts I, II (except products covered under drug as defined under clause (*b*) of section (*3*) of the Drugs and Cosmetics Act, 1940) and III of Schedule I, and submit for the said purpose an application in the form and manner, along with such fee and accompanied by such documents and information as may be specified by regulations.

It further provides that on receipt of the application for the manufacture or use of organisms and products specified under Parts I, II (except products covered under drug as defined under clause (*b*) of section (*3*) of the Drugs and Cosmetics Act, 1940) and III of Schedule I, the Authority shall forward the application to the Risk Assessment Unit which shall undertake a science-based evaluation of the application and submit its risk assessment report as to the safety of the proposed manufacture and use or organisms or products to the Authority.

It further provides that the Authority, on receipt of the risk assessment report, as to the safety for manufacture or use of organisms and products, shall forward the said risk assessment report of the Risk Assessment Unit to the Product Rulings Committee for giving its recommendations thereon, as to the safety of organisms and products.

It also provides that the Authority shall consider the recommendations of Product Rulings Committee and all relevant matters in addition to the risk assessment report submitted by Risk Assessment Unit before authorising the manufacture or use with or without conditions.

Clause 28.—This clause relates to disclosure of confidential commercial information. It seeks to provide for retaining confidential commercial information submitted by the applicant by not disclosing to any other party. This clause also confers power upon the Authority to refuse to retain the information referred above as confidential commercial information, if the Authority is satisfied that the public interest outweighs the disclosure or such disclosure shall not cause harm to any person.

Clause 29.—This clause provides for constitution of Scientific Advisory Panels and Roster of Experts. It provides that the Authority may constitute one or more Scientific Advisory Panels, from the roster of experts referred to in sub-clause (*8*) of clause 21 in such manner as may be specified by regulations, to provide scientific advice, information and recommendations to the Authority under the proposed legislation on biotechnology issues which may result from regulatory actions of the Authority and would have an impact on the safety of human health, animal health and the environment.

Clause 30.—This clause contains provisions for seeking advice from Scientific Advisory Panels and Roster of Experts. It provides that the Authority may, for the purpose of obtaining scientific advice and technical support on any issue relating to modern biotechnology, without prejudice to the other provisions of the proposed legislation, may seek advice from any member of Scientific Advisory Panel in such manner as may be specified by regulations.

Clause 31.—This clause contains provisions for authentication of decisions or orders. It provides for authentication of orders, etc., of the Authority by the signature of the Chairperson or any other officer of the Authority so authorised by the Chairperson.

Clause 32.—This clause relates to the delegation of powers. It provides for delegation of specified powers and function to the Chairperson or any Member or any officer of the Authority (except the power to make regulations under clause 83 under the proposed legislation) as the Authority may consider necessary.

Clause 33.—This clause provides for application of law relating to customs and powers of Custom Officers. It provides that the Commissioner of Customs or any officer of the Government authorised by the Central Government in this behalf, may detain any imported package which he suspects to contain any organisms and products specified under Part I, Part II [except products covered under drug as defined under clause (*b*) of section 3 of the Drugs and Cosmetics Act, 1940] and Part III of Schedule I and the import of which requires the approval of the Authority under Chapter V, and shall forthwith report such detention to the Authority, and, if necessary, forward, with the approval of the Authority, the package or sample of any suspected organisms and products found therein to the laboratory notified or research institution accredited under this Act.

Clause 34.—This clause seeks to provide for field trials. It provides that no person shall conduct field trials in respect of any organisms or products specified in Part I and Part III of Schedule I to the Bill, unless permitted by the Authority.

Clause 35.—This clause relates to the establishment of State Biotechnology Regulatory Advisory Committees. It enumerates the composition and functions of State Biotechnology Regulatory Advisory Committees. It provides that every State Biotechnology Regulatory Advisory Committee shall be convened by the State Department of Biotechnology or Biotechnology Commission or the State Department of Science and Technology, in case there is no State Department of Biotechnology or Biotechnology Commission exists and the Secretary or Commissioner or head of such Department or Commission shall preside over such State Biotechnology Regulatory Advisory Committees.

It further provides that State Biotechnology Regulatory Advisory Committee shall act as the nodal agency for interactions between the State Government and the Authority in respect of matters related to the regulation of modern biotechnology under the provisions of the proposed legislation and the rules proposed thereunder and also facilitate interdepartmental co-ordination in respect of biotechnology regulation within the State.

It further provides that the State Biotechnology Regulatory Advisory Committee will also identify state-specific needs related to the regulation of modern biotechnology and communicate the same to the Authority and it will collaborate with the Authority for undertaking capacity building and information sharing activities relating to biotechnology to ensure that information relating to activities and programmes of the Authority are communicated in a transparent and accessible fashion within the State.

It also provides for technical and financial support by the Authority for the establishment of the State Biotechnology Regulatory Advisory Committee in each State and also provides that every State Biotechnology Regulatory Advisory Committee prepare and publish an annual report which it would make available to the State, the Authority and the public.

Clause 36.—This clause provides for the convening of meetings of State Biotechnology Regulatory Advisory Committees. It provides that an annual meeting of State Biotechnology Advisory Committees would be convened by the Chairperson of the Authority to identify priority issues and activities which the State Governments which may include programs and operations related to the regulation of modern biotechnology.

Clause 37.—This clause makes the Authority responsible for enforcement of the provisions of the proposed legislation and the regulations made thereunder.

Clause 38.—This clause contains provisions relating to Monitoring Officers. It provides for appointment of the Monitoring Officers, with such qualifications and experience relating to biotechnology as may be specified by regulations, for the purpose of exercising powers or performing functions under the proposed legislation. This clause also provides for establishing mechanisms in consultation with the concerned State Biotechnology Advisory Committees to facilitate enforcement of the proposed legislation and the rules made thereunder.

Clause 39.—This clause lays down for the functions of the Monitoring Officers. It provides that the Monitoring Officers shall undertake activities as directed by the Authority to ensure compliance of the provisions of the proposed legislation and rules and regulations made thereunder.

Clause 40.—This clause empowers the Monitoring Officers. It provides that the Monitoring Officer, for the purpose of discharging his functions under the proposed legislation, and if authorised by the Authority, in relation to products or processes regulated under the proposed legislation, will, enter and inspect any premises where such products and processes may be found; inspect, examine, take measurements of, or conduct tests on, or take samples of, anything on the premises which relates to products and processes; take photographs, make video or audio recordings of the premises or anything on the premises on which products and processes have been found and inspect any book, record or document on the premises.

It further empowers the Monitoring Officer to make entry upon, and inspect any place, except with the consent of the occupant of the premises or under the authority of a warrant, and, while doing so, he shall follow the procedure provided under the provisions of the Code of Criminal Procedure,

1973 relating to the search or inspection of a place by a police officer executing a search warrant under that Code.

Clause 41.—This clause relates to the notification of accredited laboratories and research institutions. It provides for notification of laboratories or research institutions for the purposes of the proposed legislation including those accredited by other agencies.

Clause 42.—This clause empowers the Authority to designate any organisation or agency as auditor. It provides that the Authority may designate one or more organisations or agencies as an auditor for the purpose of auditing notified laboratories and research institutions to ensure compliance with activities, relating to safety of modern biotechnology, as may be specified by regulations. It further provides that every person authorised by an organisation or agency recognised for the purpose of auditing, shall have a right of access on all working days to such notified laboratories and shall be entitled to obtain necessary information the auditor may consider necessary for the performance of his duties as auditor.

Clause 43.—This clause makes provision for filing appeal to the Appellate Tribunal. It provides that any person aggrieved by a decision or order or direction of the Authority may prefer an appeal against such order or decision to the Biotechnology Regulatory Appellate Tribunal within a period of thirty days from the date of the decision or order or direction is communicated to him, in such form and manner along with such fees and such particulars as may be prescribed by the Central Government.

Clause 44.—This clause makes provision for the establishment of the Appellate Tribunal. It provides that the Central Government shall, by notification, establish an Appellate Tribunal to be known as the "Biotechnology Regulatory Appellate Tribunal" to exercise the jurisdiction, powers and authority conferred upon it under the provisions of the proposed legislation.

Clause 45.—This clause provides for the composition of Appellate Tribunal. It provides that the Appellate Tribunal shall consist of a full-time Chairperson and part-time expert Members not exceeding five as notified by the Central Government. It further provides that any one or more person having specialised knowledge and experience in a particular case can be directed to assist the Appellate Tribunal in that case.

It further provides for the sitting of the Appellate Tribunal at such place or places, as specified by the Central Government. It also provides that the Central Government may, in consultation with the Chairperson of the Appellate Tribunal, make rules regulating generally the practices and procedure of the Appellate Tribunal including, rules as to the persons who would be entitled to appear before the Appellate Tribunal, rules as to the procedure for hearing appeals and other matters pertaining to the appeals; and the minimum number of members who would hear the applications and appeals in respect of any class or classes of appeals.

Clause 46.—This clause lays down the qualifications for appointment of Chairperson and part-time expert Members. It provides that a person shall be qualified for appointment as the Chairperson of the Appellate Tribunal, if such person is, or has been, a Judge of the Supreme Court of India or the Chief Justice of a High Court.

It further provides that a person shall be qualified for appointment as part-time expert Member, if such person is an eminent scientist in the field of biological or biotechnology related to healthcare or agriculture or environmental or industrial activities and possesses an experience of at least twenty years in the field, or who has held the post in the Central Government or a State Government dealing with biological or biotechnology related to healthcare or agriculture or environmental or industrial activities equivalent to the Joint Secretary to the Government of India for at least three years and possesses special knowledge in the field.

It also provides that the Chairperson and part-time expert Members of the Appellate Tribunal would not hold any other office during their tenure as such.

Clause 47.—This clause provides for appointment of Chairperson and part-time expert Members. It provides that the Central Government shall appoint the Chairperson in consultation with the Chief

Justice of India and part-time expert Members on the recommendations of the Selection Committee in the manner as may be prescribed by rules.

Clause 48.—This clause provides for term of office and other conditions of service of Chairperson and part-time expert Members. It provides that the Chairperson and part-time expert Member of the Appellate Tribunal shall hold office as such for a term of three years from the date on which they enter upon their office and shall not be eligible for re-appointment. It further provides that the Chairperson and the part-time expert Members shall not hold office as such after they attained the age of seventy years and sixty-five years, respectively.

Clause 49.—This clause provides for resignation. It provides that the Chairperson or part-time expert Member or of the Appellate Tribunal may, by notice in writing under their hand addressed to the Central Government, resign from their office.

Clause 50.—This clause makes provisions for salaries, allowances and other terms and conditions of service of Chairperson and Members. It provides that the salaries and allowances payable to, and the other terms and conditions of service (including pension, gratuity and other retirement benefits) of, the Chairperson and allowances and fee payable to part-time expert Members of the Appellate Tribunal shall be such as may be prescribed.

It further provides that neither the salary and allowances nor the other terms and conditions of service of the Chairperson shall be varied to their disadvantage after their appointment.

Clause 51.—This clause lays down the restriction on Chairperson or Members on employment after cessation of office as Chairperson or Member of the Appellate Tribunal. It provides that the Chairperson or a Member of the Appellate Tribunal, ceasing to hold office shall not hold office for a period of one year from the date on which they cease to hold office, accept any employment in, or connected with the management or administration of, any person which has been a party to a proceeding before the Appellate Tribunal under the proposed legislation. It further provides that the above said restriction shall not apply to any employment under the Central Government, State Government, local authority, any statutory authority or any corporation or a Government company.

It also provides for restrictions with respect to acting for, or, on behalf of persons or organisations in connection with any specific proceeding, transaction, negotiation or a case to which the Authority is a party or whose matter had been before such Chairperson or Member before cessation of his office.

It also contains provisions regarding restrictions on giving advice to any person using information obtained in the capacity as the Chairperson or a Member that is not publicly available and entering into a contract of service or accept an appointment to a board of directors of, or accept an offer of employment with, an entity whose matter had been before such Chairperson or Member without the due approval of the Central Government for a period of two years from his last day in office.

Clause 52.—This clause deals with the provisions relating to removal and suspension of Chairperson and part-time expert Member. It provides that the Central Government may, in consultation with the Chief Justice of India, remove from office, the Chairperson or a Member, in case he has been adjudged an insolvent, convicted of an offence or involved in moral turpitude or has become physically or mentally incapable or acquired financial or other interest likely to affect prejudicially his functions or abused his position prejudicially to the public.

It further provides for giving a reasonable opportunity to the Chairperson and part time members before their removal and the Chairperson shall be removed from his office only after an inquiry made by a Judge of the Supreme Court.

Clause 53.—This clause provides for the part-time expert Member of the Appellate Tribunal to act as Chairperson of Appellate Tribunal and to discharge his functions in certain circumstances. It provides that in the event of the occurrence of any vacancy in the office of the Chairperson of the Appellate Tribunal by reason of his death or resignation or otherwise, the part-time expert Member of the Appellate Tribunal shall act as the Chairperson of the Tribunal until the date on which a new Chairperson is appointed in accordance with the provisions of the proposed legislation.

Clause 54.—This clause makes provision for staff of the Appellate Tribunal and their salaries and allowances. It provides that the Central Government shall determine the nature and categories of the officers and other employees required to assist the Appellate Tribunal in the discharge of its functions.

It further provides that the recruitment of the officers and other employees of the Appellate Tribunal shall be made by the Chairperson in such manner as may be prescribed by the Central Government.

It further provides that the officers and other employees of the Appellate Tribunal shall discharge their functions under the general superintendence of the Chairperson of such Appellate Tribunal and their salaries and allowances payable to, and the other terms and conditions of service of, the officers and other employees of the Appellate Tribunal shall be such as may be prescribed by the Central Government.

Clause 55.—This clause provides for financial and administrative powers of Chairperson of the Appellate Tribunal. It provides that the Chairperson of the Appellate Tribunal shall exercise financial and administrative powers as are vested in him under the rules made by the Central Government and it also contains provisions regarding delegation of financial and administrative powers by the Chairperson to any part-time expert Member or officer of the Appellate Tribunal.

Clause 56.—This clause makes provision to settle disputes by the Appellate Tribunal. It provides that the Appellate Tribunal shall have the jurisdiction over all civil cases where a substantial question relating to modern biotechnology is involved and questions arising out of the safety and use of organisms and products and processes specified under Schedule I and to hear appeals from the decisions or orders of the Authority.

It further provides that no application for deciding substantial question relating to modern biotechnology under this section shall be entertained by the Appellate Tribunal unless it is made within a period of two years from the date on which the cause of action for such question first arose.

It also provides that if it is satisfied that the applicant was prevented by sufficient cause from filing the application within the said period, the Appellate Tribunal may allow it to be filed within a further period not exceeding sixty days and such application or appeal shall be dealt with expeditiously and disposed of finally within six months from the date of filing of the application.

Clause 57.—This clause provides for the procedure and powers of the Appellate Tribunal. It provides that the Appellate Tribunal shall be guided by the principles of natural justice and not bound by the procedure laid down by the Code of Civil Procedure, 1908 or the rules of evidence contained in the Indian Evidence Act, 1872.

It further provides that the Appellate Tribunal shall have the same powers as are vested in a civil court under the Code of Civil Procedure, 1908, in respect of the matters such as, summoning and enforcing the attendance of any person and examining him on oath; requiring the discovery and production of documents; receiving evidence on affidavits subject to the provisions of sections 123 and 124 of the Indian Evidence Act, 1872; requisitioning any public record or document or copy of such record or document from any office; issuing commissions for the examination of witnesses or documents, reviewing its decision, dismissing an application for default or deciding it *ex parte;* setting aside any order of dismissal of any application for default or any order passed by it *ex parte;* pass an interim order (including granting an injunction or stay) after providing the parties concerned an opportunity of being heard, on any application made or appeal filed under the proposed legislation; and any other matter which may be prescribed.

It also provides that all proceedings before the Appellate Tribunal shall be deemed to be judicial proceedings within the meaning of sections 193, 219 and 228 for the purposes of section 196 of the Indian Penal Code, 1860 and the Appellate Tribunal shall be deemed to be a civil court for the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973.

Clause 58.—This clause provides for the binding of majority decision of the Appellate Authority. It provides that the decision of the Appellate Tribunal by majority of members shall be binding.

Clause 59.—This clause contains provisions regarding cost. It provides that while disposing of an application or an appeal under the proposed legislation, the Appellate Tribunal shall have power to make order as to costs as it may consider necessary.

Clause 60.—This clause provides for the execution of award or order of Appellate Tribunal. It provides that an award or order or decision of the Appellate Tribunal under the proposed legislation shall be executable by the Appellate Tribunal as a decree of a civil court, and for this purpose, the Appellate Tribunal shall have all the powers of a civil court.

Clause 61.—This clause makes provisions for appeal against any order of the Appellate Tribunal to the Supreme Court. It provides that notwithstanding anything contained in the Code of Civil Procedure, 1908 or in any other law, an appeal shall lie against any order, not being an interlocutory order, of the Appellate Tribunal to the Supreme Court on one or more of the grounds specified in section 100 of the Code. It further provides that no appeal shall lie against any decision or order made by the Appellate Tribunal with the consent of the parties. It also provides that every appeal under this section shall be preferred within a period of ninety days from the date of the decision or order appealed against, however the Supreme Court may entertain an appeal after the expiry of the said period of ninety days, if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

Clause 62.—This clause provides for punishment for false information. It provides that, if any person provides any information or produces any document knowing it as a false or misleading, in connection with a requirement or direction under the proposed legislation, he shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.

Clause 63.—This clause provides for punishment for conduct of unapproved field trials. Sub-clause (*1*) of this clause provides that whoever, himself or by any other person on his behalf, conducts field trials with organisms or products specified in part I or part III of Schedule I, in contravention of section 34 shall be punishable with imprisonment for a term which shall not less than six months but which may extend to one year and with fine which may extend to two lakh rupees. Sub-clause (*2*) of this clause provides that whoever, having been convicted of an offence under sub-clause (*1*), is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years and with fine which may extend to four lakh rupees.

Clause 64.—This clause provides for punishment for obstructing or impersonating an officer of Authority. It provides that if a person, without reasonable excuse, resists, obstructs, or attempts to obstruct, impersonate, threaten, intimidate or assault an officer of the Authority or any person assigned to discharge any function or in exercising his functions under the proposed legislation, shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.

Clause 65.—This clause provides for punishment in relation to audit report. It provides that if any auditor's report which is false or otherwise than in conformity with the specific areas or issues or standards or procedures directed to be audited by the Authority, the auditor concerned and the person, if any, other than the auditor who signs the report or signs or authenticates the documents, he shall, be punishable with imprisonment which may extend to three years or with fine which may extend to five thousand rupees or with both.

Clause 66.—This clause deals with the general provisions relating to offences and fine. It provides that if any person who contravenes or attempts to contravene or abets the contravention of the provision of the proposed legislation or of any rules or regulations made thereunder, for which no punishment is provided elsewhere in the proposed legislation, shall be punishable with

imprisonment for a term which may extend to two years and also with fine which may extend to ten lakh rupees.

Clause 67.—This clause contains provisions for offences by companies. It provides that where an offence under the proposed legislation has been committee by a company, every person directly in charge of, and responsible to, the company for the conduct of its business at the time of commission of offence shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. It also provides that where any offence under the proposed legislation has been committed with the consent or connivance of, or attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly. The *Explanation* to the clause seeks to define the terms "company" and "director".

Clause 68.—This clause contains provisions for offences by society, trust and university. It provides that where an offence under the proposed legislation has been committed by a society or trust or university, every person directly in charge of, and was responsible to, the society or trust or university for the conduct of its business at the time of commission of offence shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. It also provides that where any offence under the proposed legislation has been committed with the consent or connivance of, or attributable to any neglect on the part of, any governors, vice-chancellor, directors, committee, trustees, registrar or other officer of the society or trust or university, such governors, vice-chancellor, directors, committee, trustees, registrar or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Clause 69.—This clause contains provisions for offences by Government Departments. It provides that where an offence under the proposed legislation has been committed by any Department of the Government, the Head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly, in accordance with the provisions of the said clause unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence. It also provides that where any offence under the proposed legislation has been committed with the consent or connivance of, or attributable to any neglect on the part of, any officer, other than the Head of the Department, such officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Clause 70.—This clause contains provisions for cognizance of offences and provides that no court inferior to that of a Chief Metropolitan Magistrate or a Chief Judicial Magistrate shall try any offence under the proposed legislation and that cognizance of such offence shall be taken only on a complaint made by the Central Government or any authority or officer authorised by it.

Clause 71.—This clause provides for grants by the Central Government. It provides that the Central Government may, after due appropriation made by Parliament by law in this behalf, make to the Authority grants of such sums of money as the Central Government may think fit for being utilised for the purposes of the proposed legislation.

Clause 72.—This clause provides for other fees and revenues. It provides that the fees or revenue collected by the Authority shall be credited to the Consolidated Fund of India and the entire amount so deposited may, after due appropriation made by Parliament by law in this behalf, be transferred to the Authority.

Clause 73.— This clause provides for usual provisions regarding budget, accounts and audit. It provides that the Authority shall prepare a budget, maintain proper accounts and other relevant records and prepare an annual statement of accounts as may be prescribed by the Central

Government. It further provides that the accounts of the Authority shall be audited and certified by the Comptroller and Auditor-General of India, which would be laid before Parliament by the Central Government.

Clause 74.—This clause provides for furnishing of annual report to the Central Government. It provides that the Authority would prepare once in every year, in such form and at such time as may be prescribed by the Central Government, an annual report and a copy of the same is required to be laid, as soon as may be after it is received, before each House of Parliament.

Clause 75.— This clause confers powers upon the Central Government to issue directions. It provides that the Authority shall, in exercise of its powers or the performance of its functions under the proposed legislation, be bound by such directions on question of policy, other than those relating to technical and administrative matters, as the Central Government may give in writing to it from time to time. However, the Authority shall be given an opportunity to express its views before any such direction is given and the decision of the Central Government, whether a question is one of policy or not, shall be final.

Clause 76.—This clause confers power on the Central Government to supersede the Authority. It provides that if, at any time the Central Government is of the opinion, that, on account of circumstances beyond the control of the Authority, it is unable to discharge the functions or perform the duties imposed on it; or that the Authority has persistently defaulted in complying with any direction given by the Central Government and in discharging the functions or performance of the duties imposed on it by or under the provisions of the proposed legislation and as a result of such default the financial position of the Authority or the administration of the Authority has suffered; or that circumstances exist which render it necessary in the public interest so to do, the Central Government may, by notification, supersede the Authority for such period, not exceeding six months and appoint a person or persons as the President may direct to exercise powers and discharge functions under the proposed legislation.

It further provides that before issuing any such notification, the Central Government shall give a reasonable opportunity to the Authority to make representations against the proposed supersession and shall consider the representations, if any, of the Authority.

It further provides that upon the decision of the Central Government to supersede the Authority, the Chairperson and other members shall, from the date of supersession, vacate their offices; all the powers, functions and duties which may, by or under the provisions of proposed legislation, be exercised or discharge by or on behalf of the Authority shall, until the Authority is reconstituted, be exercised and discharged by the person or persons appointed for the said purpose, and all properties owned or controlled by the Authority shall, until the Authority is reconstituted, vest in the Central Government.

It also provides that, on or before the expiration of the period of supersession specified in the notification, the Central Government shall reconstitute the Authority by a fresh appointment of its Chairperson and other members and in such case persons who had vacated their office shall not to be deemed be disqualified for re-appointment.

It also provides that the Central Government shall cause a copy of the notification of superseding the Authority and a full report of action taken and the circumstances leading to such action to be laid before each House of Parliament.

Clause 77.— This clause provides for exclusion of jurisdiction of civil courts. It provides that no civil court shall have jurisdiction in respect of any matter which the Appellate Tribunal is empowered by or under the proposed legislation to determine and no injunction shall be granted by any court or other authority in respect of any action taken or to be taken in pursuance of any power conferred by or under the proposed legislation.

Clause 78.— This clause specifies the Members and staff of Authority as public servants. It provides that the Chairperson, Members, Chief Regulatory Officers, other officers and other employees of the

Authority shall be deemed to be public servants within the meaning of section 21 of the Indian Penal Code.

Clause 79.— This clause provides for protection of action taken in good faith. It provides that no suit, prosecution or other legal proceedings shall lie against, the Central Government, the Authority and other bodies constituted; any officer of the Central Government, or any Member, Chief Regulatory Officers and other officers or other employees of such Authority and bodies or any other officer, as the case may be, for anything which is in good faith done or intended to be done in pursuance of the proposed legislation or the rules made thereunder in discharge of their duties.

Clause 80.— This clause provides for non-application of provisions of the proposed legislation to the Drugs and Cosmetics Act, 1940 and the Food Safety and Standards Act, 2006. It provides that nothing contained in the proposed legislation shall apply to the food or food additive or any material or thing which is covered under the Food Safety and Standards Act, 2006 or clinical trials of a drug as defined under clause (*b*) of section 3 of the Drugs and Cosmetics Act, 1940.

Clause 81.— This clause lays down the provisions for overriding effect of the proposed legislation. It provides that the provisions of the proposed legislation shall have overriding effect, notwithstanding anything inconsistent therewith contained, in any other law for the time being in force or in any instrument having effect by virtue of any law other than the proposed legislation.

Clause 82.— This clause confers on the Central Government the power to make rules. It provides that the Central Government may, by notification in the Official Gazette, make rules for carrying out the provisions of the proposed legislation. Sub-clause(*2*) specifies matters for which such rules may be made by the Central Government.

Clause 83.— This clause empowers the Authority to make regulations. It provides that the Authority may, by notification, make regulations consistent with the provisions of the proposed legislation and the rules made thereunder to carry out the provisions of the proposed legislation. Sub-clause (*2*) specifies matters for which such regulations may be made by the Authority.

Clause 84.— This clause empowers the Central Government to amend the Schedule I which contains the list of certain organisms and products specified therein. It provides that the Central Government, after consultation with the Authority and after giving, by notification in the Official Gazette, not less than three months' notice of its intention to do so, may, by like notification, add to or otherwise amend the Schedule I of the proposed legislation and thereupon the said Schedule shall be deemed to be amended accordingly.

Clause 85.— This clause provides for laying of rules, regulations and notifications before Parliament. It provides that every rule made and every notification issued by the Central Government and every regulation made by the Authority under the proposed legislation shall be required to be laid before each House of Parliament.

Clause 86.— This clause provides for application of certain laws. It provides that the provisions of the proposed legislation shall be in addition to and not in derogation of any other law for the time being in force.

Clause 87.— This clause lays down the provisions for amendment of certain enactments and savings. It provides that the enactments specified in Parts I and II of the Schedule II to the proposed legislation shall be amended in the manner specified therein and such amendments shall take effect from such date as the Central Government may by notification, specify and that such amendments shall not, affect, the previous operations of the enactment under repeal or anything duly done or suffered thereunder; any right, privilege, obligation or liability acquired, accrued or incurred under any of the enactment or orders; any penalty, forfeiture or punishment incurred in respect of any offences committed against the enactment; or any investigation or remedy in respect of any such penalty, forfeiture or punishment, and any such investigation, legal proceedings or remedy may be instituted, continued or enforced and any such penalty, forfeiture or punishment may be imposed, as if the proposed legislation had not been passed.

It further provides that if there is any other law for the time being in force in any State corresponding to the proposed legislation, the same shall upon the commencement of the proposed legislation, stand repealed and in such case, the provisions of section 6 of the General Clauses Act, 1897 shall apply as if such provisions of the State law had been repealed.

It also provides that notwithstanding the repeal of enactment specified under sub-clause (*2*), the licences issued under any such enactment or order, which are in force on the date of commencement of the proposed legislation, shall continue to be in force till the date of their expiry for all purposes, as if they had been issued under the provisions of the proposed legislation or the rules made thereunder.

Clause 88.— This clause makes provisions for removal of difficulties. It empowers the Central Government to make, by order published in the Official Gazette, provisions for removal of difficulties in giving effect to the provisions of the proposed legislation. Such orders could be made only within two years from the commencement of the proposed legislation.

Sub-clause(*3*) provides that every order issued under this clause is required to be laid before each House of Parliament.

Schedule I.—It specifies the organisms and products proposed to be regulated by the Authority.

Schedule II.—It proposes to make certain amendments in the Drugs and Cosmetics Act, 1940 and the Food Safety and Standards Act, 2006.

FINANCIAL MEMORANDUM

Sub-clause(*1*) of clause 4 of the Bill provides that the Central Government shall establish a body to be known as the Biotechnology Regulatory Authority of India to exercise the powers conferred on, and to perform the functions assigned to it, under the Bill. Sub-clause (*4*) of clause 9 of the Bill provides that the Central Government shall prescribe the salary, allowances and other terms and conditions of the services of the Chairperson and the Members of the Authority. Sub-clause (*2*) of clause 14 provides that the salary, allowances and other terms and conditions of service of Chief Regulatory Officers and other employees of the Authority shall be prescribed by the Central Government. Sub-clause(*7*) of clause 35 provides that the Authority shall provide technical or financial support for establishment of the State Biotechnology Regulatory Advisory Committee in each State.

2. Clause 44 of the Bill provides for establishment of an Appellate Tribunal to be known as the Biotechnology Regulatory Appellate Tribunal. Clause 50 provides that the Central Government shall prescribe the salaries, fees, allowances and other terms and conditions of service of the Chairperson and part-time expert members of the Biotechnology Regulatory Appellate Tribunal. Sub-clause(*4*) of clause 54 provides that the salary, allowances and other terms of conditions of service of officers and employees of the Appellate Tribunal shall be as prescribed by the Central Government.

3. Clause 71of the Bill provides that the Central Government may, after due appropriation made by Parliament by law in this behalf, make to the Authority, grants of such sums of money as the Central Government may think fit for being utilised for the purposes of this Act. Clause 72 provides that the fees or revenue collected by the Authority shall be credited to the Consolidated Fund of India and the entire amount so credited will be transferred to the Authority.

4. The manpower requirements and the total financial implication in terms of recurring and non-recurring expenditure involved would be as per the setup of the proposed Biotechnology Regulatory Authority of India, Appellate Tribunal and the various State Biotechnology Regulatory Advisory Committees. It is difficult to estimate the exact expenditure, both recurring and non-recurring at this stage. On a representative basis, it is estimated that the recurring annual expenditure of the Authority shall be approximately in the range of Rs. 20.00 crores and the one time capital investment is estimated to be Rs.25.00 crores for the establishment of the Biotechnology Regulatory Authority of India, Appellate Tribunal and the various State Biotechnology Regulatory Advisory Committees to be borne by the Central Government.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Sub-clause(*1*) of clause 82 empowers the Central Government to make, by notification in the Official Gazette, rules for carrying out the provisions of the proposed legislation.

Sub-clause(*2*) enumerates the matters in respect of which such rules may be made. These matters, *inter alia* specifies the power and functions of the Authority which may be exercised and discharged by the Chairperson as the Chief executive of the Authority under clause 8; the form and the manner in which, and the Authority before whom, the oath of office and of secrecy to be subscribed by the Chairperson and every Member and salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and Members under clause 9; the salaries, allowances and pensions payable to, and other conditions of service of the Chief Regulatory Officers, other officers and employees of the Authority, under sub-clause(*2*) of clause 14; the other functions of the Inter-Ministerial Governing Board under sub-clause(*6*) of clause 15; the manner in which members of the Biotechnology Advisory Council appointed and the other functions of the Biotechnology Advisory Council to be specified under clause 16; the times and places at which the meetings of the Inter-Ministerial Governing Board and the Biotechnology Advisory Council to be held and procedures to be observed in regard to the transaction of business at its meetings under clause 17; the qualifications and experience of the members of the Environment Appraisal Panel under clause 26; the manner in which the Authority shall provide technical or financial assistance or such other assistance, for the establishment of State Biotechnology Regulatory Advisory Committee, and, discharge of its functions, under sub-clause(*7*) of clause 35; the form and manner in which, and the fees along with which, the appeal shall be preferred and the particulars which such appeal shall contain under clause 43; the rules regulating generally the practices and procedure of the Appellate Tribunal under clause 45; the manner in which the part-time expert Members of the Appellate Tribunal are appointed under sub-clause(*3*) of clause 47; the salaries and allowances payable to, and the other terms and conditions of service of, the Chairperson and allowance and fee payable to part-time expert Member of the Appellate Tribunal under clause 50; the procedure for inquiry and removal of the Chairperson of the Appellate Tribunal, under sub-clause(*4*) of clause 52; the financial and administrative powers of the Chairperson of the Appellate Tribunal as may be vested in him under clause 55; the form in which the Authority shall prepare a budget, maintain proper accounts and other relevant records and prepare an annual statement of accounts under sub-clause (*1*) of clause 73; the form in which and time at which the Authority shall prepare an annual report under sub-clause(*1*) of clause 74.

2. Sub-clause (*1*) of clause 83 of the proposed legislation empowers the Biotechnology Regulatory Authority of India to make, by notification in the Official Gazette, regulations, for carrying out the provisions of the proposed legislation. Sub-clause(*2*) enumerates the matters in respect of which such regulations may be made. These matters, *inter alia* specify the times and places of meetings of the Authority and the rules of procedure to be observed by the Authority in regard to the transaction of business at its meetings under sub-clause (*1*) of clause 12; measures to regulate the research, transport, import manufacture and use of organisms and products referred to in clause 18; the other qualifications and duties and functions of the Chief Regulatory Officer under clause 21; the qualifications of the scientific officers of the Risk Assessment Unit and the manner of undertaking science-based safety assessment under clause 22; the manner of constitution of the Enforcement Unit for enforcing the decision of the Authority under sub-clause (*1*) of clause 23; the form and manner for submission of application for the purpose of obtaining authorisation for research, transport or import of organisms and products, the fee payable and the documents and information to be accompanied with such applications under clause 24; the manner of constitution of a Product Rulings Committee, the fee and allowances payable to the qualified scientific experts in the roster of experts and the procedure to be observed by the Product Rulings Committee in regard to transaction of business at the meetings, including the quorum under clause 25; the form and manner for submission of application for the purpose of obtaining authorisation for the manufacture or use of organisms and products, the fee payable and the documents and information

to be accompanied with such applications under clause 27; the manner of constitution of one or more Scientific Advisory Panels under clause 29; the safeguards subject to which the Authority may permit clinical trials or field trials of organisms and products under the proviso to clause 34; the manner of convening of the annual meeting of a State Biotechnology Regulatory Advisory Committee, by the Chairperson of the Authority, under clause 36; the qualifications and experience of Monitoring Officers under sub-clause(*2*) of clause 38; the agencies which may accredit the laboratories or research institutions under clause 41; the organisations or the agencies to be designated by the Authority, and the activities relating to safety of modern biotechnology, the compliance of which shall be ensured for the purposes of auditing notified laboratories or research institutions and the criteria which an organisation or agency shall fulfill, to be designated as auditor, under clause 42.

3. Clause 85 provides that every rule made and every notification issued by the Central Government and every regulation made by the Authority is required to be laid before each House of Parliament.

4. The matters in respect of which rules and regulations may be made are matters of procedures or administrative detail and it is not practicable to provide for them in the Bill itself. The delegation of legislative power is, therefore, of a normal character.

ANNEXURE

EXTRACTS FROM THE FOOD SAFETY AND STANDARDS ACT, 2006

(34 OF 2006)

Scientific Panels

(*3*)Without prejudice to the provisions of sub-section (*1*), the Food Authority may establish as many Scientific Panels as it considers necessary in addition to the Panels on:

(*c*) genetically modified organisms and foods;

22. Genetically modified foods, organic foods, functional foods, proprietary foods, etc.

Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, neutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf.

Explanation.—For the purposes of this section,—

(*2*)"genetically engineered or modified food" means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology;

LOK SABHA

————

A

BILL

to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of regulatory procedures and provide for establishment of the Biotechnology Regulatory Authority of India to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology and for matters connected therewith or incidental thereto.

————

(Shri S. Jaipal Reddy, Minister of Science and Technology and Earth Sciences)

GMGIPMRND—5704LS(S4)—13.03.2013.

REGIONAL CENTRE FOR BIOTECHNOLOGY ACT, 2016.

LOK SABHA

————

The following Bills were introduced in Lok Sabha on 15th March, 2016:—

BILL NO. 69 OF 2016

A Bill to provide for the establishment of an institution of national importance to be known as Regional Centre for Biotechnology and to provide for matters connected therewith or incidental thereto.

WHEREAS an agreement for the establishment and operation of the Regional Centre for Biotechnology Training and Education in India was entered into between the Government of India and the United Nations Educational, Scientific and Cultural Organisation on the 14th day of July, 2006;

AND WHEREAS in pursuance of the said agreement, the Central Government through an executive order dated the 20th April, 2009, established the Regional Centre for Biotechnology Training and Education at Faridabad, Haryana;

AND WHEREAS it is expedient to make provisions for strengthening and to make the Regional Centre for Biotechnology an institution of national importance for imparting education, training and conducting research in the areas of Biotechnology and related multidisciplinary areas.

BE it enacted by Parliament in the Sixty-seventh Year of the Republic of India as follows:—

1. Short title and commencement.

(1) This Act may be called the Regional Centre for Biotechnology Act, 2016.

(2) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

2. Definitions.

In this Act, unless the context otherwise requires,—

(a) "academic staff" means Assistant Professors, Associate Professors, Professors, Deans, Sub-Deans, Executive Director and such other persons, including Visiting Professors, Professors of Eminence, Honorary Professors, Adjunct Professors and Emeritus Professors, as may be appointed or engaged for imparting education, training or conducting research in the Regional Centre for Biotechnology;

(b) "Board" means the Board of Governors constituted under section 14;

(c) "Board of Studies" means the Board of Studies of the Regional Centre referred to in section 21;

(d) "Chairperson" means the Chairperson of the Board;

(e) "employee" means any person appointed by the Regional Centre and includes officers, academic and other staff of the Regional Centre;

(f) "Executive Committee" means the Executive Committee of the Regional Centre constituted under section 18;

(g) "Executive Director" means the Executive Director of the Regional Centre appointed under sub-section *(1*) of section 23;

*(h) "*existing Regional Centre" means the Regional Centre for Biotechnology Training and Education at National Capital Region, Faridabad;

(i) "hall" means a unit of residence, by whatever name called, for the students of the Regional Centre, maintained or recognised by it;

(j) "institution" includes autonomous organisations within or outside India, for imparting education, training and conducting research in the areas of Biotechnology and supported by the Government of India or industry or universities or other organisations;

(k) "Ordinances" means the Ordinances framed by the Programme Advisory Committee under section 42;

(l) "Programme Advisory Committee" means the Programme Advisory Committee of the Regional Centre constituted under section 17;

(m) "region" means the region comprising the territories of South Asian Association for Regional Co-operation (SAARC) States and generally the Asia region;

(n) "Regional Centre" means the Regional Centre for Biotechnology established under section 3;

(o) "Regulations" means the Regulations made by any authority of the Regional Centre under section 43;

(p) "Statutes" means the Statutes framed by the Board under section 41;
*(q)"*UNESCO" means the United Nations Educational, Scientific and Cultural Organisation.

3. **Establishment and incorporation of Regional Centre for Biotechnology**.

(1) The Regional Centre for Biotechnology Training and Education at National Capital Region, Faridabad, Haryana functioning under the Department of Biotechnology,
Ministry of Science and Technology is hereby established as a body corporate by the name of "Regional Centre for Biotechnology" having perpetual succession and a common seal with power, subject to the provisions of this Act, to contract and shall, by the said name, sue or be sued.

(2) The Regional Centre shall consist of a Board of Governors and authorities specified in section 13.

(3) The headquarters of the Regional Centre shall be at its campus in the National Capital Region, Faridabad.

4. Declaration of Regional Centre for Biotechnology as an institution of national importance.

Whereas the objects of the institution known as the Regional Centre for Biotechnology are such as to make the institution one of national importance, it is hereby declared that the institution known as the Regional Centre for Biotechnology is an institution of national importance.

5. Effect of establishment of Regional Centre.

(*1*) On and from the date of commencement of this Act,—

(a) any reference to the existing Regional Centre in any law, other than this Act, or in any contract or other instrument, shall be deemed as a reference to the Regional Centre;

(b) all properties and assets, movable and immovable, of, or belonging to the existing Regional Centre shall vest in the Regional Centre;

(c) all rights and liabilities of the existing Regional Centre shall be transferred to, and be the rights and liabilities of, the Regional Centre;

(*d)* without prejudice to the provisions of clause (*c*), all debts, obligations and liabilities incurred, all contracts entered into and all matters and things engaged to be done by, with or for, the existing Regional Centre immediately before the said date, for or in connection with the purposes of the said Regional Centre shall be deemed to have incurred, entered into or engaged to be done by, with or for, the Regional Centre;

(*e)* all sums of money due to the existing Regional Centre immediately before that date shall be deemed to be due to the Regional Centre;

(f) all suits and other legal proceedings instituted or which could have been instituted by or against the existing Regional Centre immediately before that date may be continued or may be instituted by or against the Regional Centre;

(g) every employee (including those appointed for imparting instruction or giving training or conducting research in the existing Regional Centre), holding any office under the existing Regional Centre or teaching therein immediately before the commencement of this Act shall hold his office in the Regional Centre or continue teaching therein by the same tenure and upon the same terms and conditions of service as respects remuneration, leave, provident fund, retirement and other terminal benefits as he would have held such office if this Act had not been enacted and shall continue to do so as an employee of the Regional Centre or until the expiry of the period of six months from that date if such employee opts not to be the employee of the Regional Centre within such period.

(*2*) Notwithstanding anything in the Industrial Disputes Act, 1947 or in any other law for the time being in force, absorption of any employee by the Regional Centre in its regular service under this section shall not entitle such employee to any compensation under that Act or any other law and no such claim shall be entertained by any court, tribunal or other authority.

6. Jurisdiction.

The jurisdiction of the Regional Centre shall extend to whole of India and to such centres and specialised laboratories or other units for research, development and instruction, established by the Regional Centre within or outside India.

7. Objectives of Regional Centre.

The objectives of the Regional Centre shall be—

(a) to disseminate and to advance knowledge by providing instructional and research facilities in such branches of biotechnology and related fields as it may deem fit including technology policy development;

(b) to provide capacity-building through education, training, research and development in biotechnology and related academic fields for sustainable development objectives through regional and international cooperation;

(c) to facilitate transfer of knowledge and technology relating to biotechnology at the regional level;

(d) to create a hub of biotechnology expertise and to address human resources needs in the countries in the region;
(e) to promote and strengthen international co-operation to improve the social and economic conditions and welfare of the people;
(f) to promote and facilitate a network of satellite centres in the region as well as within India.

8. Functions of Regional Centre.

The functions of the Regional Centre, shall be—
(a) to establish infrastructure and technology platforms which are directly relevant to biotechnology education, training and research;
(b) to execute educational and training activities including grant of degrees in education and research in biotechnology and related fields;
(c) to produce human resource tailored to drive innovation in biotechnology, particularly in areas of new opportunities and to fill talent gap in deficient areas;
(d) to undertake research and development and scientific investigations in collaboration with relevant research centre's in the region;
(e) to hold scientific symposia and conferences within India or in the region or outside the region and to conduct short-term and long-term training courses and workshops in all areas of biotechnology;
(f) to collect universally available information with a view to setting up data banks for bio-information;
(g) to collect and disseminate, through networking, the relevant local knowledge in the field of biotechnology, ensuring protection of intellectual property rights of local stakeholder communities;
(h) to develop and implement a policy for intellectual property rights which is equitable and just to the stakeholders involved in research in the Regional Centre;
(i) to disseminate the outcome of research activities in different countries through the publication of books and articles;
(j) to promote collaborative research and development networking programme in specific areas of biotechnology with national, regional and international networks and promote exchange of scientists, at the regional level having regard to issues pertaining to intellectual property rights of collaborating institutions promoting equitable sharing of benefits with collaborating institutions.

9. Regional Centre to work in collaboration with other institutions of UNESCO.

The Regional Centre shall pursue its objects and discharge its functions in close collaboration with other national, regional and international institutions of the UNESCO.

10. Powers of Regional Centre.

(1) The Regional Centre shall have the following powers, namely:—
(a) to provide for masters degree (including integrated programmes leading to masters degree), post-graduate diploma and doctoral degrees in biotechnology and related subjects at the interface of varied disciplines including physical, chemical, biological, medical, agricultural and engineering and other relevant sciences, as may be determined by the Regional Centre, from time to time;
(b) to provide for short-term and long-term training courses in biotechnology on specific issues related to the development, extension, implementation and regulation of biotechnology and related areas, as may be specified by Statutes, from time to time;
(c) to organise and undertake extramural studies, training and extension services in biotechnology;
(d) to confer honorary degrees or other academic distinctions referred to in clause (*a*), in the manner specified by the Statutes;
(e) to institute Professorships, Associate Professorships, Assistant Professorships and other academic positions required by the Regional Centre and to appoint persons to such Professorships, Associate Professorships, Assistant Professorships or other academic positions;
(f) to recognise an institution of higher learning within India for the purposes of this Act and to withdraw such recognition in accordance with the norms laid down in the Statutes;
(g) to appoint persons working in any other institution, including those located outside the country, as academic staff of the Regional Centre for such period as may be specified by the Statutes;
(h) to create administrative, technical and other posts and to make appointments thereto, as may be specified by Statutes;
(i) to co-operate or collaborate or associate with any institution, including those located outside the country, in such manner as may be specified and for such purposes as may be determined or agreed upon by the Regional Centre;

(j) to establish and maintain centres and specialised laboratories or other units for research, development and instruction in India or outside India, as may be determined by the Statutes from time to time;
(k) to institute and award fellowships, scholarships, studentships, medals and prizes as may be specified by the Statutes;
(l) to make provision for research and advisory services and for that purpose to enter into such agreements with other institutions, industrial or other organisations, including those located outside the country as may be specified by the Statutes;
(m) to organise and conduct refresher courses, workshops, seminars and other programmes for teachers, evaluators and other stakeholders;
(n) to appoint visiting Professors, Professors of Eminence, Honorary Professors, Adjunct Professors, Emeritus Professors, Consultants and such other persons who may contribute to the advancement and objects of the Regional Centre;
(o) to determine standards of admission to the Regional Centre, including examination, evaluation or any other method of testing;
(p) to fix, demand and receive payment of fees and other charges;
(q) to establish, recognise, maintain and manage halls or residences of students of the Regional Centre and other accommodation for students and to withdraw any such recognition;
(r) to lay down conditions of service of all categories of employees, including their code of conduct;
(s) to regulate and enforce discipline among the students and the employees, and to take such disciplinary measures in this regard as may be deemed by the Regional Centre to be necessary;
(t) to make arrangements for promoting the health and general welfare of the students and employees of the Regional Centre;
(u) to receive benefactions, donations and gifts and to acquire, hold and manage, and dispose of, with the prior approval of the Central Government, any property, movable or immovable, including trust and endowment properties, for the purposes or objectives of the Regional Centre;
(v) to borrow money, with the prior approval of the Central Government on the security of the property of the Regional Centre; and
(w) to do all such other acts and things as may be necessary in furtherance of the objects specified in section 7.
(2) In exercising its powers under sub-section (*1*), it shall be the endeavour of the Regional Centre to maintain high standards of education, training and research and the Regional Centre shall, among other measures which may be necessary for the said purpose, take, in particular, the following measures, namely:—
(a) conduct innovative courses and programmes of studies with a provision for periodic review and restructuring; and
(b) promote *e*-governance with an effective management information system.

11. Regional Centre open to all castes, creed, race or class.

The Regional Centre or any institution recognised by it shall be open to persons of either sex and whatever caste, creed, race, ethnicity, nationality or class, and it shall not be lawful for the Regional Centre or such institution to adopt or impose on any person, any test whatsoever of religious belief or profession in order to entitle him to be appointed as a member of the academic staff of the Regional Centre or such institution or to hold any other office therein or to be admitted as a student in the Regional Centre or such institution or to enjoy or exercise any privilege thereof.

12. Privileges and immunities of Regional Centre.

The Regional Centre or persons attending the meetings of the Regional Centre shall enjoy such privileges and immunities as the Central Government may grant, pursuant to agreement entered into between the UNESCO and the Government of India from time to time concerning the Regional Centre.

13. Authorities of Regional Centre.

The following shall be the authorities of the Regional Centre, namely:–
(i) the Board of Governors;
(ii) the Programme Advisory Committee;
(iii) the Executive Committee;
(iv) the Finance Committee;
(v) the Board of Studies; and
(vi) such other authorities as may be declared by the Statutes to be the authorities of the Regional Centre.

14. Board of Governors.

(1) There shall be a Board of Governors which shall be responsible for the governance of the Regional Centre.
(*2*) The Board shall be the apex body of the Regional Centre and shall consist of the following members, namely:—
(a) Secretary to the Government of India in the Ministry of Science and Technology, Department of Biotechnology— *ex officio* Chairperson;
(b) three eminent scientists in the relevant field not below the rank of Joint Secretary to the Government of India or equivalent, out of whom at least one shall be a woman, to be nominated by the Central Government— *ex officio* members;
(*c*) a representative of the Director-General of UNESCO;
(d) two representatives from amongst the other member States of UNESCO, who substantially contribute resources to the running of the Regional Centre, in such manner as may be specified by the Statutes— members.
(3) The Chairperson of the Programme Advisory Committee shall be a permanent invitee of the Board.
(*4*) The Executive Director of the Regional Centre shall be the Convenor of the meetings of the Board.
(*5*) The Chairperson shall ordinarily preside over the meetings of the Board.
(*6*) The Board shall meet at least once in a year and at such times as the Chairperson may decide in such manner as may be specified by the Statutes.
(*7*) The term of office of the members of the Board, other than *ex officio* members, shall be such as may be specified by the Statutes.
(*8*) Subject to the provisions of this Act and the Statutes and the Ordinances made thereunder, the Board may regulate its own procedure (including quorum) for the conduct of meetings and transacting business.

15. Powers and functions of Board.

Subject to the provisions of this Act, the Board shall have the following powers and functions, namely:—
(a) to approve the annual plan and budget of the Regional Centre;
(*b*) to review, from time to time, the broad policies and programmes of the Regional Centre, and to suggest measures for the improvement and development of the Regional Centre;
(*c*) to consider the annual report and the annual accounts of the Regional Centre and the audit report on such accounts;
(*d*)to study and approve the internal procedures, including financial procedure and staff regulations of the Regional Centre;
(*e*)to approve the organisational structure and number of academic staff and other employees at the Regional Centre;
(*f*)to convene special consultative sessions of its members, to which it may invite representatives of other interested countries and international organisations in order to obtain proposals for strengthening the scope of services of the Regional Centre;
(g) to carry out projects and activities relevant to the Regional Centre, and to expand the fund-raising strategy and capabilities; and
(h) to frame the Statutes.

16. Powers and functions of Chairperson.

(*1*)The Chairperson shall exercise such powers and discharge such functions as may be delegated to him by the Board or as may be specified by the Statutes.
(*2*) If for any reason, the Chairperson is unable to attend any meeting of the Board, any member of the Board nominated by the Chairperson shall preside over the meeting.

17. Programme Advisory Committee.

*(1)*The Programme Advisory Committee shall be the principal academic body of the Regional Centre and shall, subject to the provisions of this Act, advice planning, execution, review and monitoring of the scientific and academic programmes of the Regional Centre.
*(2)*The Programme Advisory Committee shall consist of the following members, namely:—
(a) a Chairperson of the Programme Advisory Committee to be nominated by the Board;
(b) two members to be nominated by the UNESCO;
*(c)*three members to be nominated by rotation, from amongst the member States of UNESCO which provide maximum financial assistance;
*(d)*two members having expertise and experience in biotechnology policy and legal matters to be nominated by the Central Government;

*(e)*six members from amongst the persons being renowned scientist or academician, to be nominated by the Board.
(3) The Executive Director shall be the Member-Secretary, *ex officio,* to the Programme Advisory Committee.
(4) The Programme Advisory Committee shall be responsible for—
(a) making recommendations on matters of planning and coordinating of the education, training and research activities;
*(b)*recommending modifications or revision of education, training and research programmes of the Regional Centre and submitting reports thereon;
*(c)*reviewing annually the programmes of the Regional Centre, evaluating its progress and submitting the reports thereon;
*(d)*publishing reports on any matter concerning scientific and technical issues referred to it by the Board or by the Executive Director;
*(e)*performing all such duties and to do all such acts as may be necessary for furtherance of education, training and research under this Act;
(f) framing the Ordinances; and
(g) performing such other functions as may be specified by the Statutes.
(*5*)The fees and allowances payable to members of the Programme Advisory Committee and their term of office shall be such as may be specified by the Statutes.
*(6)*Subject to the provisions of this Act and the Statutes and Ordinances made thereunder, the Programme Advisory Committee may regulate its own procedure (including quorum) for the conduct of meetings and transacting of its business:
Provided that the Programme Advisory Committee shall place the minutes of its meetings before the Board of Governors.
18. Executive Committee.
*(1)*The Executive Committee shall be responsible for management of the Regional Centre and implementation of policies and decisions of the Board relating to management.
(2) The constitution, powers and functions of the Executive Committee and the term of office of its members shall be such as may be specified by the Statutes.
19. Finance Committee.
(1) The Finance Committee shall review finances, consider the annual budget estimates, the statements of accounts and the audit reports and make recommendations thereon, to the Board.
(2) The constitution, powers and functions of the Finance Committee and the term of office of its members shall be such as may be specified by the Statutes.
20. Other authorities of Regional Centre.
The constitution, powers and functions of other authorities referred to in clause (*vi*) of section 13, and the term of office of its members shall be such as may be specified by the Statutes.
21. Board of Studies.
The constitution, powers and functions of the Board of Studies and the term of office of its members shall be such as may be specified by the Statutes.
22. Officers of Regional Centre.
The following shall be the officers of the Regional Centre, namely:—
(i) Executive Director;
(ii) Deans;
(iii) Sub-Deans;
(iv) Associate Director (Administration);
(v) Registrar;
(vi) Finance Officer; and
(vii) such other officers as may be declared by the Statutes to be the officers of the Regional Centre.
23. Executive Director.
(1) The Executive Director shall be appointed on the recommendation of the Board in such manner and on such terms and conditions of service, as may be specified by the Statutes.
(*2*) The Executive Director shall—
(a) be the principal executive and academic officer of the Regional Centre;
(b) direct the work of the Regional Centre in conformity with the programmes and directives established by the Board;

(c) propose the draft work plan and budget to be submitted to the Board;
(d) prepare the agenda for the sessions of the Board;
(e) prepare reports on the Regional Centre's activities for submission to the Board; and
(f) exercise such other powers and perform such other functions as may be specified by the Statutes.
(3) The financial powers delegated to the Executive Director by the Board shall be such as may be specified by the Statutes.
(*4*) The Executive Director may, if he is of the opinion that immediate action is necessary on any matter, exercise any power conferred on any authority of the Regional Centre by or under this Act and shall report to such authority at its next meeting the action taken by him on such matter.

24. Deans and Sub-Deans.

The Deans and Sub-Deans shall be appointed in such manner and on such terms and conditions of service, and shall exercise such powers and perform such duties, as may be specified by the Statutes.

25. Associate Director (Administration).

(1) The Associate Director (Administration) shall be appointed in such manner, and on such terms and conditions of service, as may be specified by the Statutes.
(2) The Associate Director (Administration) shall have the power to enter into agreements, sign documents and authenticate records on behalf of the Regional Centre and shall exercise such powers and perform such duties, as may be specified by the Statutes.

26. Registrar.

The Registrar shall be appointed in such manner and on such terms and conditions of service and shall exercise such powers and perform such duties, as may be specified by the Statutes.

27. Finance officer.

The Finance officer shall be appointed in such manner and on such terms and conditions of service and shall exercise such powers and perform such duties, as may be specified by the Statutes.

28. Other officers.

The manner of appointment and powers and duties and terms and conditions of service of other officers of the Regional Centre, referred to in clause (*vii*) of section 22, shall be such as may be specified by the Statutes.

29. Grants and Loans to Regional Centre.

The Central Government may, after due appropriation made by Parliament by law, in this behalf, make to the Regional Centre grants and loans of such sums of money and in such manner as that Government may consider necessary for being utilised for the fulfilment of the objects and purposes of this Act.

30. Fund of Regional Centre.

(1) The Regional Centre shall maintain a Fund to which shall be credited—
(a) all moneys provided by the Central Government;
(b) all fees and other charges received by the Regional Centre;
(c) all moneys received by the Regional Centre by way of grants, gifts, donations, benefactions, bequests or transfers; and
(d) **a**ll moneys received by the Regional Centre in any other manner or from any other source.
(2) All moneys credited to the Fund shall be deposited in such banks or invested in such manner as the Regional Centre may, with the approval of the Central Government, decide.
(3) The fund shall be applied for meeting—
(a) the fees and allowances payable to the Chairperson and members of the Board or Chairperson of the Programme Advisory Committee and members of the other committees and the salaries, allowances and other remunerations payable to the academic staff, officers and other employees of the Regional Centre;
(b) the expenses of the Regional Centre in the discharge of its functions and for the fulfilment of its objects and for purposes as envisaged under this Act.

31. Annual report.

(*1*) The annual report of the Regional Centre shall be prepared under the directions of the Executive Director, which shall include, among other matters, the steps taken by the Regional Centre towards the fulfilment of its objectives and shall be submitted to the Board on or before such date as may be specified by the Statutes and the Board shall consider the report in its annual meeting.
(2) A copy of the annual report, as prepared under sub-section (*1*), shall be submitted to the Central Government, which shall, as soon as may be, cause the same to be laid before both Houses of Parliament.

32. Annual accounts.

(1) The annual accounts and the balance sheet of the Regional Centre shall be prepared under the directions of the Board and shall, once at least every year, and at intervals of not more than fifteen months, be audited by the Comptroller and Auditor-General of India.
(2) A copy of the accounts together with the audit report shall be submitted to the Central Government along with the observations, if any, of the Board.
(3) A copy of the annual report and annual accounts together with the audit report, shall be submitted to the Central Government which shall, as soon as may be, cause the same to be laid before each House of Parliament.
(4) The audited annual accounts, after having been laid before both Houses of Parliament, shall be published in the Official Gazette.

33. Returns and information.

The Regional Centre shall furnish to the Central Government such returns or other information with respect to its property or activities as the Central Government may, from time to time, require, within such period as may be specified by the Central Government.

34. Review of functioning of Regional Centre.

(1) There shall be a review of the functioning of the Regional Centre once in every four years by persons of eminence to be appointed by the Central Government.
(2) The Regional Centre shall meet the expenses for conducting the review under sub-section (*1*) and upon receipt of the report of such review, the Board may take appropriate action.
(3) In addition to the review under sub-section (*1*), the Board may conduct review of functioning of administrative and academic wings of the Regional Centre, in such manner and at such intervals, as may be specified by the Statutes

35. Appointment and conditions of service of employees of Regional Centre.

(1) All appointments of employees of the Regional Centre shall be made in accordance with the procedure laid down in the Statutes, by—
(*a*) the Board of Governors for the Executive Director, Deans and Sub-Deans;
(*b*) the Executive Director, in any other case.
(2) The terms and conditions of service of the employees of the Regional Centre, other than the officers referred to in clause (*vii*) of section 22, shall be such as may be specified by the Statutes.
(3) The terms and conditions of service of the academic staff shall be consistent with such staff engaged in higher education and research at Central Universities..

36. Meetings.

The meetings of the Board, Programme Advisory Committee, Executive Committee or other committees constituted by the Regional Centre may be held using contemporary tools of information and communication technologies (including video conferencing) without the members necessarily having to be physically present.

37. Filling of casual vacancies.

All casual vacancies among the members (other than *ex officio* members) of the authorities under section 13 shall be filled, as soon as may be, by the person or body who appoints, elects or co-opts the member whose place has become vacant and the person appointed, elected or co-opted to a casual vacancy shall be a member of such authority for the residue of the term for which the person whose place he fills would have been a member.

38. Proceedings of authorities not invalidated by vacancies.

No act or proceedings of any authority of the Regional Centre shall be invalid merely by reason of the existence of a vacancy or vacancies among its members.

39. Protection of action taken in good faith.

No suit or other legal proceedings shall lie against any officer or employee of the Regional Centre for anything which is in good faith done or intended to be done in pursuance of any of the provisions of this Act or the Statutes, Ordinances or the Regulations made thereunder.

40. Arbitration.

Any dispute arising between the Regional Centre and any of its employees shall, at the first instance, be resolved through such grievance redressal mechanism as may be specified by the Statutes.

41. Power to make Statutes.

(1) The Statutes of the Regional Centre shall be framed by the Board of Governors.

(2) Without prejudice to the provisions contained in sub-section *(1),* the Executive Committee may make recommendations for framing of Statutes to the Board.
(3) Subject to the provisions of this Act, the Statutes may provide for all or any of the following matters, namely:—
(a) to provide for short-term and long-term training courses in biotechnology on specific issues related to the development, extension, implementation and regulation of biotechnology and related areas, from time to time under clause (*b*) of sub-section (*1*) of section 10;
(b) the manner of conferring honorary degrees or other distinctions under clause *(d*) of sub-section (*1*) of section 10;
(c) the norms for recognition of an institution of higher learning within India and to withdraw such recognition under clause *(f)* of sub-section *(1)* of section 10;
(d) period for appointment of persons working in any other institution, including those located outside the country, as academic staff of the Regional Centre under clause *(g)* of sub-section *(1)* of section 10;
(e) to create administrative, technical and other posts under clause *(h)* of sub-section *(1)* of section 10;
(f) the manner and purposes of co-operation or collaboration or association with any institution, including those located outside the country, under clause *(i)* of sub-section *(1)* of section 10;
(g) to establish and maintain centres and specialised laboratories or other units for research, development and instruction in India or outside India, clause *(j)* of sub-section *(1)* of section 10;
(h) to institute and award fellowships, scholarships, studentships, medals and prizes, under clause *(k)* of sub-section *(1)* of section 10;
(i) the manner of entering into agreements with other institutions, industrial or other organisations, including those located outside the country, for research and advisory services under clause *(l)* of sub-section *(1)* of section 10;
(*j*) to declare other authorities to be the authorities of the Regional Centre under clause *(vi)* of section 13;
(k) the manner of appointment of representatives from amongst the member States of UNESCO, under clause *(d)* of sub-section *(2)* of section 14;
(l) the time and manner in which the Board shall meet under sub-section *(5)* of section 14;
(m) the term of office of the members of the Board, under sub-section *(6)* of section 14;
(n) such other powers and functions of the Chairperson under sub-section *(1)* of section 16;
(o) such other functions of the Programme Advisory Committee under clause *(g)* of sub-section *(4)* of section 17;
(p) the fees and allowances payable to members of the Programme Advisory Committee and their term of office under sub-section *(5)* of section 17;
(*q*) the constitution, powers and functions and the term of office of members of the Executive Committee under sub-section *(2)* of section 18;
(r) the constitution, powers and functions and term of office of members of the Finance Committee under sub-section *(2)* of section 19;
(s) the constitution, powers and functions and term of office of members of other authorities under section 20;
(t) the constitution, powers and functions and term of office of members of the Board of Studies under section 21;
(u) the other officers as may be declared to be the officers of the Regional Centre under clause *(vii)* of section 22;
(v) the manner of appointment and terms and conditions of service of the Executive Director under sub-section *(1)* of section 23;
(w) the other powers and functions of the Executive Director under clause *(f)* of sub-section *(2)* of section 23;
(*x*) the financial powers to be delegated to the Executive Director by the Board under sub-section *(3)* of section 23;
(*y*) the manner of appointment, terms and conditions of service and powers and duties of the Deans and Sub-Deans under section 24;
(z) the manner of appointment and terms and conditions of service of the Associate Director (Administration) under sub-section *(1)* and powers and duties to be performed by him under sub-section *(2)* of section 25;
(za) the manner of appointment, terms and conditions of service and powers and duties of the Registrar under section 26;

(zb) the manner of appointment, terms and conditions of service and powers and duties of the Finance officer under section 27;
(zc) the manner of appointment, powers and duties and terms and conditions of service of other officers of the Regional Centre under section 28;
(*zd*) the time for submission of the annual report of the Regional Centre to the Board under sub-section *(1)* of section 31;
(ze) the manner and frequency of conducting review of the functioning of administrative and academic wings of the Regional Centre by the Board under sub-section *(3)* of section 34;
(zf) the procedure for appointment of employees of the Regional Centre under sub-section (*1*) and their terms and conditions of service under sub-section *(2)* of section 35;
(zg) the grievance redressal mechanism for resolution of disputes arising between the Regional Centre and any of its employees under section 40;
(zh) the manner of making regulations by the authorities of the Regional Centre under section 43; and
(zi) any other matter which may be required or necessary for the purposes of this Act.

42. Power to make Ordinances.

(1) Save as otherwise provided in this Act, the Ordinances of the Regional Centre shall be made by the Programme Advisory Committee.
(2) Subject to the provisions of this Act and the Statutes made thereunder, the Ordinances of the Regional Centre may provide for all or any of the following matters, namely:—
(a) admission of students from within India and from the region to the Regional Centre and their enrolment as such;
(b) the course of study;
(c) the conditions under which students shall be admitted to the examinations of the Regional Centre and shall be eligible for degrees, diplomas and certificates;
(d) the conditions for award of fellowships, scholarships, medals and prizes;
(e) the conditions and manner of appointment, term and duties of examining bodies, examiners and moderators;
(f) the conduct of examinations;
(g) the conditions of residence of students of the Regional Centre;
(h) the maintenance of discipline among the employees and students;
(*i*) the courses of study to be laid down for all degrees, diplomas and certificates of the Regional Centre including the medium of instruction and examination;
(*j*) the award of degrees and other academic distinctions, and the manner of granting and obtaining of the same;
(k) the withdrawal of degrees, diplomas, certificates and other academic distinctions;
(*l*) the fees to be charged for courses of study and for admission to examinations, degrees and diplomas of the Regional Centre;
(*m*) the special arrangements, if any, which may be made for the residence and teaching of women students and prescribing of special courses of studies for them;
(n) the establishment, management, recognition and abolition of centres of studies, schools, departments, specialised laboratories, halls and institutions; and
(o) any other matter which by this Act or the Statutes, is to be, or may be, provided for by the Ordinances.

43. Regulations.

The authorities of the Regional Centre may make Regulations, consistent with the provisions of this Act, the Statutes and the Ordinances for the conduct of their own business and that of the Committees, if any, appointed by them and not provided for by this Act, the Statutes or the Ordinances, in the manner specified by the Statutes.

44. Statutes, Ordinances and Regulations to be published in the Official Gazette and to be laid before Parliament.

(1) Every Statute, Ordinance or Regulation made under this Act shall be published in the Official Gazette.
(2) Every Statute or Ordinance or Regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the Statute or Ordinance or Regulation or both Houses agree that the Statute or Ordinance or

Regulation should not be made, the Statute or Ordinance or Regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that Statute or Ordinance or Regulation.

45. Power to make Statutes or Ordinances or Regulations retrospectively.

The power to make Statutes or Ordinances or Regulations under section 41 or section 42 or section 43, as the case may be, shall include the power to give retrospective effect, from a date not earlier than the date of commencement of this Act, to the Statutes or Ordinances or Regulations or any of them but no retrospective effect shall be given to any Statutes or Ordinances or Regulations so as to prejudicially affect the interests of any person to whom such Statutes or Ordinances or Regulations may be applicable.

46. Power to remove difficulties.

(1) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act, as appears to it to be necessary or expedient for removing the difficulty:

Provided that no such order shall be made under this section after the expiry of two years from the commencement of this Act.

(2) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

STATEMENT OF OBJECTS AND REASONS

Modern biotechnology has been recognised globally as a rapidly advancing science wherein molecular techniques and processes are employed to develop healthcare solutions for human and animal sector, for agriculture and environment technologies. This has necessitated creation of high quality human resource in disciplinary and interdisciplinary areas by engaging students in research by integrating science, engineering and medicine. Similarly, interface between agriculture or veterinary sciences and engineers; environmental biologists, ecologists and engineers for agricultural and environmental technologies respectively, is necessary for molecular breeding, bio-energy and green technologies. For this purpose, it was necessary to create physical infrastructure in critical platform technologies to support interdisciplinary education, training and research in biotechnology.

2. In view of the above, it was decided to establish a Regional Centre for Biotechnology to produce skilled human resource tailored to drive innovation in biotechnology, particularly in the areas of new opportunities and also to fill talent gap in deficient areas. The Centre was established through an Executive Order of the Department of Biotechnology, Ministry of Science and Technology, Government of India, dated the 20th April, 2009 and is currently operational in its campus at Faridabad.

3. It is proposed to provide statutory status to the existing Regional Centre for Biotechnology Training and Education at National Capital Region, Faridabad, Haryana, establishing the same as a body corporate by the name of "Regional Centre for Biotechnology" and to declare the Regional Centre as an institution of national importance. The proposed Regional Centre would be an autonomous body which is expected to play pivotal role in human resource development in Biotechnology areas and facilitate, promote and strengthen international cooperation to improve the social and economic conditions and welfare of the people.

4. The proposed Regional Centre for Biotechnology Bill, 2016, *inter alia,* provides for,—

(a) pursuing of its objects and discharging its functions in close collaboration with other national, regional and international institutions (including those located in the member states of UNESCO);

(b) constitution of the Board of Governors, the Programme Advisory Committee, the Executive Committee, the Finance Committee, the Board of Studies and other authorities and specifying their powers and functions;

(c) appointment of officers and staff of the Regional Centre and specifying their powers, duties and conditions of service;

(d) maintenance of a Fund by the Regional Centre and submission of annual report and annual accounts to the Central Government;

(e) furnishing of returns and other information to the Central Government regarding its property or activities;

(f) review of the functioning of the Regional Centre by the Central Government;

(g) resolution of disputes between the Regional Centre and its employees by arbitration;

(h) empowering the Board of Governors to frame Statutes; the Programme Advisory Committee to make Ordinances; and the authorities to make Regulations and laying such Statutes, Ordinances and Regulations before Parliament.

5. The Bill seeks to achieve the above objectives.

DR. HARSH VARDHAN.
NEW DELHI;
The 10*th March,* 2016.

Notes on clauses

Clause 2.—This clause seeks to define certain words and expressions used in the Bill.

Clause 3.—This clause provides for the establishment of Regional Centre for Biotechnology (Regional Centre) which shall be a body corporate and having perpetual succession and a common seal with its headquarters in the National Capital Region, Faridabad.

Clause 4.—This clause seeks to declare the Regional Centre for Biotechnology as an institution of national importance.

Clause 5.—This clause provides for the effect of establishment of the Regional Centre on and from the date of commencement of the proposed legislation.

Clause 6.— This clause provides for the jurisdiction of the Regional Centre which shall extend to the whole of India and to centres established within or outside India.

Clause 7.—This clause specifies the objects of Regional Centre. It provides that the Regional Centre shall disseminate and advance knowledge by providing instructional and research facilities in such branches of biotechnology and related fields as it may deem fit including technology policy development.

It further provides that the Regional Centre shall provide capacity-building through education, training, research and development in biotechnology and related academic fields for sustainable development objectives through regional and international cooperation. It also provides that the Regional Centre shall facilitate transfer of knowledge and technology relating to biotechnology at the regional level and create a hub of biotechnology expertise and to address human resources needs in the countries in the region. It also provides that the Regional Centre shall promote and strengthen international cooperation to improve the social and economic conditions and welfare of the people and promote and facilitate a network of satellite centres in the region as well as within India.

Clause 8.—This clause provides for the functions of the Regional Centre which shall, *inter alia*, be to establish infrastructure and technology platforms which are directly relevant to biotechnology education, training and research; execute educational and training activities including grant of degrees in education and research in biotechnology and related fields; produce human resource tailored to drive innovation in biotechnology, particularly in areas of new opportunities and to fill talent gap in deficient areas; undertake research and development and scientific investigations in collaboration with relevant research centres in the region; collect universally available information with a view to setting up a data bank for bio-information, etc.

Clause 9.—This clause seeks to provide for the Regional Centre to pursue its objects and discharge its functions in close collaboration with other national, regional and international institutions of the UNESCO.

Clause 10.—This clause lays down the powers of the Regional Centre which shall, *inter alia*, be to provide for masters degree (including integrated programmes leading to masters degree), post-graduate diploma and doctoral degrees in biotechnology and related subjects; to confer honorary degrees or other academic distinctions; to create administrative, technical and other posts and to make appointments thereto, as may be specified by Statutes; to make provision for research and advisory services and for that purpose to enter into such agreements with other institutions, industrial or other organisations, including those located outside the country as may be specified by the Statutes; to appoint visiting Professors, Professors of Eminence, Honorary Professors, Adjunct Professors, Emeritus Professors, Consultants and such other persons who may contribute to the advancement and objects of the Regional Centre; to receive benefactions, donations and gifts and to acquire, hold and manage, and dispose of, with the prior approval of the Central Government, any property, movable or immovable, including trust and endowment properties, for the purposes or objectives of the Regional Centre; to borrow money, with the prior approval of the Central Government on the security of the property of the Regional Centre; and to do all such other acts and things as may be necessary in furtherance of the objects of the Regional Centre.

Clause 11.—This clause seeks to provide that the Regional Centre or any institution recognised by it shall be open to all castes, creed, race or class.

Clause 12.—This clause seeks to provide that the Regional Centre shall enjoy such privileges and immunities as the Central Government may grant, pursuant to agreement entered into between the UNESCO and the Government of India from time to time concerning the Regional Centre.

Clause 13.—This clause provides that the authorities of the Regional Centre shall be the Board of Governors, the Programme Advisory Committee, the Executive Committee, the Finance Committee, the Board of Studies and such other authorities as may be declared by the Statutes to be the authorities of the Regional Centre.

Clause 14.—This clause provides that the Board of Governors shall consist of the Secretary to the Government of India in the Department of Biotechnology, who shall be *ex officio* Chairperson; three eminent scientists in the relevant field not below the rank of Joint Secretary to the Government of India or equivalent, out of whom at least one shall be a woman, to be nominated by the Central Government; a representative of the Director-General of UNESCO; two representatives from amongst the other member States of UNESCO, who substantially contribute resources to the running of the Regional Centre, in such manner as may be specified by the Statutes. It further provides that the Chairperson of the Programme Advisory Committee shall be a permanent invitee of the Board of Governors and the Executive Director of the Regional Centre shall be the Convenor of the meetings of the Board of Governors. It also provides that the Board of Governors may evolve its own rules of procedure for the purpose of conducting its meetings and transacting business therein.

Clause 15.—This clause lays down the powers and functions of Board which shall, *inter alia*, be to approve the annual plan and budget of the Regional Centre; review, from time to time, the broad policies and its programmes, and to suggest measures for its improvement and development; convene special consultative sessions to which it shall invite representatives of other interested countries and international organisations in order to obtain proposals for strengthening the scope of services; and to carry out the projects and activities relevant to the Regional Centre, and to expand the fund-raising strategy and capabilities.

Clause 16.—This clause provides for the powers and functions of the Chairperson. It provides that the Chairperson shall exercise such powers and discharge such functions as may be delegated to him by the Board or as may be specified by the Statutes.

Clause 17.—This clause provides that the Programme Advisory Committee shall be the principal academic body of the Regional Centre who shall advise planning, execution, review and monitoring of the scientific and academic programmes of the Regional Centre. It further provides that the Programme Advisory Committee shall consist of a chairperson to be nominated by the Board; two members to be nominated by the UNESCO; three members to be nominated by rotation from amongst the member States of UNESCO; two members having expertise and experience in biotechnology policy and legal matters to be nominated by the Central Government; six members from amongst the persons being renowned scientist or academician, to be nominated by the Board; and the Executive Director as the Members-

Secretary, *ex officio.*

It also provides that the Programme Advisory Committee shall be responsible for making recommendations on the matters of planning and coordinating of the education, training and research activities; recommending modifications or revision of education, training and research programmes of the Regional Centre and on the reports thereon; reviewing annually the programmes of the Regional Centre, evaluate its progress and submit the report thereon; publishing reports on any matter concerning scientific and technical issues referred to it by the Board or the Executive Director; framing Ordinances; and performing such other functions as may be specified by the Statutes.

It also provides that the fees and allowances payable to members of the Programme Advisory Committee and their term of office shall be such as may be specified by the Statutes.

Clause 18—This clause provides that the Executive Committee shall be responsible for management of the Regional Centre and implementation of policies and decisions of the Board relating to the management. It further provides that the constitution of the Executive Committee, the term of office of its members and its powers and functions shall be such as may be specified by the Statutes.

Clause 19.—This clause seeks to provide that the Finance Committee shall review finances, consider the annual budget estimates, the statements of accounts and the audit reports and make recommendations thereon, to the Board. It further seeks to provide that the constitution, powers and functions of the Finance Committee shall be such as may be specified by the Statutes.

Clause 20.—This clause seeks to make provision for the constitution, powers and functions of other authorities of the Regional Centre.

Clause 21.—This clause seeks to make provision for the constitution, powers and functions of the Board of Studies.

Clause 22.—This clause seeks to provide that the Executive Director, the Deans, the Sub-Deans, the Associate Director (Administration), the Registrar, the Finance Officer and such other officers as may be declared by the Statutes, shall be the officers of the Regional Centre.

Clause 23.—This clause seeks to provide that the Executive Director shall be appointed on the recommendation of the Board of Governors in such manner as may be specified by the Statutes. It further provides that the Executive Director shall be the principal executive and academic officer of the Regional Centre. It also provides for the powers and functions of the Executive Director.

Clause 24.—This clause seeks to provide that the Deans and Sub-Deans shall be appointed in such manner and on such terms and conditions of service, and shall exercise such powers and perform such duties, as may be specified by the Statutes.

Clause 25.—This clause seeks to provide that the Associate Director (Administration) shall be appointed in such manner, and on such terms and conditions of service, as may be specified by the Statutes.

Clause 26.—This clause seeks to provide that the Registrar shall be appointed in such manner and on such terms and conditions of service and shall exercise such powers and perform such duties, as may be specified by the Statutes;

Clause 27.—This clause seeks to provide that the Finance Officer shall be appointed in such manner, and on such terms and conditions of service and shall exercise such powers and perform such duties, as may be specified by the Statutes.

Clause 28.—This clause seeks to provide that the manner of appointment and powers and duties of other officers of the Regional Centre shall be such as may be specified by the Statutes.

Clause 29.—This clause seeks to provide that the Central Government may, after due appropriation made by Parliament by law, in this behalf, make to the Regional Centre grants and loans of such sums of money in such manner as that Government may consider necessary for being utilised for the fulfilment of the objects and the purposes of the proposed legislation.

Clause 30.—This clause seeks to provide that the Regional Centre shall maintain a Fund to which shall be credited all moneys provided by the Central Government; all fees and other charges received by the Regional Centre; all moneys received by the Regional Centre by way of grants, gifts, donations, benefactions, bequests or transfers; and all moneys received by the Regional Centre in any other manner or from any other source.

It further provides that all moneys credited to the Fund shall be deposited in such banks or invested in such manner as the Regional Centre may, with the approval of the Central Government, decide.

It also provides that the Fund shall be applied for meeting the salary, allowances and other remuneration of Chairperson, members of the Board or Chairperson of the Programme Advisory Committee and members of the other committees, salaries, allowances and other remunerations payable to the academic staff, officers and other employees of the Regional Centre, the expenses of the Regional Centre in discharge of its function under the proposed legislation.

Clause 31.—This clause seeks to provide that the annual report of the Regional Centre shall be prepared under the direction of the Executive Director, which shall include, among other matters, the steps taken by the Regional Centre towards fulfilment of its objects and shall be submitted to the Board of Governors on or before such date as may be specified by the Statutes and the Board of Governors shall consider the report in its annual meeting. It further provides that a copy of the annual report shall be submitted to the Central Government, which shall, as soon as may be, cause the same to be laid before both Houses of Parliament.

Clause 32.—This clause seeks to provide that the annual accounts and the balance sheet of the Regional Centre shall be prepared under the directions of the Board and shall, once at least every year, and at intervals of not more than fifteen months, be audited by the Comptroller and Auditor-General of India. It further provides that a copy of the accounts together with the audit report shall be submitted to the Central Government along with the observations, if any, of the Board of Governors.

It also provides that a copy of the annual report and annual accounts together with the audit report, as submitted to the Central Government shall, as soon as may be, cause to be laid before both Houses of Parliament. It also provides that the audited annual accounts, after having been laid before both Houses of Parliament, shall be published in the Gazette of India.

Clause 33.—This clause seeks to provide that the Regional Centre shall furnish to the Central Government such returns or other information with respect to its property or activities as the Central Government may, from time to time, require, within such period as may be specified by the Central Government.

Clause 34.—This clause seeks to provide for the review of the functioning of the Regional Centre once in every four years by persons of eminence to be appointed by the Central Government. It further provides that the Regional Centre shall meet the expenses for conducting the review and upon receipt of the report of such review, may take appropriate action. It also provides that the Board may conduct review of functioning of

administrative and academic wings of the Regional Centre, in such manner and at such intervals, as may be specified in the Statutes.

Clause 35.—This clause seeks to provide for the appointment of staff of Regional Centre. It provides that the appointments shall be made in accordance with the procedure laid down in the Statutes, by the Board for Executive Director, Deans and Sub-Deans and by the Executive Director, in other case. It further provides that the terms and conditions of service of the employees of the Regional Centre shall be specified in the Statutes. It also provides that the terms and conditions of service of the academic staff shall be consistent with such staff engaged in higher education and research at the Central Universities.

Clause 36.—This clause seeks to provide that the meetings of the Board of Governors, Programme Advisory Committee, Executive Committee or other committees constituted by the Regional Centre may be held using contemporary tools of information and communication technologies (including video conferencing) without the members necessarily having to be physically present.

Clause 37.—This clause seeks to provide that the all casual vacancies among the members (other than *ex officio* members) of the authorities under clause 13 shall be filled, as soon as may be, by the person or body who appoints, elects or co-opts the member whose place has become vacant and the person appointed, elected or co-opted to a casual vacancy shall be a member of such authority for the residue of the term for which the person whose place he fills would have been a member.

Clause 38.—This clause seeks to provide that no act or proceedings of any authority or other body of the Regional Centre shall be invalid merely by reason of the existence of a vacancy or vacancies among its members.

Clause 39.—This clause seeks to provide that no suit or other legal proceedings shall lie against any officer or other employee of the Regional Centre for anything which is in good faith done or intended to be done in pursuance of any of the provisions of the proposed legislation, the Statutes, Ordinances and Regulations made thereunder.

Clause 40.—This clause seeks to provide that any dispute arising between the Regional Centre and any of its employees shall, at the first instance, be resolved through such grievance redressal mechanism as may be specified by Statutes.

Clause 41.—This clause seeks to provide that the Statutes of the Regional Centre shall be framed by the Board of Governors on the recommendation of the Executive Committee, relating to matters specified therein.

Clause 42.—This clause empowers Programme Advisory Committee to frame Ordinances relating to matters specified therein.

Clause 43.—This clause seeks to provide that the authorities of the Regional Centre may make Regulations, consistent with the provisions of the proposed legislation, the Statutes and the Ordinances, for the conduct of their own business and that of the Committees, if any, appointed by them and not provided for by the proposed legislation, the Statutes or the Ordinances, in the manner specified by the Statutes.

Clause 44.—This clause seeks to provide that every Statute or Ordinance or Regulation made under the proposed legislation shall be published in the Official Gazette and shall be laid before each House of Parliament.

Clause 45.—This clause seeks to provide that the power to make Statutes or Ordinances or Regulations shall include the power to give retrospective effect, from a date not earlier than the date of commencement of the proposed legislation, to the Statutes or Ordinances or Regulations or any of them but no retrospective effect shall be given to any Statutes or Ordinances or Regulations so as to prejudicially affect the interests of any person to whom such Statutes or Ordinances or Regulations may be applicable.

Clause 46.—This clause seeks to provide that if any difficulty arises in giving effect to the provisions of the proposed legislation, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of the proposed legislation, as appear to it to be necessary or expedient for removing the difficulty. It further provides that no such order shall be made under this section after the expiry of two years from the commencement of the proposed legislation. It also provides that every order made under this clause shall be laid, as soon as may be after it is made, before each House of Parliament.

FINANCIAL MEMORANDUM

Sub-clause (1) of clause 3 of the Bill provides for establishment of an institution to be known as the Regional Centre for Biotechnology (Regional Centre).

2. Clause 29 of the Bill provides for payment of grants and loans to the Regional Centre by the Central Government, after due appropriation made by Parliament by law, in thisbehalf.

3. Clause 30 of the Bill provides for the maintenance of a Fund which shall be applied for meeting the expenses of the Regional Centre in discharge of its functions as specified under the proposed legislation. The Fund will consist, *inter alia,* of all moneys provided by the Central Government; all fees and other charges received by the Regional Centre; all monies received by the Regional Centre by way of grants, gifts, donations, benefactions, bequests or transfer; and all monies received in any other manner and from any other source.

It further provides that the Fund shall be applied for meeting the salaries, allowances and other remuneration of Chairperson and members of the Board, Chairperson of the Programme Advisory Committee, academic staff, officers and other employees, of the Regional Centre or members of other committees set up by it.

4. A capital expenditure of Rupees 55.37 crores has been incurred towards setting up of the Regional Centre for Biotechnology Training and Education at National Capital Region, Faridabad, Haryana, since 2009. The recurring expenditure on manpower requirements, consumables, office expenses, fellowships, meetings, travel, etc., is estimated to be in the range of Rupees 25 crores per year to be met from the budgetary provision of the Central Government.

5. The Bill does not involve any other expenditure of recurring or non-recurring nature from the Consolidated Fund of India.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Sub-clause (1) of clause 41of the Bill empowers the Board of Governors of the Regional Centre to frame Statutes with respect to the matters specified under sub-clause (2) which, *inter alia*, relate to creation of administrative, technical and other posts; the manner and purposes of co-operation or collaboration or association with any institution, including those located outside the country; establishing and maintaining centres and specialised laboratories or other units for research, development and instruction in India or outside India; instituting and award of fellowships, scholarships, studentships, medals and prizes; the manner of entering into agreements with other institutions, industrial or other organisations, including those located outside the country, for research and advisory services; declaring of other authorities to be the authorities of the Regional Centre; the manner of appointment of representatives from amongst the member States of UNESCO; the fees and allowances payable to members of the Programme Advisory Committee and their term of office; and the constitution, powers and functions and the term of office of members of the Executive Committee, the Finance Committee, other authorities and of the Board of Studies.

2. Sub-clause (1) of clause 42 of the Bill empowers the Programme Advisory Committee to make Ordinances with respect to the matters specified under sub-clause (2) which, *inter alia*, relate to admission of students and their enrolment; the course of study; the conditions of award of the fellowships, scholarships, medals and prizes; the conduct of examinations; the conditions of residence of the students; the courses of study to be laid down for all degrees, diplomas and certificates including the medium of instruction and examination; the withdrawal of degrees, diplomas, certificates and other academic distinctions; the fees to be charged for courses of study and for admission to examinations, degrees and diplomas.

3. Clause 43 of the Bill empowers the authorities of the Regional Centre to make Regulations for the conduct of their own business and that of the committees, if any, appointed by them and not provided for by the proposed legislation, the Statutes or the Ordinances.

4. Sub-clause (1) of clause 44 of the Bill provides that every Statute, Ordinance and Regulation shall be published in the Official Gazette. Sub-clause (2) of the aforesaid clause 44 specifies that every Statute or Ordinance or Regulation made under the proposed legislation shall be laid before each House of Parliament.

5. The matters in respect of which the Statutes, Ordinances and Regulations may be made are matters of procedure or administrative detail and it is not practicable to provide for them in the Bill itself. The delegation of legislative power is, therefore, of a normal character.

CHILDREN BORN OF UNMARRIED MOTHERS (DETERMINATION OF PATERNITY THROUGH D.N.A. TEST) ACT, 1998.

RAJYA SABHA

The following Bills were introduced in the Rajya Sabha on the 4th December, 1998:—

I

BILL No. XXVI OF 1998

A Bill to provide for the compulsory determination of paternity of a child of an unmarried mother through DNA test so as to give legitimacy to such an offspring and to resolve the menace of growing population of illegitimate children in the country and for matters connected therewith.

BE it enacted by Parliament in the Forty-ninth Year of the Republic of India as follows:—

1. Short title, extent and commencement.

(1)This Act may be called the Children Born of Unmarried Mothers (Determination of Paternity through D.N.A. Test) Act, 1998.

(2) It extends to the whole of India.

(3) It shall come into force at once.

2. Definitions.

In this Act, unless the context otherwise requires,—

(a)"appropriate Government" means in the case of a State, the Government of that State and in other cases the Central Government;

(b)"designated authority" means an authority constituted by the appropriate Government under section 3 of this Act;

(c)"prescribed" means prescribed by rules made under this Act.

3. Appropriate Government to designate authorities.

Notwithstanding anything contained in any other law for the time being in force, the appropriate Government shall, as soon as may be but not later than six months after the commencement of this Act, designate an authority at the village, block, district and city headquarters, by notification in the Official Gazette, for carrying out the purposes of this Act

4. Functions of the designated authority.

The functions of every designated authority shall be,—

(a) to register every unmarried woman who has conceived along with the name and other particulars of the man who, according to such unmarried woman, is the father of her expected child in such manner as may be prescribed;

(b) to arrange deoxyribonucleic acid or DNA test at an appropriate laboratory for determination of the paternity of the child conceived by an unmarried woman;

(c) to issue paternity certificate in respect of a child born of an unmarried woman in such manner as may be prescribed;

(d) such other functions as may be assigned by the appropriate Government from time to time.

5.Registration of unmarried woman having conceived a child and determination of paternity of the child.

(*1*) Notwithstanding anything contained in any other law for the lime being in force, every unmarried woman having conceived, shall register her name alongwith other particulars required for the purpose with the name and other particulars of the man who fathered the child with the appropriate designated authority.

(2)If the man supposed to be the father of the expected child of the unmarried woman referred to in sub-section *(1)* denies having fathered the child, the designated authority shall get DNA test of the foetus and the man done in order to determine the paternity of the child.

(3)If the DNA test proves that the man had fathered the child, the designated authority shall declare and certify the paternity of the child so as to give legitimacy to his birth.

(4) After having the paternity of the child been proved though DNA test, the man shall give his name as the father of the child and shoulder such other responsibilities in respect of the child and his mother as may be prescribed.

(5) Notwithstanding anything in this Act, the unmarried woman having conceived a child shall be at liberty to medically terminate her foetus under the provisions of the Medical Termination of Pregnancy Act, 1971.

6. Oath of secrecy in certain cases.

The designated authority and all the persons concerned with the DNA test under this Act shall be under an oath of secrecy.

7. Penalty.

(*1*) If the DNA test conducted under sub-section *(2)* of section 5 fails to fix the paternity on the man alleged, the unmarried woman claiming that man to be the father of her child shall be liable to a fine which may extend to one thousand rupees.

(2) Whoever contravenes the provisions of section 6 shall be punished with imprisonment for a term which, may extend to one year or with fine which may extend to fifty thousand rupees or with both.

8. Power to make rules.

The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

STATEMENT OF OBJECTS AND REASONS

With our society opening up to western culture, especially with the advent of cinema, television including cable TV, young boys and girls have developed increasing tendency to promiscuous behaviour and sexual activity, irrespective of marriage, resulting in the growing problem of unmarried motherhood. It inevitably results in miserable life not only for such mothers but to a much greater degree a life tarnished with indignity and even sub-human life for the off-shoot children.

Very often even when the fatherhood of the child is clear, the persons concern refuse to own their responsibility, leaving the children to suffer immense indignity in society and serious problems beyond comprehension.

It is, therefore, necessary to determine the fatherhood of such children, especially when the' unmarried mother identifies the father of the child. A presumption should be created in favour of such mothers, under the law of evidence and the alleged father of the off-shoot of such promiscuous behaviour should be bound by law to be subjected to a DNA test to determine the fatherhood of such child.

This would not only go a long way in resolving the untold problems and indignity that goes with such children but would serve a large number of such unmarried mothers from committing suicides and for avoiding the indignity to such motherhood. This would also ensure dignified human existence and development of such children into dignified citizens of tomorrow.

Hence this Bill.

VEENA VERMA

FINANCIAL MEMORANDUM

Clause 3 of the Bill provides for the designation of authorities for carrying out the purposes of the Bill which includes registration, DNA testings, abortions etc. The Bill, if enacted and brought into operation, will involve expenditure from the Consolidated Fund of India. It is not possible at this stage to give an exact amount of expenditure which is likely to be involved for carrying out the purposes of the Act, However, it is estimated that an amount to the tune of rupees two hundred crores may involve as recurring expenditure per annum.

A non-recurring expenditure of rupees one thousand crores may also be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 8 of the Bill empowers the Central Governments to make rules for carrying out the purposes of the Bill. The rules will relate to matters of procedure and administrative details only. The delegation of legislative power is, therefore, of normal character**.**

THE DNA TECHNOLOGY (USE AND APPLICATION) REGULATION BILL, 2019

As INTRODUCED IN LOK SABHA

Bill No. 128 of 2019

THE DNA TECHNOLOGY (USE AND APPLICATION) REGULATION

A

BILL

to provide for the regulation of use and application of Deoxyribonucleic Acid (DNA) technology for the purposes of establishing the identity of certain categories of persons including the victims, offenders, suspects, undertrials, missing persons and unknown deceased persons and for matters connected therewith or incidental thereto.

BE it enacted by Parliament in the Seventieth Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

1. Short title, extent and commencement.

(*1*) This Act may be called the DNA Technology (Use and Application) Regulation Act, 2019.

(*2*) It extends to the whole of India.

(*3*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint:

Provided that different dates may be appointed for different provisions of this Act and any reference in any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.

2. Definitions.

(*1*) In this Act, unless the context otherwise requires,—

(*i*) "Board" means the DNA Regulatory Board established under sub-section (*1*) of section 3;

(*ii*)"bodily substances" means any biological material of, or from the body of, a person, whether living or dead, unidentified human remains, and includes intimate bodily substance and non-intimate bodily substance as defined in clauses (*a*) and (*c*) of sub-section (*3*) of section 23;

(*iii*) "Chairperson" means the Chairperson of the Board;

(*iv*) "crime scene index" means a list of entries of DNA profiles, in a DNA Data Bank derived from DNA samples found—

(*a*)at any place where an offence was committed or is reasonably suspected of having been committed; or

(*b*) on or within the body of the victim, or a person reasonably suspected of being a victim, of an offence; or

(*c*) on anything worn or carried by the victim at the time when an offence was, or is reasonably suspected of having been, committed; or

(*d*) on or within the body of a person, or on anything, or at any place, associated with the commission of an offence;

(*v*)"Director" means a Director of the National DNA Data Bank or a Regional DNA Data Bank appointed under section 27;

(*vi*) "DNA Data Bank" means a DNA Data Bank established under sub-section (*1*) of section 25;

(*vii*) "DNA laboratory" means any laboratory or facility established by the Central Government or a State Government or a person or an organisation which has been granted accreditation under this Act to perform DNA testing;

(*viii*)"DNA profile" means the result of analysis of a DNA sample for establishing human identification in respect of matters listed in the Schedule;

(*ix*) "DNA sample" means bodily substances of any nature collected for conducting DNA testing and includes the materials derived in a DNA laboratory from such bodily substances;

(*x*) "DNA testing" means the procedure followed in DNA laboratory to develop DNA profile;

(*xi*) "Fund" means Fund of the Board constituted under sub-section (*1*) of section 40;

(*xii*) "known sample" means the bodily substances of a person whose identity is established;
(*xiii*) "medical practitioner" means a medical practitioner who possesses any medical qualification as defined in clause (*h*) of section 2 of the Indian Medical Council Act, 1956 and whose name has been entered in a State Medical Register under that Act;
(*xiv*) "Member" means a Member of the Board and includes the Chairperson and Vice-Chairperson;
(*xv*) "Member-Secretary" means the Member-Secretary of the Board;
(*xvi*) "missing persons' index" means a list of entries of DNA profiles, in a DNA Data Bank, derived from—
(*a*) unidentified human remains; or
(*b*) the personal effects of persons who are missing; or
(*c*) the bodily substances of relatives of the missing persons;
(*xvii*) "notification" means a notification published in the Official Gazette;
(*xviii*) "offenders' index" means a list of entries of DNA profiles of samples taken from offenders, in a DNA Data Bank;
(*xix*) "prescribed" means prescribed by rules made by the Central Government under this Act;
(*xx*) "proficiency testing" means a quality assurance measure used to monitor performance and identify areas in which improvement may be needed and includes—
(*a*) internal test which is devised and administered by the DNA laboratory; and
(*b*) external test, which may be open or blind, and which is devised and administered by an external agency;
(*xxi*) "quality assurance" includes the systematic actions necessary to demonstrate that a product or service meets specified standards of quality;
(*xxii*) "quality manual" means a document which specifies the quality procedures, quality systems and practices of an organisation relating to standards, quality control and quality assurance;
(*xxiii*) "quality system" means the organisational structure, responsibilities, procedure, process and resources for implementing quality management;
(*xxiv*) "regulations" means the regulations made by the Board under this Act;
(*xxv*) "suspects' index" or "under trials' index" means a list of entries of DNA profiles derived from DNA samples taken from the suspects or, as the case may be, under trials, in a DNA Data Bank;
(*xxvi*) "unknown deceased persons' index" means a list of entries of DNA profiles derived from DNA samples taken from the remains of a deceased person, whose identity is not known, maintained in a DNA Data Bank;
(*xxvii*) "validation process" means the process by which a procedure is evaluated to determine its efficacy and reliability for casework analysis and includes—
(*a*) developmental process, being the acquisition of test data and determination of conditions and limitations, of any new DNA methodology for use on case samples; and
(*b*) internal process, being an accumulation of test data within the DNA laboratory, to demonstrate that the established methods and procedures are performed as specified in the laboratory.
(*2*) The words and expressions used and not defined in this Act but defined in the Indian Penal Code, the Indian Evidence Act, 1872 and the Code of Criminal Procedure, 1973, shall have the meanings respectively assigned to them in those Codes or that Act.

CHAPTER II
DNA REGULATORY BOARD

3. Establishment of DNA Regulatory Board.
(*1*) The Central Government may by notification, establish for the purposes of this Act, a Board to be called the DNA Regulatory Board.
(*2*) The Board shall be a body corporate by the name aforesaid, having perpetual succession and a common seal, with power, subject to the provisions of this Act, to acquire, hold and dispose of property, both movable and immovable, and to contract, and shall, by the said name, sue or be sued.

(*3*) The head office of the Board shall be at such place in the National Capital Region, as the Central Government may, by notification, specify.
(*4*) The Board may, with the approval of the Central Government, establish regional offices at such other places as it may deem necessary.

4. Composition of Board.

The Board shall consist of the following Members to be appointed by the Central Government, namely:—
(*a*) the Secretary to the Government of India in the Department of Biotechnology, who shall be the Chairperson, *ex officio*;
(*b*) an eminent person from the field of biological sciences having experience of not less than twenty-five years in the field, who shall be the Vice-Chairperson;
(*c*) a member of the National Human Rights Commission to be nominated by its Chairperson, *ex officio*;
(*d*) the Director-General of the National Investigation Agency and the Director of the Central Bureau of Investigation or their nominees not below rank of the Joint Director, to be nominated by the Central Government, *ex officio*;
(*e*) the Director-General of Police of a State, to be nominated by the Central Government by rotation every three years from amongst the States in alphabetical order, *ex officio*;
(*f*) the Director of the Centre for DNA Fingerprinting and Diagnostics, Hyderabad, to be nominated by the Central Government, *ex officio*;
(*h*) the Director of the National Accreditation Board for Testing and Calibration of Laboratories, New Delhi, to be nominated by the Central Government, *ex officio*;
(*h*) the Director of a Central Forensic Science Laboratory to be nominated by the Central Government, by rotation every three years, *ex officio*;
(*i*) an officer not below the rank of the Joint Secretary to the Government of India in the Ministry of Law and Justice, to be nominated by the Central Government, *ex officio*;
(*j*) an officer not below the rank of the Joint Secretary to the Government of India in the Ministry of Science and Technology, to be nominated by the Central Government, *ex officio*;
(*k*) one expert, from amongst persons of eminence in the field of biological sciences having experience of not less than twenty-five years in the field; and
(*l*) an officer, not below the rank of Joint Secretary to the Government of India or equivalent, with knowledge and experience in biological sciences, to be nominated by the Central Government, *ex officio*, who shall be the Member-Secretary.

5. Term of office and conditions of service of Chairperson, Vice-Chairperson and Member.

(*1*) The Chairperson shall hold the office in the Board till he remains Secretary in the Department of Biotechnology.
(*2*) The Vice-Chairperson appointed under clause (*b*) and the Member appointed under clause (*k*), of section 4, shall hold office for a period of three years or till he attains the age of sixty-five years, whichever is earlier and shall be eligible for re-nomination for a further period of three years.
(*3*) The Vice-Chairperson appointed under clause (*b*) and the Member appointed under clause (*k*), of section 4, shall be entitled to such pay and allowances as may be prescribed.
(*4*) The Chairperson and other *ex officio* Members may be entitled to such allowances as may be prescribed.

6. Meetings of Board.

(*1*) The Board shall meet at such time and place and shall, subject to this section, observe such rules of procedure with regard to the transaction of business at its meetings (including the quorum at such meetings) as may be specified by regulations.
(*2*) The Chairperson shall preside over the meetings of the Board and if, for any reason, he is unable to attend a meeting, the Vice-Chairperson and in his absence, the senior-most Member present, reckoned from the date of his appointment to the Board, shall preside over such meeting:
Provided that in case of common date of appointment of Members, the Member senior in age shall be considered as senior to the other Members.
(*3*) All questions which come up before any meeting of the Board shall be decided by a majority of votes of the Members present and voting, and in the event of an equality of votes, the Chairperson or, in his absence, the Vice-Chairperson or, in his absence, the Member presiding over the meeting, shall have a casting vote.

(*4*) Save as otherwise provided under this Act, the Chairperson shall have powers of general superintendence and direction of the affairs of the Board and may also exercise such other powers as may be delegated to him by the Board.
(*5*) All orders and decisions of the Board shall be authenticated by the Member-Secretary.

7. Member not to participate in meetings in certain cases.

Any Member having any direct or indirect interest, whether pecuniary or otherwise, in any matter coming up for consideration at a meeting of the Board, shall, as soon as possible after relevant circumstances have come to his knowledge, disclose the nature of his interest at such meeting and such disclosure shall be recorded in the proceedings of the Board, and such Member shall not take part in any deliberation or decision of the Board with respect to that matter.

8. Removal and resignation of Chairperson or Member and filling up of casual vacancies of Board.

(*1*) The Central Government may remove from office the Chairperson or any other Member, who—
(*a*) has been adjudged as an insolvent;
(*b*) has been convicted of an offence involving moral turpitude;
(*c*) has become physically or mentally incapable of acting as a Member;
(*d*) has acquired such financial or other interest as is likely to affect prejudicially his functions as a Member; or
(*e*) has so abused his position as to render his continuance in office prejudicial to the public interest:
Provided that the Chairperson or a Member shall not be removed from office on the grounds specified under clause (*d*) or clause (*e*) except by an order made by the Central Government after an inquiry made in this behalf in which the Chairperson or such Member has been given a reasonable opportunity of being heard in the matter.
(*2*) If, for any reason, other than temporary absence, any vacancy occurs in the office of a Member, the Central Government shall appoint another Member from the same category in accordance with the provisions of this Act to fill such vacancy, and such Member shall hold office for the remainder of the term of the Member in whose place he has been appointed.
(*3*) Any Member may, by a notice of not less than thirty days in writing under his hand, addressed to the Central Government, resign from office:
Provided that the Member shall, unless he is permitted by the Central Government to relinquish his office sooner, continue to hold office until the expiry of three months from the date of receipt of such notice or until a person is duly appointed in his place or till the expiry of his term of office, whichever is earlier.

9. Vacancies, etc., not to invalidate proceedings of Board.

No act or proceeding of the Board shall be invalid merely by reason of—
(*a*) any vacancy in, or any defect in the constitution of, the Board; or
(*b*) any defect in the appointment of a person acting as a Member of the Board;
or
(*c*) any irregularity in the procedure of the Board not affecting the merits of the case.

10. Delegation of powers of Board.

(*1*) The Board may, by general or special order published in the Official Gazette, delegate to the Chairperson or any other Member, subject to such conditions, if any, as may be specified in the order, its functions under this Act (except the power to make regulations), as it may deem necessary.
(*2*) An order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

11. Officers and other employees of Board.

(*1*) The Board may, with the approval of the Central Government, appoint such officers and other employees, as it considers necessary, for the efficient discharge of its functions under this Act.
(*2*) The salaries and allowances payable to, and the other terms and conditions of service, including the manner of appointment, of the officers and other employees, under sub-section (*1*) shall be such as may be prescribed.

12. Functions of Board.

The Board shall for the purposes of this Act, perform the following functions, namely:—
(*a*) advice the Central Government and the State Governments on all issues relating to establishing of DNA laboratories and DNA Data Banks, including planning, organisational structure, size, number, location and

laying down guidelines, standards and procedures for establishment and functioning of such laboratories and Data Banks including manpower, infrastructure and other related issues concerning monitoring of their performance and activities; upgradation of DNA laboratories; and making recommendations on funds required for such purposes;
(*b*) grant accreditation to laboratories and to suspend or revoke such accreditation;
(*c*) supervise DNA laboratories and DNA Data Banks, including their quality control;
(*d*) develop the training modules and frame guidelines for training of manpower, including the police and investigating agencies dealing with DNA related matters;
(*e*) regulate and audit DNA training programmes for DNA laboratories and DNA Data Banks;
(*f*) identify scientific advances and recommend research and development activities in DNA testing and related issues, including intellectual property issues;
(*g*) lay down procedures for communication of information relating to DNA profile in civil and criminal proceedings and for investigation of crimes by law enforcement and other investigating agencies;
(*h*) recommend methods for optimum use of DNA techniques and technologies for administration of justice or for such other relevant purposes as may be specified by regulations;
(*i*) adopt and disseminate best practices, concerning the collection and analysis of DNA sample to ensure quality and consistency in the use of DNA techniques, and on all ethical and human rights issues relating to DNA testing in consonance with international guidelines enumerated by the United Nations Organisation and its specialised agencies, *inter alia*, relating to—
(*i*) the rights and privacy of citizens;
(*ii*) the issues concerning civil liberties;
(*iii*) issues having ethical and other social implications in adoption of DNA testing technology; and
(*iv*) professional ethics in DNA testing;
(*j*) give advice on matters under this Act which may be referred to it by the Central Government or the State Government;
(*k*) make recommendations to the Central Government for the application of privacy protection in relation to the access to, or the use of, DNA samples and their analyses, and ensure—
(*i*) implementation and sufficiency of such protection;
(*ii*) appropriate use and dissemination of DNA information;
(*iii*) accuracy, security and confidentiality of DNA information;
(*iv*) timely removal and destruction of obsolete, expunged or inaccurate DNA information; and
(*v*) such other steps as may be required to protect privacy;
(*l*) facilitate exchange of ideas and information on DNA technology;
(*m*) create awareness among public and other stakeholders, including police officers, prosecutors and judicial officers on the use and application of DNA technology;
(*n*) assist in such manner as may be prescribed, in criminal investigation between various investigation agencies within the country and with any foreign State, international organisation or institution in dealing with DNA testing;
(*o*) advice the Central Government on any modifications required to be made in respect of any matter under the Schedule;
(*p*) frame guidelines for storage and destruction of bodily substances including known sample;
(*q*) perform such other functions as may be prescribed.

CHAPTER III
ACCREDITATION OF DNA LABORATORIES

13. Prohibition of DNA testing, etc., without accreditation.

(*1*) No laboratory shall undertake DNA testing, analysing or any other procedure to generate data and perform analysis relating thereto without obtaining accreditation from the Board:
Provided that a laboratory functioning as on the date of the commencement of this Act, may undertake DNA testing or any other procedure relating thereto, for a period of sixty days from such commencement and apply to the Board in accordance with sub-section (*2*) for obtaining accreditation:
Provided further that such laboratory may, after making an application, continue to undertake DNA testing or any other procedure relating thereto, until its application is decided by the Board.
(*2*) A laboratory seeking accreditation under sub-section (*1*) shall apply to the Board in such form and manner along with such fees and documents as may be specified by regulations.

(*3*) A laboratory seeking accreditation shall comply with such onsite assessment requirements, standards and such other requirements, as may be specified by regulations.
(*4*) The application for renewal of accreditation shall be made to the Board at least sixty days prior to the expiration of the accreditation in such form and manner and along with such fees as may be specified by regulations.

14. Granting of accreditation or renewal thereof.

(*1*) The Board may, within a period of ninety days from the receipt of application for accreditation or renewal thereof, and after carrying out inspection of the laboratory, its records and books, and if it is satisfied that the laboratory fulfils all requirements under this Act, by order, grant accreditation to such laboratory or renew it, subject to such conditions as it may deem fit:
Provided that no application for accreditation shall be rejected by the Board without recording the reasons thereof, and giving the applicant an opportunity of being heard.
(*2*) The accreditation or renewal of accreditation under this section shall be valid for a period of two years.

15. Power of Board to suspend or revoke accreditation.

(*1*) The Board may revoke the accreditation granted to a DNA laboratory, if such laboratory fails to—
(*a*) undertake DNA testing or any other procedure relating thereto;
(*b*) comply with any of the conditions subject to which the accreditation has been granted;
(*c*) comply with the provisions of this Act or the rules and regulations made thereunder or any other law for the time being in force;
(*d*) comply with the guidelines issued by the Board under this Act; or
(*e*) submit or offer for inspection its laboratory or books of account and any other relevant documents, including audit reports, when so demanded by the officers or agency authorised by the Board.
(*2*) Where the Board is of the opinion that any delay in revoking accreditation given to a DNA laboratory is prejudicial or detrimental to the public interest, it may suspend the accreditation forthwith pending final decision on such revocation.
(*3*) No revocation of accreditation of a DNA laboratory shall be made by the Board without giving the laboratory an opportunity of being heard.
(*4*) On the revocation or suspension of accreditation of the DNA laboratory, the laboratory shall hand over all DNA samples and records relating to DNA testing from its laboratory to such DNA laboratory as may be directed by the Board and it shall not retain any sample or record.

16. Appeal against rejection, suspension or revocation of accreditation.

Any laboratory aggrieved, by an order of rejection of its application for accreditation or renewal thereof under section 14 or an order of suspension or revocation of accreditation under section 15, may prefer an appeal to the Central Government or such other authority as that Government may, by notification, specify, within a period of sixty days from the date of such order, which shall be decided by the Central Government or the authority, as the case may be, within a period of sixty days from the date of receipt of such appeal.

CHAPTER IV
OBLIGATIONS OF DNA LABORATORY

17. Obligations of DNA laboratory.

(*1*) Every DNA laboratory, which has been granted accreditation for undertaking
DNA testing or any other procedure under this Act, shall—
(*a*) follow such standards and procedures for quality assurance in the collection, storage, testing and analysis of DNA sample,
(*b*) establish and maintain such documentation and quality system,
(*c*) prepare and maintain quality manuals containing such details,
(*d*) share DNA data prepared and maintained by it with the National DNA Data Bank and the Regional DNA Data Bank, in such manner, as may be specified by regulations.
(*2*) The DNA laboratory shall report the results of the DNA testing in conformity with the provisions of this Act and the regulations made thereunder.

18. Appointment of in-charge, scientific, technical and other staff, of DNA laboratory.

Every DNA laboratory shall appoint a person to be in-charge of the laboratory and employ such scientific, technical and other staff, possessing such qualifications and experience as may be specified by regulations, for discharging the duties and performing the functions under this Act.

19. Responsibilities of person in charge of DNA laboratory.

The incharge of the DNA laboratory shall,—
(*a*) take such measures for facilitating skill upgradation and advancement in the knowledge of its employees in the field of DNA testing and other related fields, as may be specified by regulations;
(*b*) ensure that its employees undergo regular training in DNA related subjects,
in such institutions, level and intervals, as may be specified by regulations;
(*c*) maintain such records relating to the laboratory and its personnel as may be specified by regulations.

20. Measures tobe taken byDNA laboratory.
(*1*) Every DNA laboratory shall,—
(*a*) possess such infrastructure,
(*b*) maintain such security and follow such procedure to avoid contamination of DNA samples,
(*c*) establish and follow such documented evidence control system to ensure integrity of physical evidence,
(*d*) establish and follow such validation process and written analytical procedure, (*e*) prepare such indices,
(*f*) use such equipment for the methods it employs,
(*h*) have such documented programme for calibration of instruments and equipment,
(*h*) conduct annual quality audits with such standards,
(*i*) install such security system for the safety of DNA laboratory and its personnel,
(*j*) charge such fees for conducting DNA testing or any other procedure relating thereto, not exceeding twenty-five thousand rupees, as may be specified by regulations.
(*2*) The DNA laboratory shall, after deriving the DNA profile and depositing it with the DNA Data Bank,—
(*a*) return the biological sample or remaining material for its preservation to the investigating officer in a criminal case till the disposal of the case or the order of the court; and
(*b*) in all other cases, destroy the biological sample or remaining material and intimate the person concerned.
(*3*) For the purposes of this section,—
(*a*) "analytical procedure" means an orderly step by step procedure designed to ensure operational uniformity;
(*b*) "quality audit" means an inspection used to evaluate, confirm or verify activity related to quality;
(*c*) "calibration" means a set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.

21. Consent for taking bodily substances to be taken from a person arrested.
(*1*) No bodily substances shall be taken from a person who is arrested for an offence (other than the specified offences) unless the consent is given in writing for the taking of the bodily substances.
Explanation.—For the purposes of this sub-section, "specified offences" means any offence punishable with death or imprisonment for a term exceeding seven years.
(*2*) If the consent required under sub-section (*1*) for taking of bodily substances from a person is refused or cannot be obtained, the person investigating the case may make an application to the Magistrate having jurisdiction for obtaining bodily substances from the arrested person.
(*3*) The Magistrate may, if he is satisfied that there is reasonable cause to believe that the bodily substances may confirm or disprove whether the person so arrested was involved in committing the offence, order for taking of bodily substances from such person.

22. Bodily substances given voluntarily.
(*1*) Subject to sub-section (*2*), any person who—
(*a*) was present at the scene of a crime when it was committed; or
(*b*) is being questioned in connection with the investigation of a crime; or
(*c*) intends to find the whereabouts of his missing or lost relative, in disaster or otherwise, may voluntarily consent in writing to bodily substances being taken from him for DNA testing.
(*2*) If the person giving voluntary consent is below the age of eighteen years and the consent of the parent or guardian of such person is refused or cannot be obtained, the person investigating the case may make an application to the Magistrate having jurisdiction, for obtaining such bodily substances and the Magistrate, if he is satisfied that there is reasonable cause for taking the bodily substances from such person, order for taking of bodily substances from that person.

23. Sources and manner of collection of samples for DNA testing.
(*1*) For the purposes of this Act, samples for DNA testing may be collected from the following sources, namely:—

(*a*) bodily substances;
(*b*) scene of occurrence or scene of crime;
(*c*) clothing and other objects; or
(*d*) such other sources as may be specified by regulations.
(*2*) For the purposes of sub-section (*1*),—
(*a*) any intimate bodily substance from living persons shall be collected, and intimate forensic procedures shall be performed, by a medical practitioner;
(*b*) any non-intimate bodily substance shall be collected and non-intimate forensic procedure shall be performed by the technical staff trained for the collection of samples for DNA testing, under the supervision of a medical practitioner or a scientist having expertise in molecular biology or such other person as may be specified by regulations:
Provided that before collecting bodily substances for DNA testing of a victim or a person reasonably suspected of being a victim who is alive, or a relative of a missing person, or a minor or a disabled person, written consent of such victim or such relative or the parent or guardian of such minor or disabled person shall be obtained and, in case of refusal, the person investigating the case may make an application to the Magistrate having jurisdiction, for obtaining such bodily substances and the Magistrate, if he is satisfied that there is reasonable cause for taking the bodily substances from such person, order for taking of bodily substances from that person.
(*3*) For the purposes of this section,—
(*a*) "intimate bodily substance" means a sample of blood, semen or any other tissue, fluid, urine or pubic hair, or a swab taken from a person's body orifice other than mouth; or skin or tissue from an internal organ or body part, taken from or of a person, living or dead;
(*b*) "intimate forensic procedure" means any of the following forensic procedures conducted on a living person, namely:—
(*i*) external examination of the genital or anal area, the buttocks and breasts in the case of a female;
(*ii*) taking of a sample of blood;
(*iii*) taking of a sample of pubic hair;
(*iv*) taking of a sample by swab or washing from the external genital or anal area, the buttocks and breasts in the case of a female;
(*v*) taking of a sample by vacuum suction, by scraping or by lifting by tape from the external genital or anal area, the buttocks and breasts in the case of a female;
(*vi*) taking of a photograph or video recording of, or an impression or cast of a wound from, the genital or anal area, buttocks and breasts in the case of a female;
(*c*) "non-intimate bodily substance" means any of the following taken from or of a person, living or dead, namely:—
(*i*) handprint, fingerprint, footprint or toe print;
(*ii*) a sample of hair other than pubic hair;
(*iii*) a sample taken from a nail or under a nail;
(*iv*) swab taken from any part of a person's body including mouth, but not any other body orifice;
(*v*) saliva; or
(*vi*) a skin impression;
(*d*) "non-intimate forensic procedure" means any of the following forensic procedures conducted on a living individual, namely:—
(*i*) examination of a part of the body other than the genital or anal area,
the buttocks and breasts in the case of a female, that requires touching of the body or removal of clothing;
(*ii*) taking of a sample of hair other than pubic hair;
(*iii*) taking of a sample from a nail or under a nail;
(*iv*) taking of a buccal swab with consent;
(*v*) taking of a sample by swab or washing from any external part of the body other than the genital or anal area, the buttocks and breasts in the case of a female;
(*vi*) scraping or lifting by tape from any external part of the body other than the genital or anal area, the buttocks and breasts in the case of a female;
(*vii*) taking of a handprint, fingerprint, footprint or toe print; or
(*viii*) taking of a photograph or video recording of, or an impression or cast of a wound from, a part of the body other than the genital or anal area, the buttocks and breasts in the case of a female.

24. Taking of bodily substances for reexamination.
If the trial court is satisfied with the plea of the accused person that the bodily substances taken from such person or collected from the place of occurrence of crime had been contaminated, the court may direct the taking of fresh bodily substances for re-examination.

CHAPTER V
DNA DATA BANK

25. Establishment of DNA Data Banks.
(*1*) The Central Government shall, by notification, establish a National DNA Data Bank and such number of Regional DNA Data Banks for every State, or two or more States, as it may deem necessary.
(*2*) A Regional DNA Data Bank shall share all DNA data stored and maintained by it with the National DNA Data Bank.
(*3*) The National DNA Data Bank shall receive DNA data from Regional DNA Data Banks and shall store the DNA profiles received from the DNA laboratories in such format as may be specified by regulations.

26. Maintenance of indices by DNA Data Bank.
(*1*) Every DNA Data Bank shall maintain the following indices for various categories of data, namely:—
(*a*) a crime scene index;
(*b*) a suspects' index or undertrials' index;
(*c*) an offenders' index;
(*d*) a missing persons' index; and
(*e*) unknown deceased persons' index.
(*2*) In addition to the indices referred to in sub-section (*1*), every DNA Data Bank shall maintain, in relation to each DNA profile, the following information, namely:—
(*a*) in case of a profile in the suspects' index or undertrials' index or offenders' index, the identity of the person from whose bodily substances the profile was derived; and
(*b*) in case of a profile, other than a profile in the suspects' index or undertrials' index or offenders' index, the case reference number of the investigation associated with the bodily substances from which the profile was derived.
(*3*) The indices maintained under sub-section (*1*) shall include information of data based on DNA testing and records relating thereto, prepared by a DNA laboratory.

27. Directors of DNA Data Banks.
(*1*) The Central Government shall appoint a Director of the National DNA Data Bank, on the recommendations of a selection committee to be constituted by that Government, in such manner and consisting of such persons, as may be prescribed, for the purposes of execution, maintenance and supervision of the National DNA Data Bank.
(*2*) The Director of the National DNA Data Bank shall be a person of eminence possessing such educational qualifications and experience in biological sciences, as may be prescribed.
(*3*) The Director of the National DNA Data Bank shall be not below the rank of a Director to the Government of India or equivalent and shall function under the supervision and control of the Board.
(*4*) The Director of the National DNA Data Bank shall exercise such powers and perform such duties, as may be specified by regulations.
(*5*) The Central Government may appoint a Director for each Regional DNA Data Bank, who shall be not below the rank of Deputy Secretary to the Government of India or equivalent, and shall function under the supervision and control of the Board.

28. Officers and other employees of National DNA Data Bank and Regional DNA Data Banks.
(*1*) The Board may, with the approval of the Central Government, appoint such officers and other employees, as it considers necessary, for the efficient discharge of the functions of the National DNA Data Bank and the Regional DNA Data Banks.
(*2*) The salaries and allowances payable to, and the terms and other conditions of service including the manner of appointment, of the Director of the National DNA Data Bank and the Director of each of the Regional DNA Data Bank shall be such as may be prescribed.
(*3*) The Board may appoint such number of officers and experts and other employees to assist the DNA Data Banks in the discharge of its functions, on such remunerations and upon such terms and conditions of service, including the manner of appointment, as may be specified by regulations.

29. Comparison and communication of DNA profiles.

(*1*) The criteria and procedure to be followed by the National DNA Data Bank on receipt of a DNA profile for comparison with DNA profiles maintained in the DNA Data Bank and communication of the results shall be made to such persons and in such manner as may be specified by regulations:
Provided that if the DNA profile is derived from the bodily substances of a living person who is neither an offender nor a suspect or an undertrial, no comparison shall be made of it with the DNA profiles in the offenders' index or suspects' index or undertrials' index maintained in the DNA Data Bank.
(*2*) Any information relating to a person's DNA profile contained in the suspects'
index or undertrials' index or offenders' index of the DNA Data Bank shall be communicated only to the authorised persons.

30. Sharing of DNA profiles with foreign Government or international organisation.

(*1*) On receipt of a DNA profile from the Government of a foreign State or an international organisation or any institution of such Government or international organisation, the National DNA Data Bank may compare such DNA profile with the DNA profiles contained in the crime scene index, the offenders' index, the suspects' index, the undertrials' index, the missing persons' index and the unknown deceased persons' index, to determine whether there is a match between the profiles and the Director of the National DNA Data Bank may, with the prior approval of the Central Government communicate any of the following information to such Government or organisation or institution, as the case may be, through any agency authorised by notification by the Central Government, namely:—
(*a*) that there is no match between the profiles;
(*b*) if there is a match between the profiles, any information relating to such matching DNA profile; or
(*c*) if, in the opinion of the Director of National DNA Data Bank, the DNA profile is similar to the one contained in the DNA Data Bank, information relating to such similar DNA profile.
(*2*) After receiving the similar DNA profile under clause (*c*) of sub-section (*1*), if the foreign Government or organisation or institution referred to in sub-section (*1*) informs that the possibility of a match between the similar DNA profile with the DNA profile provided by it has not been excluded, any further information in relation to such similar DNA profile may also be furnished in the manner specified in sub-section (*1*).
(*3*) The Central Government may, in consultation with the Board,—
(*a*) determine the nature and extent of sharing DNA profiles in respect of offenders, suspects, undertrials, missing persons and unknown deceased persons with the Government of a foreign State or an international organisation or an institution established by that Government or organisation, as the case may be;
(*b*) seek similar information from such foreign State, organisation or institutions, and the provisions of sub-sections (*1*) and (*2*) shall *mutatis mutandis*, apply.

31. Retention and removal of records.

(*1*) The information contained in the crime scene index shall be retained.
(*2*) The Director of the National DNA Data Bank shall remove from the DNA Data Bank the DNA profile,—
(*i*) of a suspect, after the filing of the police report under the statutory provisions or as per the order of the court;
(*ii*) of an undertrial, as per the order of the court,
under intimation to him, in such manner as may be specified by regulations.
(*3*) The National DNA Data Bank shall, on receiving a written request of a person who is neither an offender nor a suspect or an undertrial, but whose DNA profile is entered in the crime scene index or missing persons' index of the DNA Data Bank, for removal of his DNA profile therefrom, remove the DNA profile of such person from DNA Data Bank under intimation to the person concerned, in such manner as may be specified by regulations:
Provided that where such DNA profile is of a minor or a disabled person, removal shall be made on receiving written request from a parent or the guardian of such minor or disabled person.
(*4*) Subject to this section, the criteria for entry, retention and removal of any DNA profile in, or from, the DNA Data Bank and DNA laboratories shall be such as may be specified by regulations.

CHAPTER VI
PROTECTION OF INFORMATION

32. Security and confidentiality of information.

(*1*) Subject to the provisions of this Act, the Board shall ensure that the information relating to DNA profiles, DNA samples and any records thereof, forwarded to, or in custody of the National DNA Data Bank or the

Regional DNA Data Bank or a DNA laboratory or any other person or authority under this Act, are secured and kept confidential.

(*2*) The Board shall take all necessary measures to ensure that the information referred to in sub-section (*1*) are protected against access, use or disclosure not permitted under this Act or regulations made thereunder, and against accidental or intentional destruction, loss or damage.

(*3*) Without prejudice to sub-sections (*1*) and (*2*), the Board shall—

(*a*) adopt and implement appropriate technical and organisational security measures;

(*b*) ensure that every agency appointed or engaged for performing any functions under this Act have in place appropriate technical and organisational security measures for the information; and

(*c*) ensure that the agreements or arrangements, entered into with any investigation agency, international organisation or institution, impose obligations equivalent to those imposed on the Board under this Act, and require such agency, organisation or institution to act only on instructions from the Board.

(*4*) Notwithstanding anything contained in any other law for the time being in force, and save as otherwise provided in this Act, the Board or any of its officers or other employee, the Director of the National or Regional DNA Data Bank or any of its officers or other employees, or the in-charge and other staff of DNA laboratory or any officer or employee of the agency engaged under this Act shall not, whether during his service or thereafter, reveal any information relating to DNA profiles, DNA samples and any records thereof to anyone.

33. Use of DNA profiles, DNA samples and records, etc., for facilitating identification of persons.

All DNA data, including DNA profiles, DNA samples and records thereof, contained in any DNA laboratory and DNA Data Bank shall be used only for the purposes of facilitating identification of the person and not for any other purpose.

34. Access to information in certain cases.

Any information relating to DNA profiles, DNA samples and records thereof, maintained in a DNA Data Bank shall be made available for the following purposes, namely:—

(*a*) facilitating the identification of persons in criminal cases by the law enforcement and investigating agencies;

(*b*) judicial proceedings, in accordance with the rules of admissibility of evidence;

(c) facilitating prosecution and adjudication of criminal cases;

(*d*) taking defence by an accused in the criminal case in which he is charged;

(*e*) investigation relating to civil disputes or other civil matters or offences or cases specified in the Schedule, by making such information available to the concerned parties with the approval of the court, or to the concerned authority; or

(*f*) such other purposes, as may be specified by regulations.

35. Access to information for operation, maintenance and training.

Access to such information contained in the National DNA Data Bank and the Regional DNA Data Banks may be made available by the Director, if he considers appropriate,—

(*a*) to a person or class of persons, for the sole purpose of proper operation and maintenance of the DNA Data Bank; and

(*b*) to the personnel of any DNA laboratory for the sole purpose of training, in accordance with such terms and conditions as may be specified by regulations.

36. Access to information in DNA Data Bank for one time keyboard search.

A person who is authorised to access an index of the DNA Data Bank, including information of DNA identification records or DNA profile in that index, may also access that index for the purposes of carrying out one time keyboard search on information obtained from any DNA sample collected for the purpose of criminal investigation, except for a DNA sample voluntarily submitted solely for elimination purposes.

Explanation.—For the purposes of this section, "one time keyboard search" means a search under which information obtained from a DNA sample is compared with the information in the index of the DNA Data Bank, without resulting in the information obtained from the DNA sample being included in the index.

37. Restriction on access to information in crime scene index.

Access to the information in the crime scene index contained in the DNA Data Bank shall be restricted, in such manner as may be specified by regulations, if such information relates to a DNA profile derived from bodily substances of—

(*a*) victim of an offence which forms or formed the object of relevant investigation; or
(*b*) a person who has been eliminated as a suspect in the relevant investigation.

38. Prohibition on access to information in DNA Data Bank.

(*1*) No person who receives the DNA profile for entry in the DNA Data Bank shall use it or allow or cause it to be used for purposes other than those for which it has been collected in accordance with the provisions of this Act.
(*2*) Save as otherwise provided in this Act, no person shall communicate, or authorize the communication of, or allow or cause to be communicated, any information on DNA profiles contained in the DNA Data Banks or the information communicated under section 29 or section 30.
(*3*) No person to whom information is communicated or who has access to information under this Act shall use that information for any purpose other than for which the communication or access is permitted under the provisions of this Act.

CHAPTER VII
FINANCE, ACCOUNTS, AUDIT AND REPORTS

39. Grants by Central Government.

The Central Government may, after due appropriation made by Parliament by law, in this behalf, make to the Board grants of such sums of money as the Central Government may consider necessary.

40. DNA Regulatory Board Fund.

(*1*) There shall be constituted a Fund to be called the DNA Regulatory Board Fund and there shall be credited thereto—
(*a*) any grants and loans made to the Board under this Act;
(*b*) all sums received by the Board including fees or charges, or donations from such other source as may be decided by the Central Government; and
(*c*) any income from investment of the amount of the Fund.
(*2*) The Fund shall be applied by the Board for meeting,—
(*a*) the salaries and allowances payable to the Members, the officers, experts and the other employees, including administrative expenses, of the Board; and
(*b*) the expenses for carrying out the purposes authorised under this Act.

41. Budget.

(*1*) The Board shall prepare, in such form and at such time in each financial year, as may be prescribed, its budget for the next financial year showing the estimated receipts and expenditure of the Board and forward the same to the Central Government.
(*2*) The Board, with the prior approval of the Central Government, shall adopt financial regulation which specifies in particular, the procedure for drawing up and implementing the Board's budget.

42. Annual report.

The Board shall prepare in such form and at such time in each financial year, as may be prescribed, its annual report giving a full account of its activities during the previous financial year and submit a copy thereof to the Central Government.

43. Accounts and audit of Board.

(*1*) The Board shall maintain proper accounts and other relevant records and prepare an annual statement of accounts in such form as may be prescribed in consultation with the Comptroller and Auditor-General of India.
(*2*) The Comptroller and Auditor-General of India and any person appointed by him in connection with the audit of the accounts of the Board under this Act shall have the same rights and privileges and authority in connection with such audit as the Comptroller and Auditor-General of India generally has in connection with the audit of Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the Board.
(*3*) The accounts of the Board, as certified by the Comptroller and Auditor-General of India or any other person appointed by him in this behalf, together with the audit report thereon shall be forwarded annually to the Central Government by the Board.
(*4*) The accounts of the Board shall be audited by the Comptroller and Auditor-General of India annually and any expenditure incurred in connection with such audit shall be payable by the Board to the Comptroller and Auditor-General of India.

44. Annual report and auditor's report to be laid before Parliament.

The Central Government shall cause the annual report and auditor's report of the Board to be laid, as soon as may be after they are received, before each House of Parliament.

CHAPTER VIII
OFFENCES AND PENALTIES

45. Penalty for unauthorized disclosure of information in DNA Data Bank.

Whoever, by virtue of his employment or official position or otherwise, has in his possession, or having access to, individually identifiable DNA information kept in the DNA laboratory or DNA Data Bank, wilfully discloses it in any manner to any person or agency not entitled to receive it under this Act, or under any other law for the time being in force, shall be punishable with imprisonment for a term which may extend to three years and also with fine which may extend to one lakh rupees.

46. Penalty for obtaining information from DNA Data Bank without authorisation.

Whoever, without authorisation, wilfully obtains individually identifiable DNA information from the DNA laboratory or DNA Data Bank, shall be punishable with imprisonment for a term which may extend to three years and also with fine which may extend to one lakh rupees.

47. Penalty for using DNA sample or result without authorisation.

Whoever, without authorisation, wilfully uses any DNA sample or result of any DNA analysis, shall be punishable with imprisonment for a term which may extend to three years and also with fine which may extend to one lakh rupees.

48. Penalty for unlawful access to information in DNA Data Bank.

Whoever, accesses information stored in the DNA Data Bank, otherwise than in accordance with the provisions of this Act, shall be punishable with imprisonment for a term which may extend to two years and also with fine which may extend to fifty thousand rupees.

49. Penalty for destruction, alterations, contamination or tampering with biological evidence.

Whoever, knowingly and intentionally, destroys, alters, contaminates or tampers with biological evidence which is required to be preserved under any law for the time being in force, with the intention to prevent that evidence from being subjected to DNA testing or to prevent the production or use of that evidence in a judicial proceeding, shall be punishable with imprisonment for a term which may extend to five years and also with fine which may extend to two lakh rupees.

50. Penalty for contravention where no specific punishment is provided.

Whoever, contravenes any of the provisions of this Act or the rules and regulations made thereunder for which no penalty is provided in this Act, shall be punishable with imprisonment for a term which may extend to two years and also with fine which may extend to fifty thousand rupees.

51. Offences by companies or institutions.

(*1*) Where an offence under this Act, has been committed by a company or institution, every person who at the time the offence was committed was in-charge of, and was responsible to, the company or institution for the conduct of the business of the company or institution, as well as the company or institution, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act, if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(*2*) Notwithstanding anything contained in sub-section (*1*), where an offence under this Act has been committed by a company or institution and it is proved that the offence has been committed with the consent or connivance of or is attributable to any neglect on the part of any director, manager, secretary or other officer of the company or institution, such director, manager, secretary or other officer shall also be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

Explanation.—for the purposes of this section,—

(*a*) "company" means any body corporate and includes a firm or other association of individuals; and

(*b*) "director", in relation to a firm, means a partner in the firm.

CHAPTER IX
MISCELLANEOUS

52. Chairperson, Members, officers to be public servants.

The Chairperson, Members and other officers of the Board, National DNA Data Bank and Regional DNA Data Banks shall be deemed, when acting or purporting to act in pursuance of any of the provisions of this Act, to be public servants within the meaning of section 21 of the Indian Penal Code.

53. Protection of action taken in good faith.

No suit, prosecution or other legal proceedings shall lie against the Central Government or any officer of the Central Government or the Chairperson, Vice-Chairperson or any Member or officer of the Board or the National DNA Data Bank or the Regional DNA Data Banks acting under this Act for anything which is in good faith done or intended to be done under this Act or the rules or regulations made thereunder.

54. Power of Central Government to supersede Board.

(*1*) If at any time the Central Government is of the opinion—

(*a*) that, on account of circumstances beyond the control of the Board, it is unable to discharge the functions or perform the duties assigned to it by or under the provisions of this Act; or

(*b*) that the Board has persistently defaulted in complying with any direction issued by the Central Government under this Act or in the discharge of the functions or performance of the duties imposed on it by or under the provisions of this Act and as a result of such default, the financial position of the Board or the administration of the Board has suffered; or

(*c*) that circumstances exist which render it necessary in the public interest to do so,

it may, by notification, supersede the Board for such period, not exceeding six months, as may be specified in the notification:

Provided that before issuing any such notification, the Central Government shall give a reasonable opportunity to the Board to make representations against the proposed supersession and shall consider the representations, if any, of the Board.

(*2*) Upon the publication of a notification under sub-section (*1*) superseding the Board,—

(*a*) the Chairperson and other Members shall, as from the date of supersession, vacate their offices as such;

(*b*) all the powers, functions and duties which may, by or under this Act, be exercised or discharged by or on behalf of the Board shall, until the Board is reconstituted under sub-section (*3*), be exercised and discharged by an administrator who shall be an official not below the rank of a Secretary to the Government of India, to be appointed by the Central Government; and

(*c*) all property owned or controlled by the Board shall, until the Board is reconstituted under sub-section (*3*), vest in the Central Government.

(*3*) On the expiration of the period of supersession specified in the notification issued under sub-section (*1*), the Central Government may reconstitute the Board by a fresh appointment and in such case any person or persons who vacated their offices under clause (*a*) of sub-section (*2*), shall not be deemed to be disqualified for appointment:

Provided that the Central Government may, at any time, before the expiration of the period of supersession, take action under this sub-section.

(*4*) The Central Government shall cause a copy of the notification issued under sub-section (*1*) and a full report of any action taken under this section and the circumstances leading to such action to be laid before each House of Parliament at the earliest.

55. Power of Central Government to issue directions.

(*1*) Without prejudice to the foregoing provisions of this Act, the Board shall, in the discharge of its functions and duties under this Act, be bound by such directions on questions of policy as the Central Government may give in writing to it from time to time.

(*2*) If any dispute arises between the Central Government and the Board as to whether a question is or is not a question of policy, the decision of the Central Government thereon shall be final.

56. Power to amend Schedule.

(*1*) The Central Government may, if it is of the opinion that it is expedient so to do, by notification, amend the Schedule so as to include therein or exclude therefrom, or vary the description of, any entry in any Part thereof.

(*2*) Every notification issued under sub-section (*1*) shall, as soon as may be after it is issued, be laid before each House of Parliament.

57. Court not to have jurisdiction.

No court shall have jurisdiction to entertain any suit or proceeding in respect of any matter which the Board is empowered by or under this Act to determine.

58. Power to make rules.

(*1*) The Central Government may, by notification, make rules for carrying out the provisions of this Act.

(*2*) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

(*a*) the pay and allowances of the Vice-Chairperson and the Member under sub-section (*3*), and the allowances payable to the Chairperson and other *ex officio* Members under sub-section (*4*) of section 5;

(*b*) the salaries and allowances payable to, and the terms and other conditions of service of officers and employees of the Board under sub-section (*2*) of section 11;

(*c*) manner in which the Board shall assist and co-operate in criminal investigation between various investigation agencies within the country and with any foreign State, international organisation or institution in dealing with DNA testing under clause (*n*) of section 12;

(*d*) such other functions of the Board under clause (*q*) of section 12;

(*e*) the manner of constitution of a selection committee and persons comprising the committee, for the appointment of a Director of the National DNA Data Bank under sub-section (*1*) of section 27;

(*f*) the educational qualifications and experience of the Director of the National DNA Data Bank under sub-section (*2*) of section 27;

(*g*) the salaries and allowances payable to, and the terms and other conditions of service including the manner of appointment, of the Director of the National DNA Data Bank and the Director of each of the Regional DNA Data Bank, under sub-section (*2*) of section 28;

(*h*) the form in which and the time at which the Board shall prepare its budget under sub-section (*1*) of section 41;

(*i*) the form in which and the time at which the Board shall prepare its annual report under section 42;

(*j*) the form in which the annual statement of accounts shall be prepared by the Board under sub-section (*1*) of section 43; and

(*k*) any other matter which is to be, or may be prescribed, or in respect of which provision is to be, or may be made by rules for carrying out the provisions of this Act.

59. Power to make regulations.

(*1*) The Board may, with the previous approval of the Central Government and after previous publication, by notification, make regulations consistent with this Act and the rules made thereunder, to carry out the provisions of this Act.

(*2*) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for all or any of the following matters, namely:—

(*a*) the time and place at which the Board shall meet and the procedure it shall observe with regard to the transaction of business at its meetings (including quorum at such meetings), under sub-section (*1*) of section 6;

(*b*) the other relevant purposes for the optimum use of DNA techniques and technologies under clause (*h*) of section 12;

(*c*) the form, the fee and the manner in which an application for accreditation shall be made by a DNA laboratory under sub-section (*2*) of section 13;

(*d*) onsite assessment requirements, standards and such other requirements to be complied by a DNA laboratory under sub-section (*3*) of section 13;

(*e*) the form, the fee and the manner in which an application for renewal of accreditation shall be made by a DNA laboratory under sub-section (*4*) of section 13;

(*f*) the obligations to be carried out by a DNA laboratory under sub-section (*1*) of section 17;

(*g*) the educational qualifications experience and other eligibility criteria, in respect of person in charge of a DNA laboratory, technical and managerial staff, and other employees of DNA laboratory under section 18;

(*h*) the measures to be taken, the level and intervals in which the employees shall undergo training and the records to be maintained, by the in charge of a DNA laboratory under section 19;

(*i*) the measures to be taken by DNA laboratories under sub-section (*1*) of section 20;

(*j*) the other sources for collection of DNA sample, under clause (*d*) of sub-section (*1*), of section 23;

(*k*) such other person under whose supervision DNA sample may be collected, under clause (*b*) of sub-section (*2*) of section 23;

(*l*) the format in which the National DNA Data Bank shall receive DNA data from Regional DNA Data Banks and store the DNA profiles under sub-section (*3*) of section 25;

(*m*) the powers and duties of the Director of the National DNA Data Bank under sub-section (*4*) of section 27;

(*n*) the appointment of number of officers, experts and other employees, their remunerations, terms and conditions of service, including the manner of appointment under sub-section (*3*) of section 28;
(*o*) the criteria and the procedure to be followed by the National DNA Data Bank on receipt of a DNA profile, the person to whom the result shall be communicated and the manner of communication under sub-section (*1*) of section 29;
(*p*) the manner in which the DNA profile of a suspect or an undertrial shall be expunged by the Director of the National DNA Data Bank under sub-section (*2*) of section 31;
(*q*) the manner in which the DNA profile of a person who is neither an offender nor a suspect shall be expunged from the crime scene index or a missing persons' index under sub-section (*3*) of section 31;
(*r*) other criteria for entry, retention and expunction of any DNA profile under sub-section (*4*) of section 31;
(*s*) the other purposes for which the information relating to DNA profiles, DNA samples and records relating thereto shall be made available under clause (*f*) of section 34;
(*t*) the terms and conditions for access to information under section 35;
(*u*) the manner in which access to the information in the crime scene index shall be restricted under section 37;
(*v*) any other matter which is to be, or may be, or in respect of which provisions is to be, or may be, made by regulations for carrying out the provisions of the Act.

60. Rules and regulations to be laid before Parliament.

Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.

61. Power to remove difficulties.

(*1*) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act, as may appear to it to be necessary, for removing the difficulty:
Provided that no order shall be made under this section after the expiry of the period of two years from the date of commencement of this Act.
(*2*) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

SCHEDULE

[See* sections 2*(1)(viii),* 12*(o),* 34*(e)* and 56*(1)]

List of matters for DNA testing

PART A

Offences under Indian Penal Code (45 of 1860) where DNA testing is useful for investigation of offences.

PART B

Offences under special laws:
(*i*) The Immoral Traffic (Prevention) Act, 1956 (104 of 1956);
(*ii*) The Medical Termination of Pregnancy Act, 1971 (34 of 1971);
(*iii*) The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994);
(*iv*) The Protection of Women from Domestic Violence Act, 2005 (43 of 2005);
(*v*) The Protection of Civil Rights Act, 1955 (22 of 1955);
(*vi*) The Scheduled Castes and the Scheduled Tribes (Prevention of Atrocities) Act, 1989 (33 of 1989);
(*vii*) The Motor Vehicles Act, 1988 (59 of 1988).

PART C

Civil disputes and other civil matters:
(*i*) Parental dispute (maternity or paternity);
(*ii*) Issues relating to pedigree;
(*iii*) Issues relating to assisted reproductive technologies (surrogacy, *in-vitro* fertilisation and intrauterine implantation or such other technologies);

(*iv*) Issues relating to transplantation of human organs (donor and recipient) under the Transplantation of Human Organs Act, 1994 (42 of 1994);
(*v*) Issues relating to immigration or emigration;
(*vi*) Issues relating to establishment of individual identity.

PART D

Other cases:
(*i*) Medical negligence;
(*ii*) Unidentified human remains;
(*iii*) Identification of abandoned or disputed children and related issues.

STATEMENT OF OBJECTS AND REASONS

The Deoxyribonucleic Acid (DNA) is like a set of instructions or blueprint of all living forms, and it encodes a detailed set of plans for building different pieces of the cell of a living organism to grow and function. The DNA content of every human individual is comprised of one-half of the DNA from each of the two parents. The DNA blueprint varies from one individual to another, and it is this variation, which makes every individual (except identical twins) unique and different. The individual-to-individual variations in DNA permit its use as a means of identification and for establishment of biological relationships between individuals.

2. DNA technology, based on sound scientific principles has been found to be very effective in establishing the parentage of a child and identifying the source of a biological specimen obtained from a scene of crime. The concerns regarding appropriate use of DNA technology by the courts of law and other agencies has made it necessary to develop guidelines and standards for the DNA testing.

3. DNA technology has the potential of wide application in the justice delivery systems. In criminal cases, it helps in investigation of crimes through biological evidence including semen evidence in rape cases, blood evidence in murder cases, saliva evidence in identification of source of anonymous threat letters, etc. In civil cases, it helps in investigations relating to identification of victims of disasters like cyclones, air crash, etc. A number of crimes are committed by repeat offenders, who apprehension and conviction will be aided by comparison of biological evidence at the scene of crime with DNA profiles stored in a DNA Data Bank. At the same time, the DNA analysis offers substantial information, which if misused or improperly used, can cause harm to individuals or society.

4. Recognising the need for regulation of the use and application of DNA technology, a DNA Profiling Advisory Committee comprising of members from the fields of molecular biology, forensic science, human genetics, population biology, bioethics, legal profession, law enforcement agencies, etc., was constituted in December, 2003 to make recommendations for enacting suitable legislation. On the recommendations of the said Committee, a draft Bill was prepared. Later on, an Expert Committee chaired by the Secretary, Department of Biotechnology, was constituted in 2012 to discuss the privacy related issues. Based on the recommendations of the Expert Committee, the Bill was revised and subsequently referred to the Law Commission of India who in its two hundred and seventy-first report suggested the enactment of a legislation.

5. In view of the above, the DNA Technology (Use and Application) Regulation Bill, 2018 seeks to regulate the use of DNA technology for the purposes of establishing the identity of certain categories of persons including the victims, offenders, suspects, under trials, missing persons and unknown deceased persons. The Bill, *inter alia,* seeks to—
(*i*) prohibit laboratories from undertaking DNA testing, analysing, etc., without obtaining accreditation;
(*ii*) establish a National DNA Data Bank and Regional DNA Data Banks which shall store and maintain the DNA profiles in accordance with the provisions relating to the use and access to information, its retention and expunction;
(*iii*) establish a DNA Regulatory Board to carry out the functions assigned to it under the proposed legislation which, *inter alia,* include—
(*a*) advising the Central Govenment and the State Governments on all issues relating to establishing of DNA laboratories and DNA Data Banks and laying down guidelines, standards and procedures for establishment and functioning of such laboratories and Data Banks;
(*b*) granting accreditation to labouratories for undertaking DNA testing, analysing, etc., and to suspend or revoke such accreditation;
(*c*) assisting in criminal investigation between various investigation agencies within the country and with any foreign State, international organisation or institution; and
(*d*) making recommendations to the Central Government for the application of privacy protection in relation to the access to, or the use of, DNA samples and their analysis;

(*iv*) make provision for the security and confidentiality of information relating to DNA profiling, DNA samples and any records thereof, forwarded to or in the custody of Natioinal DNA Data Bank, Regional DNA Data Banks, DNA laboratories or any person or authority;

(*v*) provide for offences and penalties for contravention of certain provisions of the Bill.

6. The Bill seeks to achieve the above objectives.

NEW DELHI; DR. HARSH VARDHAN

The 27*th June*, 2019

Notes on Clauses

Clause 2 of the Bill seeks to define the various expressions used in the Bill.

Clause 3 of the Bill seeks to provide for the establishment of the DNA Regulatory Board as body corporate, having perpetual succession and a common seal, whose head office shall be at such place in the National Capital Region, as the Central Government may specify. The Board may, with the approval of the Central Government, establish regional offices at such other places as it may deem necessary.

Clause 4 of the Bill seeks to provide for the composition of the DNA Regulatory Board which shall consist of a Chairperson, a Vice-Chairperson, Member-Secretary and ten other Members to carry out the functions assigned to it under the Bill.

Clause 5 of the bill seeks to provide for the terms of office, conditions of service of, Chairperson, Vice-Chairperson and other Members of the Board including their pay and allowances.

Clause 6 of the Bill seeks to provide for the procedure for meetings of the Board. It further provides that the Chairperson shall have powers of general superintendence and direction of the affairs of the Board and may also exercise such other powers as may be delegated to him by the Board.

Clause 7 of the Bill seeks to provide that the Members of the Board shall not participate in meetings in certain cases.

Clause 8 of the Bill seeks to provide for the removal and resignation of Chairperson or Member and filling up of casual vacancies of Board.

Clause 9 of the Bill seeks to provide that no act or proceeding of the Board shall be invalid merely by reason of any vacancy in, or any defect in the constitution of, the Board; or any defect in the appointment of a person acting as a Member of the Board; or any irregularity in the procedure of the Board not affecting the merits of the case.

Clause 10 of the Bill seeks to provide that the Board may, by general or special order published in the Official Gazette, delegate to the Chairperson or any other Member, subject to such conditions, if any, as may be specified in the order, its functions under the Bill (except the power to make regulations), as it may deem necessary. It further provides for laying of such order before each House of Parliament.

Clause 11 of the Bill seeks to provide that the Board may, with the previous approval of the Central Government, appoint such officers and other employees, as it considers necessary, for the efficient discharge of its functions under the Bill. It further provides that the salaries and allowances payable to, and the other terms and conditions of service, including the manner of appointment, of the officers and employees, shall be prescribed by rules made by the Central Government.

Clause 12 of the Bill enumerates the various functions of the Board which shall include, *inter alia*, (*a*) advising the Central Government and the State Governments on all issues relating to estabiaing of DNA laboratories and DNA Data Banks and laying down guidelines, standards and procedures for establishment and functioning of such laboratories and Data Banks;

(*b*) granting accreditation to laboratories for undertaking DNA testing, analysing, etc., and to suspend or revoke such accreditation; (*c*) assisting in criminal investigation between various investigation agencies within the country and with any foreign State, international organisation or institution; and (*d*) making recommendations to the Central Government for the application of privacy protection in relation to the access to, or the use of, DNA samples and their analyses.

Clause 13 of the Bill seeks to provide that no laboratory shall undertake DNA testing, analysing or any other procedure to generate data and perform analysis relating thereto without obtaining accreditation from the Board. It further provides that a laboratory functioning as on the date of the commencement of the Bill, may undertake DNA testing or any other procedure relating thereto, for a period of sixty days from such commencement and apply to the Board in accordance with sub-clause (*2*) of the said clause, for obtaining accreditation and that such laboratory may, after making an application, continue to undertake DNA testing or any other procedure relating thereto, until the Board decides its application. It also provides that the application for renewal of accreditation shall be made to the Board at least sixty days prior to the expiration

of the accreditation in such form and manner and along with such fees as may be specified by regulations made by the Board.

Clause 14 of the Bill provides for grant of accreditation or renewal to the laboratory which seeks to undertake DNA testing, analysing or any other procedure to generate data and perform analysis relating thereto. It further provides that the accreditation or renewal of accreditation under this clause shall be valid for a period of two years.

Clause 15 of the Bill seeks to provide for the power of Board to suspend or revoke accreditation granted to a DNA laboratory, if such laboratory fails to comply with the conditions specified therein. It further provides that no revocation of accreditation of a DNA laboratory shall be made by the Board without giving the laboratory an opportunity of being heard. It also provides that on the revocation or suspension of accreditation of the DNA laboratory, the laboratory shall hand over all DNA samples and records relating to DNA testing from its laboratory to such DNA laboratory as may be directed by the Board and it shall not retain any sample or record.

Clause 16 of the Bill seeks to provide that any laboratory aggrieved by an order of rejection of its application for accreditation or renewal thereof under clause 14 or an order of suspension or revocation of accreditation under clause 15, may prefer an appeal to the Central Government or such other authority as that Government may, by notification, specify, within a period of sixty days from the date of such order, which shall be decided by the Central Government or the authority, as the case may be, within a period of sixty days from the date of receipt of such appeal.

Clause 17 of the Bill seeks to provide that every DNA laboratory, which has been granted accreditation for undertaking DNA testing or any other procedure under the Bill, shall follow such standards and procedures for quality assurance in the collection, storage, testing and analysis of DNA sample, establish and maintain such documentation and quality system, prepare and maintain quality manuals containing such details and share DNA data prepared and maintained by it with the National DNA Data Bank and the Regional DNA Data Banks, in such manner as may be specified by regulations.

Clause 18 of the Bill seeks to provide that every DNA laboratory shall appoint a person to be in charge of the laboratory and employ such scientific, technical and other staff, possessing such qualifications and experience as may be specified by regulations, for discharging the duties and performing the functions under the Bill.

Clause 19 of the Bill seeks to provide that the in-charge of the DNA laboratory shall take such measures for facilitating skill up gradation and advancement in the knowledge of its employees in the field of DNA testing and other related fields, as may be specified by regulations, ensure that its employees undergo regular training in DNA related subjects, in such institutions, level and intervals, as may be specified by regulations and maintain such records relating to the laboratory and its personnel as may be specified by regulations.

Clause 20 of the Bill seeks to specify the various measures to be taken by DNA laboratory.

Clause 21 of the Bill seeks to prohibit taking of bodily substances from a person who is arrested for an offence (other than the specified offences) unless the consent is given in writing for the taking of the bodily substances.

Clause 22 of the Bill seeks to provide that any person who was present at the scene of a crime when it was committed; or is being questioned in connection with the investigation of a crime; or intends to find the whereabouts of his missing or lost relative, in disaster or otherwise, may voluntarily consent in writing to bodily substances being taken from him for DNA testing, subject to certain conditions specified therein.

Clause 23 of the Bill seeks to provide for the sources and manner of collection of samples for DNA testing.

Clause 24 of the Bill seeks to provide that if the trial court is satisfied with the plea of the accused person that the bodily substances taken from such person or collected from the place of occurrence of crime had been contaminated, the court may direct the taking of fresh bodily substances for re-examination.

Clause 25 of the Bill seeks to provide for the establishment of a National DNA Data Bank and such number of Regional DNA Data Banks for every State, or two or more States, as it may deem necessary. It further provides that the Regional DNA Data Banks shall share all DNA data stored and maintained by it with the National DNA Data Bank.

Clause 26 of the Bill seeks to provide that every DNA Data Bank shall maintain the indices for various categories of data and the information specified therein.

Clause 27 of the Bill seeks to provide for the appointment of a Director for the National DNA Data Bank and Directors for each Regional DNA Data Banks.

Clause 28 of the Bill seeks to provide for appointment of the officers and other employees of the National DNA Data Bank and the Regional DNA Data Banks, their salaries and allowances, terms and other conditions of

service including the manner of appointment, of the Director of the National DNA Data Bank and the Director of each of the Regional DNA Data Bank.

Clause 29 of the Bill seeks to provide for the criteria and procedure to be followed by the National DNA Data Bank in comparing and communicating of DNA profile.

Clause 30 of the Bill seeks to provide for the manner of sharing of DNA profiles with foreign Government or organisation or institution or agencies. It further provides that the Central Government may, in consultation with the Board, determine the nature and extent of sharing DNA profiles in respect of offenders, suspects, under trials, missing persons and unknown deceased persons with the Government of a foreign State or an international organisation or an institution established by that Government or organisation, and seek similar information from such foreign State, organisation or institutions.

Clause 31 of the Bill seeks to provide for the manner of retention and removal of records in the DNA Data Bank.

Clause 32 of the Bill seeks to make provision for the security and confidentiality of Information. It requires the Board to ensure that the information relating to DNA profiles, DNA samples and any records thereof, forwarded to, or in custody of the National DNA Data Bank or the Regional DNA Data Banks or a DNA laboratory or any other person or authority under the Bill, are secured and kept confidential.

Clause 33 of the Bill seeks to provide all DNA data, including DNA profiles, DNA samples and records thereof, contained in any DNA laboratory and DNA Data Bank shall be used only for the purposes of facilitating identification of the person and not for any other purpose.

Clause 34 of the Bill seeks to provide for the access to information in certain cases.

Clause 35 of the Bill seeks to provide for the access to information for the sole purpose of operation, maintenance and training, in accordance with such terms and conditions as may be specified by regulations.

Clause 36 of the Bill seeks to provide for the access to information in DNA Data Bank for one time keyboard search by the person specified therein.

Clause 37 of the Bill seeks to provide for the restriction on access to information in crime scene index, in such manner as may be specified by regulations, if such information relates to a DNA profile derived from bodily substances of a victim of an offence which

forms or formed the object of relevant investigation; or a person who has been eliminated as a suspect in the relevant investigation.

Clause 38 of the Bill seeks to provide for the prohibition on access to information in DNA Data Banks.

Clause 39 of the Bill seeks to provide for the grants to the Board by the Central Government.

Clause 40 of the Bill seeks to provide for the constitution of the DNA Regulatory Board Fund.

Clause 41 of the Bill seeks to provide for the preparation of the budget by the Board showing the estimated receipts and expenditure of the Board and forwarding the same to the Central Government.

Clause 42 of the Bill seeks to provide for the preparation of the annual report by the Board giving a full account of its activities during the previous financial year and submit a copy thereof to the Central Government.

Clause 43 of the Bill seeks to provide that the accounts and other relevant records of the Board shall be maintained in the form specified by the Central Government by notification and the same shall be audited by the Comptroller and Auditor-General of India.

Clause 44 of the Bill seeks to provide that the annual report and auditor's report of the Board shall be laid before each House of Parliament.

Clause 45 of the Bill seeks to specify the punishment for unauthorised disclosure of Information in DNA Data Bank. It provides that whoever, by virtue of his employment or official position or otherwise, has in his possession, or has access to, individually identifiable DNA information kept in the DNA laboratory or DNA Data Bank, wilfully discloses it in any manner to any person or agency not entitled to receive it under the Bill, or under any other law for the time being in force, shall be punishable with imprisonment for a term which may extend to three years and also with fine which may extend to one lakh rupees.

Clause 46 of the Bill seeks to specify the punishment for obtaining information from DNA Data Bank without authorisation. It provides that whoever, without authorisation, wilfully obtains individually identifiable DNA information from the DNA laboratory or DNA Data Bank, shall be punishable with imprisonment for a term which may extend to three years and also with fine which may extend to one lakh rupees.

Clause 47 of the Bill seeks to specify the punishment for using DNA sample or result without authorisation. It provides that whoever, without authorisation, wilfully uses any DNA sample or result of any DNA analysis,

shall be punishable with imprisonment for a term which may extend to three years and also with fine which may extend to one lakh rupees.

Clause 48 of the Bill seeks to specify the punishment for unlawful access of information in DNA Data Bank. It provides that whoever, accesses information stored in the DNA Data Bank, otherwise than in accordance with the provisions of the Bill, shall be punishable with imprisonment for a term which may extend to two years and also with fine which may extend to fifty thousand rupees.

Clause 49 of the Bill seeks to specify the punishment for destruction, alterations, contamination or tampering with biological evidence. It provides that whoever, knowingly and intentionally, destroys, alters, contaminates or tampers with biological evidence which is required to be preserved under any law for the time being in force, with the intention to prevent that evidence from being subjected to DNA testing or to prevent the production or use of that evidence in a judicial proceeding, shall be punishable with imprisonment for a term which may extend to five years and also with fine which may extend to two lakh rupees.

Clause 50 of the Bill seeks to specify the punishment for contravention when no specific punishment is provided. It provides that whoever, contravenes any of the provisions of the Bill or the rules and regulations made there under for which no penalty is provided in the Bill, shall be punishable with imprisonment for a term which may extend to two years and also with fine which may extend to fifty thousand rupees. *Clause* 51 of the Bill seeks to specify the punishment for offences by companies or institutions.

Clause 52 of the Bill seeks to provide that the Chairperson, Members and other officers of the Board, National DNA Data Bank and Regional DNA Data Banks shall be deemed, when acting or purporting to act in pursuance of any of the provisions of the Bill, to be public servants within the meaning of section 21 of the Indian Penal Code.

Clause 53 of the Bill seeks to provide for the protection of action taken in good faith by any officer of the Central Government or Board or any Member or officer or other employee of the Board.

Clause 54 of the Bill seeks to empower the Central Government to supersede Board in the circumstances specified therein.

Clause 55 of the Bill seeks to empower the Central Government to issue directions.

Clause 56 of Bill seeks to empower the Central Government to amend the Schedule.

Clause 57 of the Bill seeks to provide that no court shall have jurisdiction to entertain any suit or proceeding in respect of any matter which the Board is empowered by or under the Bill to determine.

Clause 58 of the Bill seeks to empower the Central Government to make rules on matters enumerated therein.

*Clause*59 of the Bill seeks to provide that the Board may, with the previous approval of the Central Government and after previous publication, by notification in Official Gazette, make regulations consistent with the Bill and the rules made there under, to carry out the provisions of the Bill.

Clause 60 of the Bill seeks to provide that every rule and regulation made under the Bill shall be laid before each House of Parliament.

Clause 61 of the Bill seeks to empower the Central Government, by order published in the Official Gazette, to remove difficulties which may arise in giving effect to the provisions of the Bill within a period of two years from the date of enforcement of the Act. It further requires every such order to be laid before each House of Parliament.

FINANCIAL MEMORANDUM

Clause 3 of the Bill provides for the establishment of a DNA Regulatory Board to exercise powers conferred on, and perform the functions assigned to it, under the proposed legislation.

2. Clause 25 of the Bill provides for the establishment of a National DNA Data Bank and Regional DNA Data Banks.

3. Clause 40 of the Bill provides for constitution of a Fund to be called the DNA Regulatory Board Fund, into which shall be credited grants and loans made to the Board, all sums received by the Board including fees or charges, or donations from such other source as may be decided by the Central Government and any income from investment of the amount of the Fund.

4. It is estimated that there would be an expenditure of approximately twenty crore rupees as non-recurring capital expenditure and a further recurring expenditure of five crore rupees per annum to carry out all the activities envisaged under the proposed legislation.

5. The Bill, if enacted and brought into operation, would not involve any other expenditure of a recurring or non-recurring nature from the Consolidated Fund of India.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 58 of the Bill empowers the Central Government to make rules with respect to the matters specified under sub-clause (*2*) which, *inter alia*, relate to

(*a*) the allowances payable to the Chairperson and other *ex officio* Members and the pay and allowances of the Vice-Chairperson and the expert Member;

(*b*) the salaries and allowances payable to, and the terms and other conditions of service of officers and employees of the Board;

(*c*) the manner in which the Board shall assist and co-operate in criminal investigation between various investigation agencies within the country and with any foreign State, international organisation or institution in dealing with DNA testing;

(*d*) the manner of constitution of a selection committee and persons comprising the committee, for the appointment of a Director of National DNA Data Bank;

(*e*) the salaries and allowances payable to, and the terms and other conditions of service including the manner of appointment, of the Director of the National DNA Data Bank and the Director of each of the Regional DNA Data Banks;

(*f*) and the form for preparation of the annual report and the annual statement of accounts by the Board.

2. Clause 59 of the Bill empowers the Board to make regulations with the previous approval of the Central Government. The matters in respect of which the Board may make regulations, *inter alia*, relate to

(*a*) the time and place of meeting of the Board and the procedure with regard to the transaction of business at its meetings;

(*b*) the form, the fee and the manner in which an application for accreditation shall be made by a DNA laboratory;

(*c*) onsite assessment requirements, standards and such other requirements to be complied by a DNA laboratory; (*d*) the obligations to be carried out by a DNA laboratory;

(*e*) the educational qualifications and experience and other eligibility criteria in respect of person in-charge of a DNA laboratory, technical and managerial staff, and other employees of DNA laboratory;

(*f*) the measures to be taken by DNA laboratories;

(*g*) the format in which the National DNA Data Bank shall receive DNA data from Regional DNA Data Banks and store the DNA profiles;

(*h*) the manner in which the DNA profile of a suspect or an under trial and of a person who is neither an offender nor a suspect shall be expunged; (*i*) the terms and conditions for access to information; and

(*j*) the manner in which access to the information

in the crime scene index shall be restricted.

3. Clause 60 of the Bill requires that the rules and regulations made under the proposed legislation be laid before each House of Parliament.

4. The matters in respect of which the rules or regulations may be made are matters of procedure and administrative detail, and as such, it is not practicable to provide for them in the Bill itself. The delegation of legislative power is, therefore, of a normal character.

LOK SABHA

————

A

BILL

to provide for the regulation of use and application of Deoxyribonucleic Acid (DNA) technology for the purposes of establishing the identity of certain categories of persons including the victims, offenders, suspects, undertrials, missing persons and unknown deceased persons and for matters connected therewith or incidental thereto.

————

(Dr. Harsh Vardhan, Minister of Science and Technology and Earth Sciences)

MGIPMRND—1057LS(S3)—01-07-2019.

Epidemic Disease Act 1897

THE EPIDEMIC DISEASES ACT, 1897
ACT NO. 3 OF 18971
[4*th February*, 1897.]

An Act to provide for the better prevention of the spread of Dangerous Epidemic Diseases. WHEREAS it is expedient to provide for the better prevention of the spread of dangerous epidemic disease; It is hereby enacted as follows :—

1.Short title and extent.—(*1*) This Act may be called the Epidemic Diseases Act, 1897.

(*2*)It extends to the whole of India except 3[the territories which, immediately before the 1st November, 1956, were comprised in Part B States.

2.Power to take special measures and prescribe regulations as to dangerous epidemic disease.—(*1*) When at any time the State Government is satisfied that the State or any part thereof is visited by, or threatened with, an outbreak of any dangerous epidemic disease, the State Government, if it thinks that the ordinary provisions of the law for the time being in force are insufficient for the purpose, may take, or require or empower any person to take, such me assures and, by public notice, prescribe such temporary regulations to be observed by the public or by any person or class of persons as it shall deem necessary to prevent the outbreak of such disease or the spread thereof, and may determine in what manner and by whom any expenses incurred (including compensation if any) shall be defrayed.

(*2*)In particular and without prejudice to the generality of the foregoing provisions, the State Government] may take measures and prescribe regulations for—

(*b*) the inspection of persons travelling by railway or otherwise, and the segregation, in hospital, temporary accommodation or otherwise, of persons suspected by the inspecting officer of being infected with any such disease.

2A.Powers of Central Government.—When the Central Government is satisfied that India or any part thereof is visited by, or threatened with, an outbreak of any dangerous epidemic disease and that the ordinary provisions of the law for the time being in force are insufficient to prevent the outbreak of such disease or the spread thereof, the Central Government may take measures and prescribe regulations for the inspection of any ship or vessel leaving or arriving at any port in 2[the territories to which this Act extends] and for such detention thereof, or of any person intending to sail therein, or arriving thereby, as may be necessary.

3.Penalty.—Any person disobeying any regulation or order made under this Act shall be deemed to have committed an offence punishable under section 188 of the Indian Penal Code (45 of 1860).

4.Protection to persons acting under Act.—No sui t or other legal proceeding shall lie against any person for anything done or in good faith intended to be done under this Act.

HOSPITAL-ACQUIRED INFECTIONS (PREVENTION, CONTROL AND MANDATORY REPORTING) BILL, 2015

THE HOSPITAL-ACQUIRED INFECTIONS (PREVENTION, CONTROL AND MANDATORY REPORTING) BILL, 2015

AS INTRODUCED IN LOK SABHA

Bill No. 160 of 2015

B*y*

SHRI PREM DAS RAI, M.P.

A

BILL

to provide for a comprehensive inspection control policy and antimicrobial stewardship programme for hospitals and other healthcare facilities to prevent and control the incidence of hospital-acquired infections, mandatory reporting system for such infections and for matters connected herewith.

BE it enacted by Parliament in the Sixty-sixth Year of the Republic of India as follows:—

1. Short title, extent and commencement.

(*1*) This Act may be called the Hospital-Acquired Infections (Prevention, Control and Mandatory Reporting) Act, 2015.

(*2*) It extends to the Union territories only.

(*3*) It shall come into force on such date, as the Central Government may, by notification in the Official Gazette, appoint.

2. Definitions.

In this Act, unless the context otherwise requires,—

(*a*)"Committee" means the Hospital-Acquired Infection Advisory Committee constituted under section 3;

(*b*)"data" means any information submitted by a hospital or a healthcare facility to the Central Government;

(*c*) "healthcare facility" means any general, critical care or specialized healthcare institute;

(*d*)"hospital-acquired infection" means any localized or systemic condition resulting from an adverse reaction due to the presence of an infectious agent or its toxin that occurs in a patient in a hospital or a healthcare facility; and

(*e*) "prescribed" means prescribed by rules made under this Act.

3. Constitution of Hospital- Acquired Infections Advisory Committee.

(*1*)The Central Government shall, by notification in the Official Gazette, constitute a Hospital-Acquired Infections Advisory Committee.

(*2*) The Committee shall consist of a Chairperson and such number of members, including experts from the medical profession, pharmacy, public health and health communities, as may be prescribed.

(*3*) The Chairperson and members of the Committee shall be appointed by the Central Government in such manner, as may be prescribed.

(*4*) The salary and allowances payable to and other terms and conditions of service of the Chairperson and members of the Committee shall be such as may be prescribed.

(*5*) The Committee shall have its headquarter at New Delhi.

(*6*) The Committee may also set up offices at such conspicuous places with prior approval of the Central Government for carrying out the purposes of this Act.

(*7*) The Central Government shall appoint such number of officers and staff, as may be necessary, for the efficient functioning of the Committee**.**

4. Functions of the Committee.

The Committee shall—

(*a*) advise the Central Government in preparation of an action plan for prevention, control and mandatory reporting of hospital-acquired infections;

(*b*) define the criteria for determining healthcare facilities which shall be covered under this Act;

(*c*) evolve a system for mandatory reporting by hospitals and healthcare facilities of hospital-acquired infections;
(*d*) frame a comprehensive infection control policy to prevent hospital-acquired infections;
(*e*) frame an antimicrobial stewardship programme to promote rational use of antibiotics in hospitals and healthcare facilities;
(*f*) suggest measures to address hospital-acquired infections;
(*g*)submit periodical reports on the extent, pattern and trends of hospital acquired infections, in such form and manner, as may be prescribed;
(*h*) recommend to the Central Government the penalties, which may be imposed on a hospital or a heathcare facility for non-compliance of the provisions of this Act;
*(i)*create public awareness about effective measures to reduce the spread of infections in communities, hospitals and healthcare facilities; and
(*j*) perform such other tasks as may be assigned to it by the Central Government for carrying out the purposes of this Act.

5. Mandatory Reporting system.

(*1*) The mandatory reporting system under clause (*c*) of section 4 shall include—
(*i*) patient's diagnosis at the time of admission;
(*ii*) specific infectious agents or toxins and site of each infection;
(*iii*) clinical department or unit within the hospital or a healthcare facility where the patient gets infected or is diagnosed with infection for the first time;
(*iv*) any relevant, specific, surgical, medical or diagnostic procedure performed during admission;
(*v*) data regarding implementation and evaluation of interventions to reduce hospital-acquired infections; and
(*vi*) any other informations deemed appropriate by the Central Government.
(*2*) The instructions under the mandatory reporting system shall be—
(*i*) based upon scientific evidence; and
(*ii*) capable of being used and easily understood by the public including patients.

6. Central Government to provide adequate funds to the Committee.

The Central Government shall provide adequate funds to the Committee for carrying out the purposes of this Act.

7. Role of hospitals and healthcare facilities.

(*1*) Every hospital and healthcare facility shall maintain a programme capable of identifying, tracking and mandatory reporting of, hospital-acquired infections, in such form and manner, as may be specified by the Committee.
(*2*) Every hospital and healthcare facility shall submit data relating to prevention, control and mandatory reporting of hospital-acquired infections to the Committee in such form and manner as may be prescribed.

8. Constitution of task force.

Every hospital and healthcare facility shall constitute a task force to ensure effective implementation of the infection control policy framed by the committee under clause (d) of section 4.

9. Formulation an antimicrobial stewardship programme.

Every hospital and healthcare facility shall formulate a mechanism to ensure implementation of the antimicrobial stewardship programme framed by the Committee to promote rational use of antibiotics.

10. Act to have overriding effect.

The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force or in any instrument having effect by virtue of any law other than this Act.

11. Power to make rules.

(*1*) The Central Government may, by notification in Official Gazette, make rules for carrying out the purposes of this Act.
(*2*) Every rule made under this Act by the Central Government shall be laid as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both the Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have

effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

STATEMENT OF OBJECTS AND REASONS

Hospital-acquired infections are infections that patients acquire during the course of receiving treatment for other conditions in a hospital or in a healthcare facility. Hospital acquired infections are global public health issues. World Health Organization (WHO) suggests that hospital-acquired infections are the most frequent adverse events in healthcare delivery worldwide and at any given time, seven per cent. and ten per cent. patients in developed and developing countries, respectively, acquire at least one hositpal-acquired infection.

Hospital-acquired infections are undesirable from the perspective of both the patient and the hospital and result in increased mortality, prolonged hospital stay, increased resistance to antimicrobials, increased recovery time and in some cases create long term disability. The additional financial burden of cost attributable to these infections has serious financial implications for patients, particularly in view of low health insurance coverage in India.

At present, no national data is available on the prevalence of hospital-acquired infections in India. The knowledge about prevalence of hospital-acquired infections in India comes from studies conducted in a few hospitals. A report estimated that one in four patients admitted into hospitals in India developed hospital-acquired infections, compared to incidence of five to ten per cent. in most developed nations.

Lack of national surveillance system has hampered assessment of healthcare burden associated with hospital-acquired infections in India. Continued surveillance, effective infection control programmes, rational use of antibiotics and enhanced public awareness can reduce the incidence of hospital-acquired infections, improve patient care and help better prioritization of resources.

The Bill, therefore, seeks to provide, *inter-alia,* for the following measures—

(*a*) constitution of Hospital-Acquired Infection Advisory Committee to advise the Central Government in preparation of an action plan for the prevention, control and mandatory reporting of hospital-acquired infections;

(*b*) mandatory reporting of hospital-acquired infections by every hospital and healthcare facility;

(*c*) constitution of a task force in every hospital and healthcare facility to ensure effective implementation of infection control policy framed by the Committee;

(*d*) antimicrobial stewardship programme to promote rational use of antibiotics; and

(*e*) creation of public awareness about effective measures to reduce the spread of infections in communities, hospitals and healthcare facilities.

Hence this Bill.

NEW DELHI; PREM DAS RAI

April 5, 2015

FINANCIAL MEMORANDUM

Clause 3 of the Bill provides for Constitution of a Hospital-Acquired Infections Advisory Committee for the prevention, control and mandatory reporting of hospital-acquired infections in hospitals and health facilities. Clause 4 provides, *inter-alia*, that the Committee shall create public awareness about effective measures to reduce the spread of infections in communities, hospitals and healthcare facilities. Clause 6 provides that the Central Government shall provide adequate funds to the Committee for carrying out the purposes of this Act. Clause 7 provides that every hospital and healthcare facility shall maintain a programme capable of identifying, tracking and mandatory reporting of hospital-acquired infections and submit data relating to prevention, control and mandatory reporting of hospital acquired infections to the Committee. Clause 8 provides for Constitution of a task force by every hospital and healthcare facility to ensure effective implementation of infection control policy prepared by the Committee. The Bill, therefore, if enacted, will involve expenditure from the Consolidated Fund of India. It is estimated that a recurring expenditure of rupees five hundred crore per annum would be involved.

A non-recurring expenditure of about rupees five hundred crore is also likely to be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 11 of the Bill empowers the Central Government to make rules for carrying out the purposes of the Bill. As the rules will relate to matters of detail only, the delegation of legislative powers is of a normal character.

LOK SABHA

———

A

BILL

to provide for a comprehensive inspection control policy and antimicrobial stewardship programme for hospitals and other healthcare facilities to prevent and control the incidence of hospital-acquired infections, mandatory reporting system for such infections and for matters connected herewith.

———

(Shri Prem Das Rai, M.P.)

GMGIPMRND—1358LS(S3)—14-07-2015.

HUMAN IMMUNODEFICIENCY VIRUS(HIV) AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

THE HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (PREVENTION AND CONTROL) BILL, 2014

AS INTRODUCED IN THE RAJYA SABHA

Bill No. III of 2014

THE HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (PREVENTION AND CONTROL) BILL, 2014

A

BILL

to provide for the prevention and control of the spread of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome and for the protection of human rights of persons affected by the said virus and syndrome and for matters connected therewith or incidental thereto.

WHEREAS the spread of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome is a matter of grave concern to all and there is an urgent need for the prevention and control of said virus and syndrome;

AND WHEREAS there is a need to protect and secure the human rights of persons who are HIV-positive, affected by Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome and vulnerable to the said virus and syndrome;

AND WHEREAS there is a necessity for effective care, support and treatment for Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome;

AND WHEREAS there is a need to protect the rights of healthcare providers and other persons in relation to Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome;

AND WHEREAS the General Assembly of the United Nations, recalling and reaffirming its previous commitments on Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome, has adopted the Declaration of Commitment on Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (2001) to address the problems of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome in all its aspects and to secure a global commitment to enhancing coordination and intensification of national, regional and international efforts to combat it in a comprehensive manner;

AND WHEREAS the Republic of India, being a signatory to the aforesaid Declaration, it is expedient to give effect to the said Declaration;

BE it enacted by Parliament in the Sixty-fifth Year of the Republic of India as follows:––

CHAPTER I
PRELIMINARY

1. Short title, extent and commencement.

(*1*) This Act may be called the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act**,** 2014.

(*2*) It extends to the whole of India.

(*3*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

2. Definitions. In this Act, unless the context otherwise requires,—

(*a*)"AIDS" means Acquired Immune Deficiency Syndrome, a condition characterised by a combination of signs and symptoms, caused by Human Immunodeficiency Virus, which attacks and weakens the body's immune system making the HIV-positive person susceptible to life threatening conditions or other conditions, as may be specified from time to time;

(*b*)"capacity to consent" means ability of an individual, determined on an objective basis, to understand and appreciate the nature and consequences of a proposed action and to make an informed decision concerning such action;

(*c*)"child affected by HIV" means a person below the age of eighteen years, who is HIV-positive or whose parents or guardian (with whom such child normally resides**)** is HIV-positive or has lost a parent or guardian **(**with whom such child resided) due to AIDS or lives in a household fostering children orphaned by AIDS;
(*d*)"discrimination" means any act or omission which directly or indirectly, expressly or by effect, immediately or over a period of time,—
(*i*) imposes any burden, obligation, liability, disability or disadvantage on any person or category of persons, based on one or more HIV-related grounds;
or
(*ii*)denies or withholds any benefit, opportunity or advantage from any person or category of persons, based on one or more HIV-related grounds**,** and the expression "discriminate" to be construed accordingly.
Explanation.—For the purposes of this clause, HIV-related grounds include—
(*i*) being an HIV-positive person;
(*ii*) ordinarily living, residing or cohabiting with a person who is HIV positive person;
(*iii*) ordinarily lived, resided or cohabited with a person who was HIV positive;
(*e*)"domestic relationship" means a relationship as defined under clause (*f*) of section 2 of the Protection of Women from Domestic Violence Act, 2005;
(*f*)"establishment" means a body corporate or co-operative society or any organisation or institution or two or more persons jointly carrying out a systematic activity for a period of twelve months or more at one or more places for consideration or otherwise, for the production, supply or distribution of goods or services;
(*g*)"guidelines" means any statement or any other document issued by the Central Government indicating policy or procedure or course of action relating HIV and AIDS to be followed by the Central Government, State Governments, governmental and non-governmental organisations and establishments and individuals dealing with prevention, control and treatment of HIV or AIDS;
(*h*)"healthcare provider" means any individual whose vocation or profession is directly or indirectly related to the maintenance of the health of another individual and includes any physician, nurse, paramedic, psychologist, counsellor or other individual providing medical, nursing, psychological or other healthcare services including HIV prevention and treatment services;
(*i*)"HIV" means Human Immunodeficiency Virus;
(*j*)"HIV-affected person" means an individual who is HIV-positive or whose partner (with whom such individual normally resides) is HIV-positive or has lost a partner (with whom such individual resided) due to AIDS;
(*k*)"HIV-positive person" means a person whose HIV test has been confirmed positive;
(*l*)"HIV-related information" means any information relating to the HIV status of a person and includes—
(*i*) information relating to the undertaking performing the HIV test or result of an HIV test;
(*ii*) information relating to the care, support or treatment of that person;
(*iii*) information which may identify that person; and
(*iv*)any other information concerning that person, which is collected, received, accessed or recorded in connection with an HIV test, HIV treatment or HIV-related research or the HIV status of that person;
(*m*)"HIV test" means a test to determine the presence of an antibody or antigen of HIV;
(*n*)"informed consent" means consent given by any individual or his representative specific to a proposed intervention without any coercion, undue influence, fraud, mistake or misrepresentation and such consent obtained after informing such individual or his representative, as the case may be, such information, as specified in the guidelines, relating to risks and benefits of, and alternatives to, the proposed intervention in such language and in such manner as understood by that individual or his representative, as the case may be**;**

(*o*)"notification" means a notification published in the Official Gazette;
(*p*)"partner" means a spouse, *de facto* spouse or a person with whom another person has relationship in the nature of marriage;
(*q*)"person" includes an individual, a Hindu Undivided Family, a company, a firm, an association of persons or a body of individuals, whether incorporated or not, in India or outside India, any corporation established by or under any Central or State Act or any company including a Government company incorporated under the Companies Act, 1956, any Limited Liability Partnership under the Limited Liability Partnership Act, 2008, anybody corporate incorporated by or under the laws of a country outside India, a co-operative society registered under any law relating to cooperative societies, a local authority, and every other artificial juridical person**;**
(*r*)"prescribed" means prescribed by rules made by the Central Government or the State Government, as the case may be;
(*s*)"protected person" means a person who is—
(*i*)HIV-Positive; or
(*ii*)ordinarily living, residing or cohabiting with a person who is HIV positive person; or
(*iii*)ordinarily lived, resided or cohabited with a person who was HIV positive;
(*t*)"reasonable accommodation" means minor adjustments to a job or work that enables an HIV-positive person who is otherwise qualified to enjoy equal benefits or to perform the essential functions of the job or work, as the case may be;
(*u*)"relative", with reference to the protected person, means—
(*i*) spouse of the protected person;
(*ii*) parents of the protected person;
(*iii*) brother or sister of the protected person;
(*iv*)brother or sister of the spouse of the protected person;
(*v*)brother or sister of either of the parents of the protected person;
(*vi*) in the absence of any of the relatives mentioned at sub-clauses (*i*) to (*v*), any lineal ascendant or descendant of the protected person;
(*vii*) in the absence of any of the relatives mentioned at sub-clauses (*i*) to (*vi*), any lineal ascendant or descendant of the spouse of the protected person;
(*v*)"significant risk" means—
(*a*) the presence of significant-risk body substances;
(*b*)a circumstance which constitutes significant risk for transmitting or contracting HIV infection; or
(*c*) the presence of an infectious source and an uninfected person.
Explanation.— For the purpose of this clause,—
(*i*)"significant-risk body substances" are blood, blood products, semen, vaginal secretions, breast milk, tissue and the body fluids, namely, cerebrospinal, amniotic, peritoneal, synovial, pericardial and pleural;
*(ii)"*circumstances which constitute significant risk for transmitting or contracting HIV infection" are—
(*A*)sexual intercourse including vaginal, anal or oral sexual intercourse which exposes an uninfected person to blood, blood products, semen or vaginal secretions of an HIV-positive person;
(*B*) sharing of needles and other paraphernalia used for preparing and injecting drugs between HIV-positive persons and uninfected persons;
(*C*)the gestation, giving birth or breast feeding of an infant when the mother is an HIV-positive person;
(*D*) transfusion of blood, blood products, and transplantation of organs or other tissues from an HIV-positive person to an uninfected person, provided such blood, blood products, organs or other tissues have not been tested conclusively for the antibody or antigen of HIV and have not been rendered non-infective by heat or chemical treatment; and

(*E*)other circumstances during which a significant-risk body substance, other than breast milk, of an HIV-positive person contacts or may contact mucous membranes including eyes, nose or mouth, non-intact skin including open wounds, skin with a dermatitis condition or abraded areas or the vascular system of an uninfected person, and including such circumstances not limited to needle-stick or puncture wound injuries and direct saturation or permeation of these body surfaces by the significant -risk body substance:

Provided that "significant risk" shall not include—

(*i*)exposure to urine, faeces, sputum, nasal secretions, saliva, sweat, tears or vomit that does not contain blood that is visible to the naked eye;

(*ii*) human bites where there is no direct blood to blood, or no blood to mucous membrane contact;

(*iii*)exposure of intact skin to blood or any other blood substance; and

(*iv*)occupational centres where individuals use scientifically accepted Universal Precautions, prohibitive techniques and preventive practices in circumstances which would otherwise pose a significant risk and such techniques are not breached and remain intact;

(*w*)"State AIDS Control Society" means the nodal agency of the State Government responsible for implementing programmes in the field of HIV and AIDS;

(*x*)**"**State Government", in relation to a Union territory, means the Administrator of that Union territory appointed by the President under article 239 of the Constitution; and

(*y*)"Universal Precautions" means control measures that prevent exposure to or reduce, the risk of transmission of pathogenic agents (including HIV) and includes education, training, personal protective equipment such as gloves, gowns and masks, hand washing, and employing safe work practices.

CHAPTER II
PROHIBITION OF CERTAIN ACTS

3. Prohibition of discrimination. No person shall discriminate against the protected person on any ground including any of the following, namely:—

(*a*)the denial of, or termination from, employment or occupation, unless, in the case of termination, the person, who is otherwise qualified, is furnished with—

(*i*)a copy of the written assessment of a qualified and independent healthcare provider competent to do so that such protected person poses a significant risk of transmission of HIV to other person in the workplace, or is unfit to perform the duties of the job; and

(*ii*)a copy of a written statement by the employer stating the nature and extent of administrative or financial hardship for not providing him reasonable accommodation;

(*b*) the unfair treatment in, or in relation to, employment or occupation;

(*c*) the denial or discontinuation of, or, unfair treatment in, healthcare services;

(*d*) the denial or discontinuation of, or unfair treatment in, educational, establishments and services thereof;

(*e*)the denial or discontinuation of, or unfair treatment with regard to, access to, or provision or enjoyment or use of any goods, accommodation, service, facility, benefit, privilege or opportunity dedicated to the use of the general public or customarily available to the public, whether or not for a fee, including shops, public restaurants, hotels and places of public entertainment or the use of wells, tanks, bathing ghats, roads, burial grounds or funeral ceremonies and places of public resort;

(*f*)the denial, or, discontinuation of, or unfair treatment with regard to, the right of movement;

(*g*)the denial or discontinuation of, or, unfair treatment with regard to, the right to reside, purchase, rent, or otherwise occupy, any property;

(*h*) the denial or discontinuation of, or, unfair treatment in, the opportunity to stand for, or, hold public or private office;

(*i*)the denial of access to, removal from, or unfair treatment in, Government or private establishment in whose care or custody a person may be;

(*j*)the denial of, or unfair treatment in, the provision of insurance unless such unfair treatment is based on and supported by actuarial studies;
(*k*) the isolation or segregation of a protected person;
(*l*)HIV testing as a pre-requisite for obtaining employment, or accessing healthcare services or education or, for the continuation of the same or, for accessing or using any other service or facility**:**
Provided that, in case of failure to furnish the written assessment under subclause (*i*) of clause (*a*), it shall be presumed that there is no significant risk and that the person is fit to perform the duties of the job, as the case may be, and in case of the failure to furnish the written statement under sub-clause (*ii*) of that clause, it shall be presumed that there is no such undue administrative or financial hardship.

4. Prohibition of certain acts.

No person shall, by words, either spoken or written, publish, propagate, advocate or communicate by signs or by visible representation or otherwise the feelings of hatred against any protected persons or group of protected person in general or specifically or disseminate, broadcast or display any information, advertisement or notice, which may reasonably be construed to demonstrate an intention to propagate hatred or which is likely to expose protected persons to hatred, discrimination or physical violence.

CHAPTER III
INFORMED CONSENT

5. Informed consent for undertaking HIV test or treatment.

(*1*) Subject to the provisions of this Act,—
(*a*) no HIV test shall be undertaken or performed upon any person; or
(*b*) no protected person shall be subject to medical treatment, medical interventions or research,
except with the informed consent of such person or his representative and in such manner, as may be specified in the guidelines.
(*2*) The informed consent for HIV test shall include pre-test and post-test counseling to the person being tested or such person's representative in the manner as may be specified in the guidelines.

6. Informed consent not required for conducting HIV tests in certain cases.

The informed consent for conducting an HIV test shall not be required—
(*a*) where a court determines, by an order that the carrying out of the HIV test of any person either as part of a medical examination or otherwise, is necessary for the determination of issues in the matter before it;
(*b*)for procuring, processing, distribution or use of a human body or any part thereof including tissues, blood, semen or other body fluids for use in medical research or therapy:
Provided that where the test results are requested by a donor prior to donation, the donor shall be referred to counselling and testing centre and such donor shall not be entitled to the results of the test unless he has received post-test counselling from such centre;
(*c*) for epidemiological or surveillance purposes where the HIV test is anonymous and is not for the purpose of determining the HIV status of a person:
Provided that persons who are subjects of such epidemiological or surveillance studies shall be informed of the purposes of such studies; and
(*d*) for screening purposes in any licensed blood bank.

7. Guidelines for testing centres, etc.

No HIV test shall be conducted or performed by any testing or diagnostic centre or pathology laboratory or blood bank, unless such centre or laboratory or blood bank follows the guideline**s** laid down for such test.

CHAPTER IV
DISCLOSURE OF HIV STATUS

8.Disclosure of HIV status.

(*1*) Notwithstanding anything contained in any other law for the time being in force, —

(*i*) no person shall be compelled to disclose his HIV status except by an order that the disclosure of such information is necessary in the interest of justice for the determination of issues in the matter before it;
(*ii*) no person shall disclose or be compelled to disclose the HIV status or any other private information of other person imparted in confidence or in a relationship of a fiduciary nature, except with the informed consent of that other person or a representative of such another person obtained in the manner as specified in section 5, as the case may be, and the fact of such consent has been recorded in writing by the person making such disclosure:
Provided that, in case of a relationship of a fiduciary nature, informed consent shall be recorded in writing.
(*2*)The informed consent for disclosure of HIV-related information under clause (*ii*) of sub-section (*1*) is not required where the disclosure is made—
(*a*)by a healthcare provider to another healthcare provider who is involved in the care, treatment or counselling of such person, when such disclosure is necessary to provide care or treatment to that person;
(*b*)by an order of a court that the disclosure of such information is necessary in the interest of justice for the determination of issues and in the matter before it;
(*c*)in suits or legal proceedings between persons, where the disclosure of such information is necessary in filing suits or legal proceedings or for instructing their counsel;
(*d*) as required under the provisions of section 9;
(*e*)if it relates to statistical or other information of a person that could not reasonably be expected to lead to the identification of that person; and
(*f*)to the officers of the Central Government or the State Government or State AIDS Control Society of the concerned State Government, as the case may be, for the purposes of monitoring, evaluation or supervision.

9. Disclosure of HIV positive status to partner of HIV positive person.

(*1*) No healthcare provider, except a physician or a counsellor, shall disclose the HIV-positive status of a person to his or her partner.
(*2*)A healthcare provider, who is a physician or counsellor, may disclose the HIV positive status of a person under his direct care to his or her partner, if such healthcare provider—
(*a*) reasonably believes that the partner is at the significant risk of transmission of HIV from such person; and
(*b*) such HIV-positive person has been counselled to inform such partner; and
(*c*)is satisfied that the HIV-positive person will not inform such partner; and
(*d*) has informed the HIV-positive person of the intention to disclose the HIV positive status to such partner:
Provided that disclosure under this sub-section to the partner shall be made in person after counselling:
Provided further that such healthcare provider shall have no obligation to identify or locate the partner of an HIV-positive person:
Provided also that such healthcare provider shall not inform the partner of a woman where there is a reasonable apprehension that such information may result in violence, abandonment or actions which may have a severe negative effect on the physical or mental health or safety of such woman, her children, her relatives or someone who is close to her.
(*3*)The healthcare provider under sub-section (*1*) shall not be liable for any criminal or civil action for any disclosure or non-disclosure of confidential HIV-related information made to a partner under this section.

10. Duty to prevent transmission of HIV.

Every person, who is HIV positive and has been counselled in accordance with the guidelines issued or is aware of the nature of HIV and its transmission, shall take all reasonable precautions to prevent the transmission of HIV to other persons which may include adopting strategies for the

reduction of risk or informing in advance his HIV status before any sexual contact with any person or with whom needles are shared with:

Provided that the provisions of this section shall not be applicable to prevent transmission through a sexual contact in the case of a woman, where there is a reasonable apprehension that such information may result in violence, abandonment or actions which may have a severe negative effect on the physical or mental health or safety of such woman, her children, her relatives or someone who is close to her.

CHAPTER V
OBLIGATION OF ESTABLISHMENTS

11. Confidentiality of data.

Every establishment keeping the records of HIV-related information of protected persons shall adopt data protection measures in accordance with the guidelines to ensure that such information is protected from disclosure.

Explanation.— For the purpose of this section, data protection measures shall include procedures for protecting information from disclosure, procedures for accessing information, provision for security systems to protect the information stored in any form and mechanisms to ensure accountability and liability of persons in the establishment.

12. HIV and AIDS Policy for establishments.

The Central Government shall notify model HIV and AIDS policy for establishments, in such manner, as may be prescribed.

CHAPTER VI
ANTI RETROVIRAL THERAPY AND OPPORTUNISTIC INFECTION MANAGEMENT FOR PEOPLE LIVING WITH HIV

13. Central Government and State Government to take measures.

The Central Government and every State Government, as the case may be, shall take all such measures as it deems necessary and expedient for the prevention of spread of HIV or AIDS, in accordance with the guidelines.

14.Antiretroviral therapy and Opportunistic Infection Management by Central and State Government.

(*1*)The measures to be taken by the Central Government or the State Government under section 13 shall include the measures for providing, as far as possible, Anti-retroviral Therapy and Opportunistic Infection Management to people living with HIV or AIDS.

(*2*)The Central Government shall issue necessary guidelines in respect of protocols for HIV and AIDS relating to Anti-retroviral Therapy and Opportunistic Infection Management which shall be applicable to all persons and shall ensure their wide dissemination.

CHAPTER VII
WELFARE MEASURES BY THE CENTRAL AND STATE GOVERNMENT

15. Welfare measures by Central Government and State Government

(*1*)The Central Government and every State Government shall take measures to facilitate better access to welfare schemes to persons infected or affected by HIV or AIDS.

(*2*) Without prejudice to the provisions of sub-section (*1*), the Central and State Governments shall frame schemes to address the needs of HIV and AIDS affected women and children.

16. Protection of property of children affected by HIV or AIDS.

(*1*)The Central Government or the State Government, as the case may be, shall take appropriate steps to protect the property of children affected by HIV or AIDS for the protection of property of child affected by HIV or AIDS.

(*2*)The parents or guardians of children affected by HIV and AIDS, or any person acting for protecting their interest, or a child affected by HIV and AIDS may approach the Child Welfare Committee for the safe keeping and deposit of documents related to the property rights of such

child or to make complaints relating to such child being dispossessed or actual dispossession or trespass into such child's house.

Explanation.— For the purpose of this section, "Child Welfare Committee" means a Committee set up under section 29 of the Juvenile Justice (Care and Protection of Children) Act, 2000.

17.Promotion of HIV and AIDS related information, education and communication programmes.

The Central Government and the State Government shall formulate HIV and AIDS related information, education and communication programmes which are age-appropriate, gender-sensitive, non-stigmatising and non-discriminatory.

18. Women and Children infected with HIV or AIDS.

(*1*) The Central Government shall lay down guidelines for care, support and treatment of children infected with HIV or AIDS.

(*2*) Without prejudice to the generality of the provisions of sub section(*1*) and notwithstanding anything contained in any other law for the time being in force, the Central Government, or the State Government as the case may be, shall take measures to counsel and provide information regarding the outcome of pregnancy and HIV- related treatment to the HIV infected women.

(*3*) No HIV positive woman, who is pregnant, shall be subjected to sterilisation or abortion without obtaining her informed consent.

CHAPTER VIII
SAFE WORKING ENVIRONMENT

19.Obligation of establishments to provide safe working environment.

Every establishment, engaged in the healthcare services and every such other establishment where there is a significant risk of occupational exposure to HIV, shall, for the purpose of ensuring safe working environment,—

(*i*) provide, in accordance with the guidelines,—

(*a*)Universal Precautions to all persons working in such establishment who may be occupationally exposed to HIV; and

(*b*) training for the use of such Universal Precautions;

(*c*)Post Exposure Prophylaxis to all persons working in such establishment who may be occupationally exposed to HIV or AIDS; and

(*ii*) inform and educate all persons working in the establishment of the availability of Universal Precautions and Post Exposure Prophylaxis.

20. General responsibility of establishments.

(*1*)The provisions of this Chapter shall be applicable to all establishments consisting of one hundred or more persons, whether as an employee or officer or member or director or trustee or manager, as the case may be:

Provided that in the case of healthcare establishments, the provisions of this sub-section shall have the effect as if for the words "one hundred or more", the words "twenty or more" had been substituted.

(*2*)Every person, who is in charge of an establishment, referred to in sub-section (*1*), for the conduct of the activities of such establishment, shall ensure compliance of the provisions of this Act.

21. Grievance Redressal mechanism.

Every establishment referred to in sub-section (*1*) of section 20 shall designate such person, as it deems fit, as the Complaints Officer who shall, on a day-to-day basis, deal with complaints of violations of the provisions of this Act in the establishment, in such manner as may be prescribed.

CHAPTER IX
PROMOTION OF STRATEGIES FOR REDUCTION OF RISK

22. Strategies for reduction of risk.

Notwithstanding anything contained in any other law for the time being in force any strategy or mechanism or technique adopted or implemented for reducing the risk of HIV transmission, or any

act pursuant thereto, as carried out by persons, establishments or organizations in the manner as may be specified in the guidelines issued by the Central Government shall not be restricted or prohibited in any manner, and shall not amount to a criminal offence or attract civil liability.

Explanation.—For the purpose of this section, strategies for reducing risk of HIV transmission means promoting actions or practices that minimise a person's risk of exposure to HIV or mitigate the adverse impacts related to HIV or AIDS including—

(*i*) the provisions of information, education and counselling services relating to prevention of HIV and safe practices;

(*ii*) the provision and use of safer sex tools, including condoms, and safe intravenous drug use practices; and

(*iii*) drug substitution, drug maintenance, needle and syringe exchange programmes.

Illustrations

(*a*) A supplies condoms to B who is a sex worker or to C, who is a client of B. Neither A nor B nor C can be held criminally or civilly liable for such actions or be prohibited, impeded, restricted or prevented from implementing or using the strategy.

(*b*) M carries on an intervention project on HIV or AIDS and sexual health information, education and counselling for men, who have sex with men, provides safer sex information, material and condoms to N, who has sex with other men. Neither M nor N can be held criminally or civilly liable for such actions or be prohibited, impeded, restricted or prevented from implementing or using the intervention.

(*c*) X, who undertakes an intervention providing registered needle exchange programme services to injecting drug users, supplies a clean needle to Y, an injecting drug user who exchanges the same for a used needle. Neither X nor Y can be held criminally or civilly liable for such actions or be prohibited, impeded, restricted or prevented from implementing or using the intervention.

(*d*) D, who carries on an intervention programme providing Opioid Substitution Treatment (OST), administers OST to E, an injecting drug user. Neither D nor E can be held criminally or civilly liable for such actions or be prohibited, impeded, restricted or prevented from implementing or using the intervention.

CHAPTER X
APPOINTMENT OF OMBUDSMAN

23. Appointment of Ombudsman.

(*1*) Every State Government shall appoint one or more Ombudsman,—

(*a*) possessing such qualification and experience as may be prescribed, or

(*b*) designate any of its officers not below such rank, as may be prescribed, by that Government,

to exercise such powers and discharge such functions, as may be conferred on Ombudsman under this Act.

(*2*)The terms and condition of the service of an Ombudsman appointed under clause(*a*) of sub-section (*1*) shall be such as may be prescribed by the State Government.

(*3*)The Ombudsman appointed under sub-section (*1*) shall have such jurisdiction in respect of such area or areas as the State Government may, by notification, specify.

24. Powers of Ombudsman.

(*1*) The Ombudsman shall, upon a complaint made by any person, inquire into the violations of the provisions of this Act, in relation to healthcare services by any person, in such manner as may be prescribed by the State Government.

(*2*)The Ombudsman may require any person to furnish information on such points or matters, as he considers necessary, for inquiring into the matter and any person so required shall be deemed to be legally bound to furnish such information and failure to do so shall be punishable under sections 176 and 177 of the Indian Penal Code.

(*3*)The Ombudsman shall maintain records in such manner as may be prescribed by the State Government.

25. Procedure of complaint.
The complaints may be made to the Ombudsman under sub-section (*1*) of section 26 in such manner, as may be prescribed, by the State Government.
26. Orders of Ombudsman.
The Ombudsman shall, after giving an opportunity of being heard to the parties, pass such order, as he deems fit, giving reasons therefor**.**
27. Authorities to assist Ombudsman.
All authorities including the Civil authorities functioning in the area for which the Ombudsman has been appointed under section 23 shall assist in execution of orders passed by the Ombudsman**.**
28. Report to State Government.
The Ombudsman shall, after every six months, report to the State Government, the number and nature of complaints received, the action taken and orders passed in relation to such complaints and such report shall be published on the website of the Ombudsman and a copy thereof be forwarded to the Central Government.

CHAPTER XI
SPECIAL PROVISIONS

29. Right of residence.
Every protected person, who is a woman or who is a person below the age of eighteen years, shall have the right to reside in the shared household, the right not to be excluded from the shared household or any part of it and the right to enjoy and use the facilities of such shared household in a non-discriminatory manner.
Explanation.—For the purposes of this section, the expression "shared household" means a household where a person lives or at any stage has lived in a domestic relationship either singly or along with another person and includes such a household, whether owned or tenanted, either jointly or singly, any such household in respect of which either person or both, jointly or singly, have any right, title, interest or equity or a household which may belong to a joint family of which either person is a member, irrespective of whether either person has any right, title or interest in the shared household.
30. HIV-related information, education and communication before marriage.
The Central Government shall specify guidelines for the provision of HIV-related information, education and communication before marriage and ensure their wide dissemination.
31. Persons in care or custody of State.
(*1*)Every person who is in the care or custody of the State shall have the right to HIV prevention, counselling, testing and treatment services in accordance with the guidelines issued in this regard.
(*2*)For the purposes of this section, persons in the care or custody of the State include persons convicted of a crime and serving a sentence, persons awaiting trial, person detained under preventive detention laws, persons under the care or custody of the State under the Juvenile Justice (Care and Protection of Children) Act, 2000, the Immoral Traffic (Prevention) Act, 1956 or any other law and persons in the care or custody of State run homes and shelters.
32. Recognition of guardianship of older sibling.
Notwithstanding anything contained in any law for the time being in force, a person below the age of eighteen but not below twelve years, who has sufficient maturity of understanding and who is managing the affairs of his family affected by HIV and AIDS, shall be competent to act as guardian of other sibling below the age of eighteen years for the following purposes, namely:—
(*a*) admission to educational establishments;
(*b*) care and protection;
(*c*) treatment;
(*d*) operating bank accounts;
(*e*) managing property; and
(*f*) any other purpose that may be required to discharge his duties as a guardian.

Explanation.— For the purposes of this section, a family affected by HIV or AIDS means where both parents and the legal guardian is incapacitated due to HIV-related illness or AIDS or the legal guardian and parents are unable to discharge their duties in relation to such children.

33. Living wills for guardianship and testamentary guardianship.

(*1*) Notwithstanding anything contained in any law for the time being in force, a parent or legal guardian of a child affected by HIV and AIDS may appoint, by making a will, an adult person who is a relative or friend, or a person below the age of eighteen years who is the managing member of the family affected by HIV and AIDS, as referred to in section 33, to act as legal guardian immediately upon incapacity or death of such parent or legal guardian, as the case may be.

(*2*) Nothing in this section shall divest a parent or legal guardian of their rights, and the guardianship referred to in sub-section (*1*) shall cease to operate upon by the parent or legal guardian regaining their capacity.

(*3*) Any parent or legal guardian of children affected by HIV and AIDS may make a will appointing a guardian for care and protection of such children and for the property that such children would inherit or which is bequeathed through the will made by such parent or legal guardian.

CHAPTER XII
SPECIAL PROCEDURE IN COURT

34. Suppression of identity.

(*1*) In any legal proceeding in which a protected person is a party or such person is an applicant, the court, on an application by such person or any other person on his behalf may pass, in the interest of justice, any or all of the following orders, namely —

(*a*) that the proceeding or any part thereof be conducted by suppressing the identity of the applicant by substituting the name of such person with a pseudonym in the records of the proceedings in such manner as may be prescribed;

(*b*) that the proceeding or any part thereof may be conducted in camera;

(*c*) restraining any person from publishing in any manner any matter leading to the disclosure of the name or status or identity of the applicant**.**

(*2*) In any legal proceeding concerning or relating to an HIV-positive person, the court shall take up and dispose-off the proceeding on priority basis.

35.Maintenance applications.

In any maintenance application filed by or on behalf of a protected person under any law for the time being in force, the court shall consider the application for interim maintenance and, in passing any order of maintenance, shall take into account the medical expenses and other HIV-related costs that may be incurred by the applicant.

36. Sentencing.

In passing any order relating to sentencing, the HIV-positive status of the persons in respect of whom such an order is passed shall be a relevant factor to be considered by the court to determine the custodial place where such person shall be transferred to, based on the availability of proper healthcare services at such place.

CHAPTER XIII
PENALTIES

37.Penalty for contravention.

Notwithstanding any action that may be taken under any other law for the time being in force, whoever contravenes the provisions of section 4 shall be punished with imprisonment for a term which shall not be less than three months but which may extend to two years and with fine which may extend to one lakh rupees, or with both.

38.Penalty for failure to comply with orders of Ombudsman.

Whoever fails to comply with any order given by an Ombudsman within such time as may be specified in such order, under section 25, shall be liable to pay a fine which may extend to ten

thousand rupees and in case the failure continues, with an additional fine which may extend to five thousand rupees for every day during which such failure continues.

39. Penalty for breach of confidentiality in legal proceedings.

Notwithstanding any action that may be taken under any law for the time being in force, whoever discloses information regarding the HIV status of a protected person which is obtained by him in the course of, or in relation to, any proceedings before any court, shall be punishable with fine which may extend to one lakh rupees unless such disclosure is pursuant to any order or direction of a court.

40. Prohibition of victimization.

No person shall subject any other person or persons to any detriment on the ground that such person or persons have taken any of the following actions, namely:—

(*a*) made complaint under this Act;

(*b*) brought proceedings under this Act against any person;

(*c*) furnished any information or produced any document to a person exercising or performing any power or function under this Act; or

(*d*) appeared as a witness in a proceeding under this Act.

41.Court to try offences.

No court other than the court of a Judicial Magistrate First Class shall take cognizance of an offence under this Act.

42.Offences to be cognizable and bailable.

Notwithstanding anything contained in the Code of Criminal Procedure, 1973, offences under this Act shall be cognizable and bailable.

CHAPTER XIV
MISCELLANEOUS

43. Act to have overriding effect.

The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time in force or in any instrument having effect by virtue of any law other than this Act.

44. Protection of action taken in good faith

. No suit, prosecution or other legal proceeding shall lie against the Central Government, the State Government, the Central Government or AIDS Control Society of the State Government Ombudsman or any member thereof or any officer or other employee or person acting under the direction either of the Central Government, the State Government, the Central Government, or Ombudsman in respect of anything which is in good faith done or intended to be done in pursuance of this Act or any rules or guidelines made thereunder or in respect of the publication by or under the authority of the Central Government, the State Government, the Central Government or AIDS Control Society of the State Government Ombudsman.

45. Delegation of powers.

The Central and State Government, as the case may be, may, by general or special order, direct that any power exercisable by it under this Act shall, in such circumstances and under such conditions, if any, as may be mentioned in the order, be exercisable also by an officer subordinate to that Government or the local authority.

46. Guidelines.

(*1*) The Central Government may, by notification, make guidelines consistent with this Act and any rules thereunder, generally to carry out the provisions of this Act.

(*2*) In particular and without prejudice to the generality of the foregoing power, such guidelines may provide for all or any of the following matters, namely :—

(*a*) information relating to risk and benefits or alternatives to the proposed intervention under clause (*n*) of section 2 ;

(*b*) the manner of obtaining the informed consent under sub-section (*1*) and the manner of pretest and post-test counselling under sub-section (*2*) of section 5;
(*c*) guidelines to be followed by a testing or diagnostic centre or pathology laboratory or blood bank for HIV test under section 7;
(*d*) the manner of taking data protection measures under section 11;
(*e*) guidelines in respect of protocols for HIV/AIDS relating to Antiretroviral Therapy and Opportunistic Infections Management under sub-section (*2*) of section 14;
(*f*) care, support and treatment of children infected with HIV or AIDS under sub-section (*1*) of section 18;
(*g*) guidelines for Universal Precautions and post exposure prophylaxis under section 19;
(*h*) manner of carrying out the strategy or mechanism or technique for reduction of risk of HIV transmission under section 22;
(*i*) manner of implementation of a drugs substitution, drug maintenance and needle and syringe exchange programme under section 22;
(*j*) provision of HIV-related information, education and communication before marriage under section 30;
(*k*) manner of HIV or AIDS prevention, counselling, testing and treatment of persons in custody under section 31;
(*l*) any other matter which ought to be specified in guidelines for the purposes of this Act.

47. Power of Central Government to make rules.

(*1*) The Central Government may, by notification, make rules to carry out the provisions of this Act.
(*2*) In particular, and without prejudice to the generality of the foregoing provision, such rules may provide for all or any of the following matters, namely:—
(*a*) manner of notifying model HIV or AIDS policy for the establishments under section 12;
(*b*) any other matter which may be or ought to be prescribed by the Central Government.

48. Laying of rules before both Houses of Parliament.

Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive session aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

49.Power of State Government to make rules and laying thereof.

(*1*) The State Government may, by notification, make rules for carrying out the provisions of this Act.
(*2*) In particular, and without prejudice to the generality of foregoing power, such rules may provide for all or any of the following matters, namely :—
(*a*) measures to provide Anti-retroviral Therapy and Opportunistic Infection Management to people living with HIV or AIDS and for the prevention of spread of HIV or AIDS in accordance with the guidelines under section 14;
(*b*) qualification and experience for the appointment of a person as an Ombudsman under clause (*a*) or rank of officer of the State Government to be designated as Ombudsman under clause (*b*) of sub-section (*1*) of section 23;
(*c*) terms and conditions of services of Ombudsman under sub-section (*2*) of section 23;
(*d*) manner of inquiring into complaints by the Ombudsman under sub-section (*1*) and maintaining of records by him under sub-section (*3*) of section 24;
(*e*) manner of making the complaints to the ombudsman under section 25; and

(*f*) manner of recording pseudonym in legal proceedings under clause (*a*) of sub-section (*1*) of section 34;

(*3*) Every rule made by the State Government under this Act shall be laid, as soon as may be, after it is made before the Legislature of that State.

50. Power to remove difficulties.

(*1*) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act, as may appear to be necessary for removing the difficulty:

Provided that no order shall be made under this section after the expiry of the period of two years from the date of commencement of this Act.

(*2*) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

STATEMENT OF OBJECTS AND REASONS

At present, India is estimated to have 2.39 million people living with HIV/AIDS (PLHIV), the third highest number after South Africa and Nigeria. Currently, the epidemic is "concentrated", *i.e.,* the Human Immunodeficiency Virus (HIV) is more prevalent in high risk groups such as female sex workers, men-who-have-sex-with-men and injecting drug users. It is, therefore, important for these groups to access services such as treatment of sexually transmitted infections, HIV testing, condoms, clean needles and syringes to prevent transmission of HIV to the general population.

2. As the route of transmission is primarily sexual, there is a stigma arising out of HIV infection and those affected by it leading to discrimination which includes denial of, and access to, healthcare and treatment; discrimination against admission or continuance of their children in schools; denial of, and/or removal from, employment and denial of various services including insurance, medical benefits, etc., in both public and private establishments.

3. Given this situation, it is necessary to address the issue of stigma faced by those infected by HIV and AIDS, to ensure confidentiality and privacy while providing HIV and AIDS related services and to strengthen the existing National AIDS Control Programme by bringing in legal accountability. It is also important that existing establishments, both private and public, recognise the need to safeguard the rights of people infected with HIV/AIDS, particularly, women and children.

4. It is proposed, *inter alia,* to prohibit certain specific acts of HIV-related discrimination, provide for informed consent for undertaking HIV test or treatment and also for disclosure of HIV status to ensure confidentiality and privacy, obligation of the establishments to provide for safe working environment, safeguard the rights of people infected with HIV/AIDS, particularly women and children, and establish formal mechanisms for redressing grievances and inquiring into complaints.

5. The Bill seeks to achieve the above objects.

NEW DELHI; GHULAM NABI AZAD.

The 31st *January*, 2014.

Notes on clauses

Clause 1.— This clause seeks to provide for short title, extent and commencement of the Act.

Clause 2.—This clause seeks to provide the definitions of certain words, such as, "AIDS", "capacity to consent", "discrimination", "HIV-affected person", "informed consent", "significant risk", etc., used in various provisions of the Bill.

Clause 3.— This clause relates to prohibition of discrimination. It seeks to provide that no person shall discriminate against the protected person on any ground including the denial of, or termination from, employment or occupation, the unfair treatment in, or in relation to, employment or occupation, the denial or discontinuation of, or, unfair treatment in, healthcare services and in educational establishments and services thereof, the denial or discontinuation of, or, unfair treatment with regard to, access to, or, provision or enjoyment or use of any goods, accommodation, service, facility, benefit, privilege, or opportunity, dedicated to the use of the general public or customarily available to the public, the denial or discontinuation of, or, unfair treatment with regard to the right of movement, the right to reside, purchase, rent, or otherwise

occupy, any property, the opportunity to stand for, or, hold public or private office, the isolation or segregation or a protected person, HIV testing as a pre-requisite for obtaining employment, etc.

The said clause further seeks to provide that in case of failure to furnish the written assessment under sub-clause (*i*) of clause (a), it shall be presumed that there is no significant risk and that the person is fit to perform the duties of the job, as the case may be, and in case of the failure to furnish the written statement under sub-clause (ii) of that clause, it shall be presumed that there is no such undue administrative or financial hardship.

Clause 4.— This clause relates to prohibition of certain acts. It seeks to provide that no person shall, by words, either spoken or written, publish, propagate, advocate or communicate by signs or by visible representation or otherwise the feelings of hatred against any protected person or group of protected person in general or specifically or disseminate, broadcast or display any information, advertisement or notice, which may reasonably be construed to demonstrate an intention to propagate hatred or which is likely to expose the protected persons to hatred, discrimination or physical violence.

Clause 5.— This clause relates to informed consent for undertaking HIV test or treatment. It seeks to provide that no HIV test shall be undertaken or performed upon any person or no protected person shall be subjected to medical treatment, medical interventions or research, except with the informed consent of such person or his representative and in such manner, as may be specified in the guidelines. The informed consent for HIV test shall include pre-test and post-test counselling to the person being tested or such person's representative in the manner as may be specified in the guidelines.

Clause 6.— This clause relates to informed consent not required for conducting HIV tests in certain cases. It seeks to provide that informed consent for conducting HIV test shall not be required where a court determines, by an order that the carrying out of the HIV test of any person either as part of a medical examination or otherwise, is necessary for the determination of issues in the matter before it, for procuring, processing, distribution or use of a human body or any part thereof including tissues, blood, semen or other body fluids for use in medical research or therapy and where the test results are requested by a donor prior to donation, the donor shall be referred to counselling and testing centre and such donor shall not be entitled to the results of the test unless he received post-test counselling from such centre and provide for epidemiological or surveillance purposes where the HIV test is anonymous and is not for the purpose of determining the HIV status of a person and the persons who are subjects of such epidemiological or surveillance studies shall be informed of the purposes of such studies and for screening purposes in any licensed blood bank.

Clause 7.—This clause relates to guidelines for testing centres, etc. It seeks to provide that no HIV test shall be conducted or performed by any testing or diagnostic centre or pathology laboratory or blood bank, unless such centre or laboratory or blood bank follows the guidelines laid down for such test.

Clause 8.— This clause deals with disclosure of HIV status. Sub-clause (*1*) seeks to provide that no person shall be compelled to disclose his HIV status except by an order that the disclosure of such information is necessary in the interest of justice for determination of issues in the matter before it and no person shall disclose or be compelled to disclose the HIV status or any other private information of other person imparted in confidence or in a relationship of a fiduciary nature, except with the informed consent of that other person or a representative of such another person obtained in the manner as specified in clause 5, as the case may be, and the fact of such consent has been recorded in writing by the person making such disclosure and in case of a relationship of a fiduciary nature, informed consent shall be recorded in writing. Sub-clause (*2*) provides for circumstances when the informed consent is not required where the disclosure is made.

Clause 9.— This clause deals with disclosure of HIV positive status to partner of HIV positive person. Sub-clause (*1*) seeks to provide that no healthcare provider, except a physician or a counsellor, shall disclose the HIV-positive status of a person to his or her partner.

Sub-clause(*2*) of the said clause seeks to provide that a healthcare provider or a physician or counsell or may disclose in person the HIV positive status of a person under his direct care to his or her partner if he reasonably believes that the partner is at the significant risk of transmission of HIV from such person, and such HIV positive person has been counselled to inform such partner; and is satisfied that the HIV positive person will not inform such partner; and has informed the HIV positive person of the intention to disclose the HIV positive status to such partner but such healthcare provider shall not inform the partner of a woman where there is a reasonably apprehension that such information may result in violence.

Sub-clause (*3*) of the said clause seeks to provide that the healthcare provider under sub-clause (*1*) shall not be liable for any criminal or civil action for any disclosure or nondisclosure of confidential HIV-related information made to a partner under this section.

Clause 10.— This clause deals with duty to prevent transmission of HIV. It seeks to provide that every person, who is HIV positive and has been counselled in accordance with the guidelines issued or is aware of the nature of HIV and its transmission, shall take all reasonable precautions to prevent the transmission of HIV to other persons which may include adopting strategies for the reduction of risk or informing in advance his HIV status before any sexual contact with any person or with whom needless are shared with. The said clause further seeks to provides that in case where there is a reasonable apprehension that such information may result in violence, the provisions of the said clause shall not be applicable.

Clause 11.— This clause relates to confidentiality of data. It seeks to provide that every establishment keeping the records of HIV-related information of protected persons shall adopt data protection measures in accordance with the guidelines to ensure that such information is protected from disclosure. The said clause seeks to provide for an explanation relating to data protection measures.

Clause 12.— This clause relates to HIV and AIDS policy for establishments. It seeks to provide that the Central Government shall notify model HIV and AIDS policy for establishments, in such manner, as may be prescribed.

Clause 13.— This clause relates to Central Government and State Government to take measures. It seeks to provide that the Central Government and every State Government, as the case may be, shall take all such measures as it deems necessary and expedient for the prevention of spread of HIV or AIDS, in accordance with the guidelines.

Clause 14.— This clause relates to Anti-retroviral Therapy and Opportunistic Infection Management by Central and State Government. It seeks to provide that the measures to be taken by the Central Government or the State Government under clause 13 and shall include the measures for providing, as far as possible, Anti-retroviral Therapy and Opportunistic Infection Management to people living with HIV or AIDS and the Central Government shall issue necessary guidelines in respect of protocols for HIV and AIDS relating to Anti-retroviral Therapy and Opportunistic Infection Management which shall be applicable to all persons and ensure their wide dissemination.

Clause 15.— This clause deals with welfare measures by Central Government and State Government. It seeks to provide that the Central Government and every State Government shall take measures to facilitate better access to welfare schemes to persons infected or affected by HIV or AIDS and further provides to frame schemes to address the needs of HIV and AIDS affected women and children.

Clause 16.— This clause deals with protection of property of children affected by HIV or AIDS. Sub-clause (*1*) seeks to provide that the Central Government or the State Government, as the case may be, shall take appropriate steps to protect the property of children affected by HIV or AIDS.

Sub-clause (*2*) of the said clause seeks to provide for a situation when the parents or guardians of children affected by HIV and AIDS, or any person acting for protecting their interest, or a child affected by HIV and AIDS may approach the Child Welfare Committee. An explanation has been provided to define "Child Welfare Committee" which means a Committee set up under section 29 of the Juvenile Justice (Care and Protection of Children) Act, 2000.

Clause 17.— This clause deals with promotion of HIV and AIDS related information, education and communication programmes. It seeks to provide that the Central Government and the State Government shall formulate HIV and AIDS related information, education and communication programmes which are age-appropriate, gender-sensitive, non-stigmatising and non-discriminatory.

Clause 18.— This clause relates to women and children infected with HIV or AIDS. Sub-clause (*1*) seeks to provide that the Central Government shall lay down guidelines for care, support and treatment of children infected with HIV or AIDS. Sub-clause (*2*) seeks to provide that the Central Government, or the State Government, as the case may be, shall take measures to counsel and provide information regarding the outcome of pregnancy and HIV related treatment to the HIV infected women. Sub-clause (*3*) seeks to provide that no HIV positive woman, who is pregnant, shall be compelled to undergo sterilisation or abortion without obtaining her informed consent.

Clause 19.— This clause relates to obligation of establishments to provide safe working environment. It seeks to provide that every establishment, engaged in the healthcare services and every such other establishment where there is a significant risk of occupational exposure to HIV, shall, for the purpose of ensuring safe working environment shall provide in accordance with the guidelines the Universal Precautions to all persons

working in such establishment who may be occupationally exposed to HIV and training for the use of such Universal Precautions and Post Exposure Prophylaxis to all persons working in such establishment who may be occupationally exposed to HIV or AIDS and inform and educate all persons working in the establishment of the availability of Universal Precautions and Post Exposure Prophylaxis.

Clause 20.— This clause relates to general responsibility of establishments. Subclause(*1*) seeks to provide that the provisions of Chapter VII shall be applicable to all establishments consisting of one hundred or more persons, whether as an employee or officer or member or director or trustee or manager, as the case may be, and provide that in the case of healthcare establishments, the provisions of sub-clause (*1*) shall have the effect as if for the words "one hundred or more", the words "twenty or more" had been substituted. Sub-clause (*2*) seeks to provide that every person, who is in charge of an establishment, referred to in sub-clause (*1*), for the conduct of the activities of such establishment, shall ensure compliance of the provisions of this Act.

Clause 21.— This clause relates to grievance redressal mechanism. It seeks to provide that every establishment referred to in sub-clause (*1*) of clause 20 shall designate such person, as it deems fit, as the Complaints Officer who shall, on a day-to-day basis, deal with complaints of violations of the provisions of this Act in the establishment, in such manner as may be prescribed.

Clause 22.— This clause relates to strategies for reduction of risk. It seeks to provide that any strategy or mechanism or technique adopted or implemented for reducing the risk of HIV transmission, or any act pursuant thereto, as carried out by persons, establishments or organisations in the manner as may be specified in the guidelines issued by the Central Government and shall not be restricted or prohibited in any manner, and shall not amount to a criminal offence or attract civil liability. An explanation has been provided to define "the strategies for reducing risk of HIV transmission". Illustrations have been provided in this regard.

Clause 23.— This clause relates to appointment of Ombudsman. Sub-clause (*1*) seeks to provide that every State Government shall appoint one or more Ombudsman possessing such qualification and experience as may be prescribed, or designate any of its officers not below such rank, as may be prescribed, by that Government, to exercise such powers and discharge such functions as may be conferred on Ombudsman under this Act. Sub-clause (*2*) seeks to provide that the terms and condition of the service of the Ombudsman appointed under item (a) of sub-clause (*1*) shall be such as may be prescribed by the State Government. Sub-clause (*3*) seeks to provide that the Ombudsman appointed under sub-clause (*1*) shall have such jurisdiction in respect of such area or areas as the State Government may, by notification, specify.

Clause 24.— This clause relates to powers of Ombudsman. Sub-clause (*1*) seeks to provide that the Ombudsman shall, upon a complaint made by any person inquire into violations of the provisions of this Act, in relation to healthcare services by any person, in such manner as may be prescribed by the State Government. Sub-clause (*2*) seeks to provide that the Ombudsman may require any person to furnish information on such points or matters as he considers necessary, for inquiring into the matter and any person so required shall be deemed to be legally bound to furnish such information and failure to do so shall be punishable under sections 176 and 177 of the Indian Penal Code. Sub-clause (*3*) seeks to provide that the Ombudsman shall maintain records in such manner as may be prescribed by the State Government.

Clause 25.— This clause relates to procedure of complaint. It seeks to provide that the complaints may be made to the Ombudsman under sub-clause (*1*) of clause 26, in such manner, as may be prescribed, by the State Government.

Clause 26.— This clause relates to orders of Ombudsman. It seeks to provide that the Ombudsman shall hear both the parties and pass orders, giving reasons for the same.

Clause 27.— This clause deals with authorities to assist Ombudsman. It seeks to provide that all authorities including Civil authorities functioning in the area for which the Ombudsman shall assist in execution of orders passed by the Ombudsman.

Clause 28.— This clause deals with report to the State Government. It seeks to provide that the Ombudsman shall, after every six months, report to the State Government, the number and nature of complaints received, the action taken and orders passed in relation to such complaints and such report shall be published on the website of the Ombudsman and a copy thereof be forwarded to the Central Government.

Clause 29.— This clause relates to right of residence. It seeks to provide that every HIV infection or affected woman has the right to reside in a shared household.

Clause 30.— This clause deals with HIV-related information, education and communication before marriage. It seeks to provide that the Central Government shall specify guidelines for HIV-related information, education and communication before marriage.

Clause 31.— This clause relates to persons in care or custody of State. It seeks to provide that every person who is in the care or custody of the State shall have the right to HIV prevention, counseling, testing and treatment services in accordance with the guidelines issued in this regard.

Clause 32.— Clause 32 relates to recognition of guardianship of older sibling. It seeks to provide that a person below the age of eighteen but not below twelve years, who has sufficient maturity of understanding and who is managing the affairs of his family affected by HIV and AIDS, shall be competent to act as guardian of other sibling below the age of eighteen years for the following purposes, namely, (a) admission to educational establishments, (b) care and protection, (c) treatment, (d) operating bank accounts, (e) managing property and (f) any other purpose that may be required to discharge his duties as a guardian.

Clause 33.— This clause deals with living wills for guardianship and testamentary guardianship. It provides that a parent or legal guardian of a child affected by HIV and AIDS may appoint, by making a will, an adult person who is a relative or friend, or a person below the age of eighteen years who is the managing member of the family affected by HIV and AIDS, as referred to in section 33, to act as legal guardian immediately upon incapacity or death of such parent or legal guardian, as the case may be.

Clause 34.— Clause 34 relates to suppression of identity. It provides that in any legal proceeding in which a protected person is a party or such person is an applicant, the court, on an application by such person or any other person on his behalf may pass, in the interest of justice, any or all of the following orders, namely, (a) that the proceeding or any part thereof be conducted by suppressing the identity of the applicant by substituting the name of such person with a pseudonym in the records of the proceedings in such manner as may be prescribed; (b) that the proceeding or any part thereof may be conducted in camera; (c) restraining any person from publishing in any manner any matter leading to the disclosure of the name or status or identity of the applicant.

Clause 35.— This clause relates to maintenance applications. It provides that in any maintenance application filed by or on behalf of a protected person under any law for the time being in force, the court shall consider the application for interim maintenance and, in passing any order of maintenance, shall take into account the medical expenses and other HIV-related costs that may be incurred by the applicant.

Clause 36.— This clause relates to sentencing. It seeks to provide that in passing any order relating to sentencing, the HIV positive status of the persons in respect of whom such an order is passed shall be a relevant factor to be considered by the court to determine the custodial place where such person shall be transferred to, based on the availability of proper healthcare services at such place.

Clause 37.— This clause deals with penalty for contravention. It seeks to provide that whoever contravenes the provisions of section 4 shall be punished with imprisonment for a term which shall not be less than three months but which may extend to two years and with fine which may extend to one lakh rupees or both.

Clause 38.— This clause deals with penalty for failure to comply with the orders of the Ombudsman. It seeks to whoever fails to comply with any order given by an Ombudsman within such time as may be specified in such order, under section 25, shall be liable to pay a fine which may extend to ten thousand rupees and in case the failure continues, with an additional fine which may extend to five thousand rupees for every day during which such failure continues.

Clause 39.— This clause deals with penalty for breach of confidentiality in legal proceedings. It seeks to provide that whoever discloses information regarding the HIV status of a protected person which is obtained by him in the course of, or in relation to, any proceedings before any court, shall be punishable with fine which may extend to one lakh rupees unless such disclosure is pursuant to any order or direction of a court.

Clause 40.— This clause relates to prohibition of victimization. It seeks to provide that no person shall subject any other person or persons to any detriment on the ground that such person or persons who have made complaint under this Act; or brought proceedings under this Act against any person; or furnished any information or produced any document to a person exercising or performing any power or function under this Act; or appeared as a witness in a proceeding under this Act.

Clause 41.— This clause deals with the court to try offences. It seeks to provide that No court other than the court of a Judicial Magistrate First Class shall take cognizance of an offence under this Act.

Clause 42.— This clause deals with offences to be cognizable and bailable. It seeks to provide that notwithstanding anything contained in the Code of Criminal Procedure, 1973, offences under this Act shall be cognizable and bailable.

Clause 43.— This clause deals with the overriding effect of the Act. It seeks to provide that the provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force or in any instrument having effect by virtue of any law other than this Act.

Clause 44.—This clause relates to protection of action taken in good faith. It seeks to provide that no suit, prosecution or other legal proceeding shall lie against the Central Government, the State Government, the Central Government or AIDS Control Society of the State Government Ombudsman or any member thereof or any officer or other employee or person acting under the direction either of the Central Government, the State Government, the Central Government, or Ombudsman in respect of anything which is in good faith done or intended to be done in pursuance of this Act or any rules or guidelines made thereunder or in respect of the publication by or under the authority of the Central Government, the State Government, the Central Government or AIDS Control Society of the State Government Ombudsman.

Clause 45.—This clause relates to delegation of powers. It seeks to provide that the Central and State Government, may, by general or special order, direct that any power exercisable by it under this Act shall, in such circumstances and under such conditions, if any, as may be mentioned in the order, be exercisable also by an officer subordinate to that Government or the local authority.

Clause 46.—This clause relates to power of the Central Government to make guidelines. Sub-clause(*1*) of the clause provides that the Central Government may, by notification, make guidelines consistent with this Act and any rules thereunder, generally to carry out the provisions of this Act. Sub-clause(*2*) of the said clause seeks to provide that such guidelines may provide for all or any of the following matters, namely, (*a*) information relating to risk and benefits or alternatives to the proposed intervention under clause(*n*) of section 2;(*b*)the manner of obtaining the informed consent under sub-section(*1*) and the manner of pre test and post test counselling under sub-section(*2*) of section 5;(*c*) guidelines to be followed by a testing or diagnostic centre or pathology laboratory or blood bank for HIV test under section 7;(*d*) the manner of taking data protection measures under section 11;(*e*) guidelines in respect of protocols for HIV/AIDS relating to Anti retroviral Therapy and Opportunistic Infections Management under sub-section(*2*) of section 14;(*f*) care, support and treatment of children infected with HIV or AIDS under sub-section(*1*) of section 18;(*g*) guidelines for Universal Precautions and post exposure prophylaxis under section 19;(*h*) manner of carrying out the strategies or mechanism or technique for reduction of risk of HIV transmission by any person, establishment or organisation under section 22;(*i*) manner of implementation of a drugs substitution, drug maintenance and needle and syringe exchange programme under section 22;(*j*) provision of HIV-related information, education and communication before marriage under section 30;(*k*) manner of HIV or AIDS prevention, counselling, testing and treatment of persons in custody under section 31;(*l*) any other matter which ought to be specified in guidelines for the purposes of this Act.

Clause 47.—This clause relates to power of the Central Government to make rules. Sub-clause (*1*) of the said clause seeks to provide that the Central Government may, by notification, make rules to carry out the provisions of this Act. Sub-clause(*2*) of the said clause seeks to provide that provide, such rules may provide for all or any of the following matters, namely:—(*a*)manner of notifying model HIV or AIDS policy for the establishments under section 12; (*b*) any other matter which may be or ought to be prescribed by the Central Government.

Clause 48.—This clause relates to laying of rules before both Houses of Parliament. It seeks to provide that every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive session aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

Clause 49.— This Clause relates to power of State Government to make rules and laying thereof. Sub-clause (*1*) of the clause seeks to provide that the State Government may, by notification, make rules for carrying out the provisions of this Act. Sub-clause(*2*) of the said clause provides that such rules may provide for all or any of the following matters, namely :—(*a*)measures to provide Anti-retroviral Therapy and Opportunistic Infection Management to people living with HIV or AIDS and for the prevention of spread of HIV or AIDS in accordance with the guidelines under section 14; (*b*) qualification and experience for the appointment of a person as an Ombudsman under clause (*a*) or rank of the officer of the State Government to be designated as an Ombudsman under clause b of sub-section(*1*) of section 23; (*c*) terms and conditions of services of Ombudsman under sub-section(2) of section 23;(*d*) manner of inquiring into complaints by the Ombudsman under sub-section(*1*)

and maintaining of records by him under sub-section (*3*) of section 24; (*e*) manner of making the complaints to the ombudsman under section 25; (*f*) manner of recording pseudonym in legal proceedings under clause (*a*) of sub-section (*1*) of section 34. Sub-clause the said clause provides that every rule made by the State Government under this Act shall be laid, as soon as may be, after it is made before the Legislature of that State.

Clause 50.—This clause deals with power to remove difficulties. Sub-clasue(*1*) of the said clause seeks to provide that if any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act within a period of two years from the commencement of the Act. Sub-clause(*2*) provides that every such order made shall be laid, as soon as may be after it is made, before each House of Parliament.

FINANCIAL MEMORANDUM

The current National AIDS Control Programme takes care of the concerns expressed in the Bill for prevention and control of HIV and AIDS. The Planning Commission has allocated Rupees 11,394 Crore for the Department of AIDS Control as part of the Twelfth Plan (2012-2017) Outlay. It is difficult to estimate the provision required for new activities such as number of persons who will be appointed as Ombudsman by the State Governments, the schemes to be drawn out by the Central Government and State Governments, etc. In addition, there are some schemes which need to be framed and implemented by other Departments and Ministries for people infected/affected with HIV or AIDS.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 46 of the Bill seeks to empower the Central Government to make guidelines consistant with the proposed legislation and rules thereunder to carry out its provisions. Sub-clause(*2*) of this clause enumerates the matters with respect to which guidelines may be made. These matters relate to (a) information relating to risk and benefits or alternatives to the proposed intervention under clause (n) of section 2;(b) the manner of obtaining the informed consent under sub-section(1) and the manner of pretest and posttest counseling under sub-section(2) of section 5;(c) guidelines to be followed by a testing or diagnostic centre or pathology laboratory or blood bank for HIV test under section 7;(d) the manner of taking data protection measures under section 11;(e) guidelines in respect of protocols for HIV/AIDS relating to Anti-retroviral Therapy and Opportunistic Infections Management under sub-section(2) of section 14;(f) care, support and treatment of children infected with HIV or AIDS under sub-section(1) of section 18;(g) guidelines for Universal Precautions and post exposure prophylaxis under section 19;(h) manner of carrying out the strategy or mechanism or technique adopted for reducing the risk of HIV transmission by person, establishment or organisations including the manner of implementation of drugs substitution, drug maintenance and needle and syringe exchange programme under section 22;(i) provision of HIV-related information, education and communication before marriage under section 30; (j) manner of HIV or AIDS prevention, counselling, testing and treatment of persons in custody under section 31 and any other matter which ought to be specified in the guidelines for the purposes of the proposed legislation.

2.Clause 47 of the Bill seeks to empower the Central Government to make rules to carry out the provisions of the Act. Sub-clause (*2*) of this clause seeks to provide for the manner of notifying model HIV or AIDS policy for the establishments under section 12 and any other matter which may be or ought to be prescribed by the Central Government.

3.Clause 48 of the Bill provides that the rules made under the proposed legislation are required to be laid before each House of Parliament.

4. Clause 49 of the Bill seeks to empower the State Government to make rules to carry out the provisions of the Act. Sub-clause(*2*) of this clause enumerates the matters with respect to which rules may be made. These matters relate to (a) measures to provide Antiretroviral Therapy and Opportunistic Infection Management to people living with HIV or AIDS and for the prevention of spread of HIV or AIDS in accordance with the guidelines under section 14;(b) qualification and experience for the appointment of a person, or rank of officers of State Government to be designated, as an Ombudsman under sub-section(1) of section 23;(c) terms and conditions of services of Ombudsman under sub-section(2) of section 23;(d) manner of inquiring into complaints by the Ombudsman under sub-section(1) and maintaining of records by him under sub-section (3) of section 24;(e) manner of making the complaints to the Ombudsman under section 25;(f) manner of recording pseudonym in legal proceedings under clause (a) of sub-section(1) of section 34.

Sub-clause(*3*) of clause 49 of the Bill provides that the rules made by the State Government under the proposed legislation are required to be laid before the Legislature of that state.

5.The matters in respect of which rules may be made under the aforesaid provisions are matters of procedure and administrative detail and it is not practical to provide for them in the Bill itself. The delegation of legislative power is, therefore, of a normal character.

RAJYA SABHA

———

A

BILL

to provide for the prevention and control of the spread of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome and for the protection of human rights of persons affected by the said virus and syndrome and for matters connected therewith or incidental thereto.

———

(Shri Ghulam Nabi Azad, Minister of Health and Family Welfare)

GMGIPMRND—4161RS(S-3)—06-02-2014.

MAHARASHTRA GAZETTE ON HIV & AIDS ACT ACCEPTANCE
The Government of Maharashtra Published the HIV & AIDS Act 2017 in Gazette of Maharashtra Part VI dated 30 December 2017 which was assented in Rajyasabha and published by Govt. of India in part II section 1 dated April 21, 2017 in Gazette of India.

RNI No. MAHBIL /2012/46128

महाराष्ट्र शासन राजपत्र

भाग सहा

वर्ष ३, अंक ७] गुरुवार ते बुधवार, नोव्हेंबर ३०-डिसेंबर ६, २०१७/अग्रहायण ९-१५, शके १९३९ [पृष्ठे ३०९, किंमत : रुपये १४.००

प्राधिकृत प्रकाशन

संसदेचे अधिनियम व राष्ट्रपतींनी प्रख्यापित केलेले अध्यादेश

अनुक्रमणिका

HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (PREVENTION AND CONTROL) ACT, 2017 (16 OF 2017),

Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention And Control) Act, 2017 (16 of 2017), is published in Gazette of India.

रजिस्ट्री सं॰ डी॰ एल॰—(एन)04/0007/2003—17 REGISTERED NO. DL—(N)04/0007/2003—17

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II — खण्ड 1
PART II — Section 1
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं॰ 16] नई दिल्ली, शुक्रवार, अप्रैल 21, 2017/वैशाख 1, 1939 (शक)
No. 16] NEW DELHI, FRIDAY, APRIL, 21, 2017/VAISAKHA 1, 1939 (SAKA)

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE
(Legislative Department)

New Delhi, the 21st April, 2017/*Vaisakha* 1, 1939 (*Saka*)

The following Act of Parliament received the assent of the President on the 20th April, 2017, and is hereby published for general information:—

THE HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (PREVENTION AND CONTROL) ACT, 2017

No. 16 OF 2017

[20*th April,* 2017.]

10th Day of September 2018 as date on which the provision of the **HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (PREVENTION AND CONTROL) ACT, 2017 (16 OF 2017), said act shall come into force.**

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 3568] नई दिल्ली, सोमवार, सितम्बर 10, 2018/भाद्र 19, 1940
No. 3568] NEW DELHI, MONDAY, SEPTEMBER 10, 2018/BHADRA 19, 1940

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 10 सितम्बर, 2018

का.आ. 4715(अ).—केन्द्रीय सरकार, मानव रोगक्षम अल्पता विषाणु और अर्जित रोगक्षम अल्पता संलक्षण (निवारण और नियंत्रण) अधिनियम, 2017 (2017 का 16) की धारा 1 की उपधारा (3) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, 10 सितंबर, 2018 को उस तारीख के रूप में नियत करती है, जिसको उक्त अधिनियम के उपबंध प्रवत्त होंगे।

[फा. सं. टी-11020/50/1999-नाको(पीएंडसी)]

आलोक सक्सेना, संयुक्त सचिव

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 10th September, 2018

S.O. 4715(E).—In exercise of the powers conferred by sub-section (3) of section 1 of the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017 (16 of 2017), the Central Government hereby appoints the 10th day of September, 2018, as the date on which the provisions of the said Act shall come into force.

[F. No. T-11020/50/1999-NACO (P&C)]

ALOK SAXENA, Jt. Secy.

5298 GI/2018

Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (PREVENTION AND CONTROL) RULES, 2018.

Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Rules, 2018.

MINISTRY OF HEALTH AND FAMILY WELFARE
(National AIDS Control Organisation)
NOTIFICATION

New Delhi, the 17th September, 2018

G.S.R. 888I.—In exercise of the powers conferred by section 47 of the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention And Control) Act, 2017 (16 of 2017), the Central Government hereby makes the following rules, namely:—

Chapter – I
Preliminary

1. Short title and commencement.- (1) These rules may be called the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention And Control) Rules, 2018.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions.-

(1) In these rules, unless the context otherwise requires,—

(a) "Act" means the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention And Control) Act, 2017 (16 of 2017);

(b) "appropriate authority" means;

(i) the National AIDS Control Organisation in case of Central Government; and

(ii) the State AIDS Control Society in case of State Government;

(c) “high burden district” means a district which has-

(i) more than one percent prevalence among antenatal care in Sentinel Surveillance; or

(ii) more than five percent prevalence among high-risk population in Sentinel Surveillance; or

(iii) HIV positivity of more than national average among general clients in Integrated Counselling and Testing Centre notified by the appropriate authority under the Central Government from time to time;

(2) Words and expressions used herein and not defined in these rules but defined in the Act shall have the meanings assigned to them in the Act.

Chapter – II
Manner of Notifying HIV and AIDS Policy for Establishments

3. The appropriate authority under the Central Government shall, before notifying a model HIV and AIDS policy for establishments consult -

(a) all stakeholders including representatives of HIV -positive persons;

(b) HIV -affected persons and protected persons;

(c) healthcare providers;

(d) establishments engaged in providing education, healthcare services, experts and organizations working in the field of

4.HIV and AIDS, employers, trade unions, and other relevant stakeholders on such policy. The appropriate authority under the Central Government shall notify a model HIV and AIDS policy for establishments in the Official Gazette.

5. The appropriate authority under the Central Government shall review and update from time to time the model HIV and AIDS policy for establishments in accordance with rules 3 and 4.

6. (1) The model HIV and AIDS policy applicable to an establishment, engaged in the provision of healthcare services and every other establishment where there is a significant risk of occupational exposure to HIV shall provide for a safe working environment and for informed consent for testing, treatment and research in accordance with the provisions of the Act.

(2) The model HIV and AIDS Policy applicable to an establishment consisting of one hundred or more persons, whether as an employee or officer or member or director or trustee or manager, as the case may be, shall provide for a grievance redressal mechanism in accordance with the provisions of the Act and these rules:

Provided that in the case of healthcare establishments, the provisions of this sub-rule shall have the effect as if for the words "one hundred or more", the words "twenty or more" had been substituted.

7. (1) The model HIV and AIDS policy as may be applicable and as may be amended and updated from time to time by

the appropriate authority under the Central Government shall be adopted by every establishment upon its notification.

(2) The text of the HIV and AIDS policy shall be communicated to all persons working in the establishment by the person in charge of or responsible to the establishment.

(3) The person in charge or responsible for the establishment shall prominently post the text of the HIV and AIDS policy as a notice in English and in the language understood by majority of persons working in or accessing such establishment on special boards to be maintained for such purpose, at or near the entrance through which the majority of the persons working in or accessing the services of the establishment enter such establishment.

(4) The establishment shall conduct annual training sessions for persons working in such establishment in understanding and implementing the HIV and AIDS policy.

8. (1) The notice referred to in sub- rule (3) of rule 7 shall state the manner in which copies of the HIV and AIDS policy shall be obtained and persons working in or accessing the services of the establishment shall be entitled to a copy of such policy free of charge.

(2) The copies of the HIV and AIDS policy of establishments shall be made available in the public domain by those to whom the policy has been made available including on their website if any and in case of hard copies for a nominal price.

(3) The appropriate authority of every State shall make available the copy of HIV and AIDS policy to heads of all educational establishments who shall further provide a copy of the policy to the learners and their parents or guardians free of charge immediately upon admission of the learner to the establishment.

Chapter – III
Grievance Redressal Mechanism for Establishments

9. (1) Every establishment having one hundred or more persons, whether as an employee or officer or member or director or trustee or manager, as the case may be, shall within one hundred and eighty days of the commencement of the Act, designate such person of senior rank, as it deems fit, as the Complaints Officer who shall dispose of complaints of violations of the provisions of the Act in the establishment, in accordance with these rules:

Provided that every branch of an establishment having one hundred or more persons, whether as an employee or officer or member or director or trustee or manager, as the case may be, shall within one hundred and eighty days of the commencement of the Act, designate such person of senior rank, as it deems fit, as an additional Complaints Officer for such branch who shall dispose of complaints of violations of the provisions of the Act in the establishment, in accordance with these rules:

Provided further that in the case of healthcare establishments, the provisions of this rule shall have the effect as if for the words "one hundred or more", the words "twenty or more" had been substituted.

(2) The establishment shall within thirty days of appointment, provide training to the Complaints Officer on the provisions of the Act including information on prevention, care, support and treatment related to HIV, human sexuality, sexual orientation and gender identity, drug use, sex work, people vulnerable to HIV, stigma and discrimination, principles of the greater involvement of

people living with HIV, strategies of risk reduction, etc. During the training assistance of experts including protected persons and persons vulnerable to HIV may be provided to the Complaints Officer.

10. (1) Any person may make a complaint to the Complaints Officer, within three months from the date that the person making the complaint became aware of the alleged violation of the Act in the establishment:

Provided that the Complaints Officer may, for reasons to be recorded in writing, extend the time limit to make the complaint by a further period of three months, if he is satisfied that circumstances prevented the complainant from making the complaint within the stipulated period.

(2) Every complaint shall be made to the Complaints Officer in writing in the Form set annexed to these rules:

Provided that where a complaint cannot be made in writing the Complaints Officer shall render all reasonable assistance to the complainant to reduce the complaint in writing.

(3) The Complaints Officer may receive complaint made in person, or by post or telephonically or in electronic form:

Provided that the establishment shall within a period of thirty days of appointing the Complaints Officer, establish a method for receipt of complaints in electronic form either through dedicated website, webpage or by providing an official email address for the submission of complaints to the Complaints Officer.

(4) The Complaints Officer shall, on receipt of a complaint, provide an acknowledgment to the complainant and record the Complaint in a register to be kept solely for that purpose.

(5) The time of the complaint and the action taken on the complaint shall be entered in a register.

(6) Every complaint shall be numbered sequentially in the register.

(7) The Complaints Officer shall act in an objective and independent manner while deciding complaints made under the Act.

(8) The Complaints Officer shall decide a complaint promptly and in any case within seven working days:

Provided that in case of emergency or in the case of healthcare establishment where the complaint relates to discrimination in the provision of, or access to health care services or provision of universal precautions, the Complaints Officer shall decide the complaint on the same day on which he receives the complaint.

11. (1) The Complaints Officer, if satisfied that a violation of the Act has taken place as alleged in the complaint, shall-

(a) firstly, direct the establishment to take measures to rectify the violation;

(b) secondly, counsel the person who has committed the violation and require such person to undergo training in relation to HIV and AIDS, provisions of the Act, rules and guidelines, particularly in relation stigma and discrimination, for a period amounting to one week, and a fixed period of social service, which shall include working with a non-governmental organisation working on HIV and Acquired Immunodeficiency Virus, a protected person's network, or the appropriate authority under the State Government that shall be monitored, and may also require that the person supervising the violator undergo such training.

(2) Upon subsequent violation of the Act by the same person, the Complaints Officer may recommend the establishment to take disciplinary action in accordance with the law.

(3) The Complaints Officer shall inform the complainant of the action taken in relation to the complaint and of the complainant's right to approach the Ombudsman or to any other appropriate legal recourse in case the complainant is dissatisfied with the action taken.

(4) The Complaints Officer shall, on deciding a complaint, provide brief reasons in writing for the decision to the establishment and the concerned parties to the complaint within a period of ten days from the date of decision.

12. (1) The Complaints Officer shall ensure that the complaint, its nature and number and the action taken are reported to the appropriate authority under the Central Government every six months subject to the provisions of section 11 of the Act and rule 13 of these rules.
(2) The Complaints Officer shall ensure that the complaint, the nature of the complaint, the number of the complaint and the action taken are published on an annual basis or the establishment publishes annual report or on the website of the establishment or in such annual report , subject to the provisions of rule 13 and section 11 of the Act.
13. (1) The Complaints Officer shall, if requested by a protected person who is part of any complaint, ensure the protection of the identity of the protected person in the following manner, namely:-
(a) the Complaints Officer shall file one copy of the document bearing the full name, identity and identifying details of such protected person which shall be kept in a sealed cover and in safe custody with the Complaints Officer;
(b) the Complaints Officer shall provide pseudonyms to protected person involved in complaints before him;
(c) the identity of protected person involved in complaints before the Complaints Officer and their identifying details shall be displayed in pseudonym in all documentation and records generated by the Complaints Officer and the establishment in relation to the complaints including in the register of complaints under sub-rule (4) of rule 10;
(d) the identity and identifying details of the protected person involved in a complaint before the Complaints Officer shall not be revealed by any person or their representatives including assistants and staff.
(2) No person shall print or publish any matter in relation to a complaint before a Complaint Officer unless the identity of the protected persons in the complaint is protected.
(3) The Complaints Officer shall comply with the data protection measures in accordance with the provisions of section 11 of the Act.
14. Every establishment which requires to appoint a Complaints Officer shall-
(a) on an annual basis, organise workshops and awareness programmes for sensitising its employees with the provisions of the Act and orientation programmes for the Complaints Officer;
(b) provide necessary facilities for the Complaints Officer for deciding the complaint; and
(c) make available such information as the Complaints Officer may require in deciding the complaint.
15. The appropriate authority under the Central Government shall-
(a) develop and disseminate information, education, communication and training materials to advance the understanding of the public generally and in particular of protected persons, civil authorities and healthcare workers of the provisions of the Act including relating to redressal of rights;
(b) formulate and disseminate orientation and training programmes that may be used by establishments in the training of Complaints Officers under sub-rule (2) of rule 9 and in the counselling of persons found to have violated the provisions of the Act and clause (b) of sub-rule (1) of rule 11;
(c) provide training for the establishments in high burden districts, in coordination with the appropriate authority under the State Government and their Complaints officers in such districts on the implementation of the Act and the rules and shall further provide such trainings on an annual basis;
(d) provide training for civil authorities, and healthcare workers including Accredited Social Health Activists and Anganwadi Workers in high burden districts, in coordination with the appropriate authority under the State Government in such districts on the implementation of the Act and the rules and shall further provide such trainings on an annual basis.

16. Nothing contained in these rules prohibits, limits or otherwise restricts the right of a person to other remedies provided under the Act or any other law for the time being in force to address violations of the provisions of the Act.

FORM

Form for making Complaint to Complaints Officer under rule 10

1. Date of Incident ____
2. Place of Incident ____
3. Description of incident _____
4. Person or institution responsible for the incident _____

Signature or Thumb Impression of Complainant*

Name: Date:

Mobile No. or email or Fax or Address:

For Official Use only:

Complaint Number: ____

**Where the complaint is received orally or telephonically and reduced to writing by the Complaints Officer, the Complaints Officer shall sign and date the Form.*

[F. No. T-11020/50/1999-NACO (P&C)]

ALOK SAXENA, Jt. Secy.

INFLUENZA

The Government of India declared in 1957 that influenza in an infectious disease and its period of incubation is of 5 days.

REGISTERED No. D. 221

The Gazette of India

EXTRAORDINARY

PART II—Section 3

PUBLISHED BY AUTHORITY

No. 248] NEW DELHI, THURSDAY, MAY 16, 1957/VAISAKHA 26, 1879

MINISTRY OF HEALTH

New Delhi-2, the 16th May 1957.

NOTIFICATIONS

S.R.O. 1643.—In pursuance of clauses (11) and (15) of rule 2 of the Indian Aircraft (Public Health) Rules, 1954, the Central Government hereby declares influenza to be an infectious disease and a period of five days to be the period of incubation of that disease.

[No. F. 16-2/57-I.H.]

S.R.O. 1644.—In pursuance of clauses (8) and (13) (b) of rule 2 of the Indian Port Health Rules, 1955, the Central Government hereby declares influenza to be an infectious disease and the period of five days to be the period of incubation of that disease.

[No. F. 15-1/57-I.H.]

V. K. B. PILLAI, Secy.

POST-POLIO SYNDROME (EDUCATION, TRAINING AND AWARENESS) BILL, 2010

THE POST-POLIO SYNDROME (EDUCATION, TRAINING AND AWARENESS) BILL, 2010

TO BE INTRODUCED IN LOK SABHA

Bill No. 112 of 2010

By

SHRI BALKRISHNA KHANDERAO SHUKLA, M.P.

A

BILL

to provide for education and training in and creating awareness about post-polio syndrome and for matters connected therewith.

BE it enacted by Parliament in the Sixty-first Year of the Republic of India as follows:—

1. Short title, extent and commencement.

(*1*) This Act may be called the Post-Polio Syndrome (Education, Training and Awareness) Act, 2010.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

2. Definitions.:-

In this Act, unless the context otherwise requires, "post-polio syndrome" means a medical condition where such symptoms of polio as progressive muscle and joint weakness, pain or muscle atrophy, breathing or swallowing problems, sleep related breathing disorders or general fatigue and exhaustion with minimal activity occur at a later stage in a person affected by polio.

3. Certain steps to be taken by Central Government in regard to post-polio syndrome.

On and from the date of commencement of this Act, the Central Government shall—

(*i*) provide education and training in the field of post-polio syndrome to health professionals;

(*ii*) create awareness in general public about post-polio syndrome;

(*iii*) make study of post-polio syndrome an integral part of the healthcare system and medical education in the country;

(*iv*) provide incentives to non-Governmental Organisations working in the field of post-polio syndrome; and

(*v*) take such other steps, as it may deem necessary, to provide adequate care and to promote the welfare of persons suffering from post-polio syndrome.

4. Medical colleges to impart teaching in post-polio syndrome.

It shall be compulsory for every medical college or institution to provide teaching and training in post-polio syndrome within a period of two years from the date of commencement of this Act.

5. Power to make rules.

(*1*)The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

(*2*)Every rule made under this Act shall be laid as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both the Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

STATEMENT OF OBJECTS AND REASONS

Post-Polio Syndrome (PPS) is a condition that affects polio survivors years after their recovery from an initial acute attack of the poliomyelitis virus. Post-Polio Syndrome is mainly characterized by new weakening in muscles that were previously affected by polio infection and also in muscles that were seemingly unaffected.

Post-Polio Syndrome is rarely life-threatening. However, untreated respiratory muscle weakness may result in life-threatening condition of the patients and weakness in swallowing muscles may result in aspiration pneumonia.

The severity of residual weakness and disability after acute poliomyelitis tends to predict the development of post-polio syndrome. Patients who had minimal symptoms from the original illness will most likely experience only mild post-polio syndrome symptoms.

People originally hit hard by the polio virus and who attained a greater recovery may develop a more severe case of post-polio syndrom with a greater loss of muscle function and more severe fatigue.

Through years of studies, scientists at the National Institute of Neurological Disorders and Stroke and at other institutions have shown that the weakness of post-polio syndrome is a very slowly progressing condition marked by periods of stability followed by new declines in the ability to carry out usual daily activities.

At present, there is no effective pharmaceutical or specific treatment for the syndrome itself. Although there is no cure, there are recommended management strategies. Seeking medical advice from a physician experienced in treating neuromuscular disorders is one of them. Learning about post-polio syndrom is important for polio survivors and their families.

Management of post-polio syndrome may involve changes in lifestyle. Support groups that encourage self-help, group participation and positive action can be helpful. Presently, no medical intervention has been found to stop the deterioration of surviving neurons.

Presently, there are eight million polio patients in India. But, unfortunately, society is largely ignorant about the onset of post-polio syndrome. Therefore, it is the responsibility of the Central Government to provide education, training and create awareness about the disease among the medical professionals and people particularly among persons suffering from post-polio syndrome in the country. With right kind of education and awareness, a large number of people can be saved from the sufferings of post-polio syndrome. Therefore, there is an urgent need to bring a legislative proposal on the subject to address this problem.

Hence this Bill.

NEW DELHI; BALKRISHNA KHANDERAO SHUKLA

August 10, 2010.

FINANCIAL MEMORANDUM

Clause 3 of the Bill provides that the Central Government shall take steps to provide education and training in post-polio syndrome to health professionals, create awareness among general public and provide incentives to Non-Governmental Organisations working in the field of post-polio syndrome.

Clause 4 provides for medical colleges to impart teaching in post-polio syndrome. The Bill, therefore, if enacted, will involve expenditure from the Consolidated Fund of India. It is estimated that an annual recurring expenditure of about rupees five crore will be involved.

An non-recurring expenditure of about rupees one hundred crore is also likely to be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 5 of the Bill empowers the Central Government to make rules for carrying out the purposes of the Bill. As the rules will relate to matters of detail only, the delegation of the legislative power is of a normal character.

LOK SABHA

————

A

BILL

to provide for education and training in and creating awareness about post-polio syndrome and for matters connected therewith.

————

(*Shri Balkrishna Khanderao Shukla, M.P.*)

GMGIPMRND—4657LS(S3)—22-10-2010.

RIGHTS OF PERSONS AFFECTED BY LEPROSY AND MEMBERS OF THEIR FAMILY (PROTECTION AGAINST DISCRIMINATION AND GUARANTEE OF SOCIAL WELFARE) BILL, 2017

THE RIGHTS OF PERSONS AFFECTED BY LEPROSY AND MEMBERS OF THEIR FAMILY (PROTECTION AGAINST DISCRIMINATION AND GUARANTEE OF SOCIAL WELFARE) BILL, 2017

AS INTRODUCED IN THE RAJYA SABHA ON THE 29TH DECEMBER, 2017

Bill No. XXXII of 2017

A

BILL

to protect the human rights of persons affected by leprosy, to eliminate discrimination against them and their families, to promote their social welfare, to take steps for the prevention and control of leprosy and for matters connected therewith or incidental thereto.

WHEREAS the spread of leprosy and discrimination against persons affected by leprosy and their family members is a matter of grave concern to all, and there is an urgent need for the protection of the human rights of such persons, by repealing and amending existing laws the discriminate against them;

AND WHEREAS there is a necessity for effective care, support, treatment and social inclusion and integration of persons affected by leprosy and their families;

AND WHEREAS the Rights of Persons with Disabilities Act, 2016 does not cover persons affected by leprosy that are still to be diagnosed or those undergoing treatment and also does not recognise the discrimination and stigma faced by the family members of persons affected and cured of leprosy;

AND WHEREAS the General Assembly of the United Nations, of which India is a member, recalling and reaffirming its previous commitments on leprosy, has unanimously adopted a Resolution on the Elimination of Discrimination against Persons affected by Leprosy and their Family Members in 2010, accompanied by Principals and Guidelines listing out measures to improve the living conditions and social inclusion of such persons;

AND WHEREAS the United Nations Convention on the Rights of Persons with Disabilities 2006 ("UNCRPD") to which India is a party, promotes, protects and ensures the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities;

AND WHEREAS the Republic of India, having signed the Resolution of the General Assembly of the United Nations on leprosy and having signed and ratified the UNCRPD, 2006 has to make provision to give effect to the said Resolution and Convention;

Be it enacted by Parliament in the Sixty-eighth Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

1. Short title, extent and commencement.

(*1*) This Act may be called the Rights of Persons Affected by Leprosy and Members of their Family (Protection against Discrimination and Guarantee of Social Welfare) Act, 2017.

(*2*) It extends to the whole of India.

(*3*) It shall come into force on such date as the Central Government may. by notification in the Official Gazette, appoint.

2. Definitions.:-In this Act, unless the context otherwise requires,—

(*a*) 'abuse' means any unwelcome verbal or non-verbal act or behavious towards a person affected by leprosy or a member of the family of a person affected by leprosy which causes:—

(*i*) bodily pain or harm to a person affected by leprosy or a member of the family of a person affected by leprosy;

(*ii*) humiliation or embarrassment to a person affected by leprosy or a member of the family of a person affected by leprosy; or

(*iii*) deprivation of economic and financial resources, foods and fluids or any other form of support, to which a person affected by leprosy or a member of the family of a person affected by leprosy is entitled:

Provided that the word 'leper' shall be included within the meaning of 'abuse' when any person affected by leprosy is referred to by such word;

(*b*) ‘appropriated Government’ means;
(*i*) in relation to an establishment of the Central Government, or any establishment, wholly or substantially owned or financed by that Government or a Cantonment Board constituted under the Cantonments Act, or a Union Territory without legislature, or the provider of a service which pertains to List I in Schedule VII of the Constitution, the Central Government;
(*ii*) in all other cases, the State Government or, as the case may be, the Government of a Union Territory with legislature.
(*c*) 'barrier' means any factor including attitudinal, cultural, economic, institutional, political, religious, social or structural factors which hampers the full and effective participation, of a person affected by leprosy or a member of the family of a person affected by leprosy in society;

THE TUBERCULOSIS (PREVENTION AND CONTROL) BILL, 2017

AS INTRODUCED IN LOK SABHA

Bill No. 230 of 2017

THE TUBERCULOSIS (PREVENTION AND CONTROL) BILL, 2017

B*y*

DR. KIRIT PREMJIBHAI SOLANKI, M.P.

A

BILL

to provide for the prevention, diagnosis, treatment and control of the spread of tuberculosis and for the protection of the rights of patients affected by the tuberculosis disease and for matters connected therewith or incidental thereto.

WHEREAS the continued spread of tuberculosis is a matter of grave concern to all and there is an urgent need for the prevention and control of the said disease;

AND WHEREAS there is a need to protect and secure the rights of persons who are affected with tuberculosis and vulnerable to the said disease;

AND WHEREAS there is a necessity for effective care, support and treatment for tuberculosis;

AND WHEREAS the General Assembly of the United Nations has adopted the Sustainable Development Goals, which call for a reduction in tuberculosis-related deaths and the World Health Organization has adopted the End TB Strategy for a reduction in the incidence of Tuberculosis by 2035 through collective global efforts;

AND WHEREAS the Republic of India, being a signatory to the aforementioned Goals and Strategy, it is expedient to give effect to the said Goals and Strategy.

BE it enacted by Parliament in the Sixty-eighth Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

1. Short title, extent and commencement.

(*1*) This Act may be called the Tuberculosis (Prevention and Control) Act, 2017.

(*2*) It extends to the whole of India.

(*3*) It shall come into force on such date as the Central Government, may, by notification in the Official Gazette, appoint.

2. Definitions.

In this Act, unless the context otherwise requires,—

(*a*) "Aadhaar" means Aadhaar number issued by the Unique Identification Authority of India under sub-section (*3*) of section 3 of the Aadhaar (Targeted Delivery of Financial and other Subsidies Benefits and Services) Act, 2016;

(*b*) "discrimination" means any act or omission which directly or indirectly, expressly or by effect, immediately or over a period of time,—

(*i*) imposes any burden, obligation, liability, disability or disadvantage on any person or category of persons, based on one or more tuberculosis-related grounds; or

(*ii*) denies or withholds any benefit, opportunity or advantage from any person or category of persons, based on one or more tuberculosis-related grounds, and the expression "discriminate" to be construed accordingly;

(*c*) "guidelines" means any statement or any other document issued by the Central Government indicating policy or procedure or course of action relating to tuberculosis to be followed by the Central Government, State Governments, Governmental and non-Governmental organisations and establishments and individuals dealing with prevention, control and treatment of tuberculosis;

(*d*) "HIV-positive person" means a person whose HIV test has been confirmed positive;

(*e*) "Multi-drug Resistant Tuberculosis (MDR-TB)" means a strain of the tuberculosis bacteria resistant to two of the most effective anti-tuberculosis drugs available, isoniazid and rifampicin;

(*f*) "notification" means a notification published in the Official Gazette;

(*g*) "NIKSHAY" means a web based solution for monitoring of tuberculosis patients developed by the National Informatics Centre;

(*h*) "person" includes an individual, a Hindu Undivided Family, a company, a firm, an association of persons or a body of individuals, whether incorporated or not, in India or outside India, any corporation established by or under any Central or State Act or any company including a Government company incorporated under the

Companies Act, 1956, any Limited Liability Partnership under the Limited Liability Partnership Act, 2008, any body corporate incorporated by or under the laws of a country outside India, a co-operative society registered under any law relating to cooperative societies, a local authority and every other artificial juridical person;

(*i*) "prescribed" means prescribed by rules made by the Central Government or the State Government, as the case may be;

(*j*) "Revised National Tuberculosis Control Program (RNTCP)" means the program launched by the Ministry of Health and Family Welfare in 1997;

(*k*) "State Government" in relation to a Union territory, means the Administrator of that Union territory appointed by the President under article 239 of the Constitution;

(*l*) "tuberculosis" means an infectious disease caused by a bacterium, Mycobacterium Tuberculosis that is spread through the air; and

(*m*) "tuberculosis-affected person" means an individual who is suffering from any strain of the tuberculosis disease.

CHAPTER II
PROHIBITION OF DISCRIMINATION

3. Prohibition of discrimination.

No person shall discriminate against the tuberculosis-affected person on any ground including any of the following, namely:—

(*a*) the unfair treatment in, or in relation to employment or occupation;

(*b*) the denial or discontinuation of, or unfair treatment in, healthcare services;

(*c*) the denial or discontinuation of, or unfair treatment in educational establishments and services thereof;

(*d*) the denial or discontinuation of, or unfair treatment with regard to, the right of movement;

(*e*) the denial or discontinuation of, or unfair treatment with regard to the right to reside, purchase, rent or otherwise occupy, any property;

(*f*) the denial of access to, removal from, or unfair treatment in, Government or private establishment in whose care or custody a person may be;

(*g*) the isolation or segregation of a tuberculosis-affected person.

CHAPTER III
MOLECULAR TESTING AND DAILY DOSAGE TREATMENT

4. Central and State Governments to take measures.

The Central Government and every State Government, as the case may be, shall take all measures as it deems necessary and expedient for the prevention of spread of tuberculosis, in accordance with the guidelines.

5. Molecular Testing and daily dose of Multi-drug Resistant (MDR-TB) Tuberculosis.

(*1*) The measures to be taken by the Central Government or the State Government under section 4 shall include the measures for providing, as far as possible, Molecular Testing methods for diagnosis and daily dosage treatment for those living with Multi-drug Resistant (MDR-TB) Tuberculosis, in particular.

(*2*) The Central Government shall issue necessary guidelines in respect of protocols for tuberculosis relating to Molecular Testing and Daily Dosage treatment, which shall be applicable to all persons and shall ensure their wide dissemination.

6. Availability of latest anti-tuberculosis drugs.

The Central Government shall take steps to ensure the introduction and availability of the latest anti-tuberculosis drugs in all public hospitals and Government run pharmacies.

7. Guidelines for testing centres.

No diagnostic centre or laboratory shall conduct a diagnostic test for tuberculosis or Multi-drug Resistant Tuberculosis except in accordance with the guidelines laid down for such test under this Act.

CHAPTER IV
DIGITAL DATABASE AND TRACKING OF TUBERCULOSIS TREATMENT AND CARE

8. Mandatory notification of Tuberculosis patients.

Every public and private hospitals and clinics shall notify tuberculosis patients under their treatment and care on the web-based NIKSHAY platform under the Revised National Tuberculosis Control Programme to facilitate real time tracking of treatment and care such patients.

9. Enrolment under Aadhaar for Tuberculosis patients seeking treatment.

The Central Government and every State Government shall take measures to ensure that every Tuberculosis-affected person is enrolled under Aadhaar to ensure unique identification of patients seeking care and facilitate direct benefit transfers under the welfare measures mentioned under Chapter VI of this Act.

CHAPTER V

IDENTIFICATION OF VULNERABLE SECTIONS OF THE POPULATION

10. Identification of vulnerable sections of the population.

(*1*) Every State Government shall, with the assistance from the Central Government, carry out identification of the poor and vulnerable sections of the population within the jurisdiction of each tuberculosis program in such manner as may be prescribed.

(*2*) The identification under sub-section (*1*) shall include, but shall not be limited to women, children, below poverty line households and HIV-positive persons.

11. State Government to present list of vulnerable sections to the Central Government.

Every State Government shall, within six months of the Act coming into force, present the Central Government with a list of vulnerable sections within every tuberculosis program and formulate a plan to create awareness and initiate preventive measures about disease among such vulnerable sections.

CHAPTER VI

WELFARE MEAURES BY CENTRAL AND STATE GOVERNMENT

12. Nutritional, financial and psycho-social support for Tuberculosis patients.

(*1*) The Central Government and every State Government shall take measures to facilitate better access to welfare, access to persons infected or affected by tuberculosis, which shall include but will not be limited to:

(*a*) nutritional support, if malnutrition or undernourishment is detected, under the public distribution scheme or any other related food security scheme;

(*b*) financial support, under a health insurance or coverage scheme, for below poverty line patients to reduce out of pocket expenditure;

(*c*) psychological and social support, through free counseling, for patients and their families.

(*2*) Without prejudice to the provisions of sub-section (*1*), the Central and State Governments shall frame schemes to address the needs of tuberculosis-affected women and children as well those from vulnerable sections of society, including those who are HIV positive.

13. Tuberculosis related awareness programs.

The Central Government and State Government shall formulate tuberculosis related information, education and communication programmes which are non-discriminatory.

14. Guidelines for care, etc. of children and HIV-persons affected by tuberculosis.

The Central Government shall lay down guidelines for care, support and treatment of children affected with tuberculosis and HIV-positive persons affected by tuberculosis.

CHAPTER VII

NATIONAL AND STATE TUBERCULOSIS ELIMINATION BOARDS

15. Constitution of the National Tuberculosis Elimination Board.

(*1*) The Central Government shall, by notification in the Official Gazette, constitute a National Tuberculosis Elimination Board, to facilitate the eradication of tuberculosis in the country.

(*2*) The National Board shall include,—

(*a*) The Union Minister of Health and Family Welfare— *Chairperson;*

(*b*) The Secretary, Union Ministry of Health and Family Welfare— *Member;*

(*c*) representatives from the Indian Council of Medical Research to be nominated by the Central Government in such manner as may be prescribed— *Member;*

(*d*) representatives from Health Departments of every State Government to be nominated by the Central Government in such manner as may be prescribed— *Member;*

(*e*) medical practitioners from private medical hospitals and clinics to be nominated by the Central Government in such manner as may be prescribed— *Member;*

(*f*) members from affected communities to be nominated by the Central Government in such manner as may be prescribed— *Member;* and

(*g*) representatives from non-Governmental Organisations working in the field of prevention, control and treatment of tuberculosis to be nominated by the Central Government in such manner as may be prescribed— *Member*.

(*3*) The salary and allowance payable to and other terms and conditions of service of members of the National Board shall be such as may be prescribed.

16. Functions of the National Board.

The National Board shall,—

(*a*) formulate a comprehensive strategy to ensure the elimination of the disease, with an aim to achieving national and international commitments;

(*b*) keep track of new medical diagnostic technologies and anti-tuberculosis drugs and ensuring their easy availability;

(*c*) provide incentives to the private sector to assist in the elimination of tuberculosis;

(*d*) create awareness and prevention strategies on the basis of the mapping and identification conducted by every State Government under section 10;

(*e*) track the activities of the Ombudsman appointed under section 18;

(*f*) receive quarterly reports from the State Tuberculosis Elimination Boards;

(*g*) ensure that adequate financial, nutritional and psycho-social support is provided to tuberculosis-affected patients under a variety of Government schemes; and

(*h*) take decisions regarding any other policy or scheme related to tuberculosis and the rights of the patients seeking treatment and care for the said disease.

17. Constitution of State Tuberculosis Elimination Boards.

(*1*) Every State Government shall, by notification in the Official Gazette, constitute a State Tuberculosis Elimination Board to carry out the functions of this Act.

(*2*) The State Tuberculosis Elimination Boards shall consist of a Chairperson and such other number of members as may be determined by the State Government in consultation with the National Board.

(*3*) The salary and allowance payable to Chairperson and other member of the State Tuberculosis Elimination Board shall be such as may be prescribed.

CHAPTER VIII
APPOINTMENT OF OMBUDSMAN

18. Appointment of Ombudsman.

(*1*) Every State Government shall appoint one or more Ombudsman—

(*a*) possessing such qualification and experience as may be prescribed, or (*b*) designate such number of officers not below the rank of District Magistrate, to exercise such powers and discharge such functions, as may be conferred on Ombudsman under this Act.

(*2*) The terms and conditions of the service of an Ombudsman appointed under clause (*a*) of sub-section (*a*) shall be such as may be prescribed by the State Government.

(*3*) The Ombudsman appointed under sub-section (*1*) shall have such jurisdiction in respect of such are or areas as the State Government may, by notification, specify.

19. Powers of Ombudsman.

(*1*) The Ombudsman shall, upon a complaint made by any person, inquire into the violation of the provisions of this Act, in relation to healthcare services by any person, in such manner as may be prescribed by the State Government.

(*2*) The Ombudsman shall maintain records of complaints in such manner as may be prescribed.

20. Procedure of complaint.

The complaints shall be made to the Ombudsman in such manner, as may be prescribed.

21. Reasonable opportunity of being heard.

The Ombudsman shall, after giving an opportunity of being heard to the parties, pass such order, as he deems fit, giving reasons therefor.

22. Authorities to assist Ombudsman.

All authorities including the civil authorities functioning in the area for which the Ombudsman has been appointed under section 18 shall assist in execution of orders passed by the Ombudsman.

23. Report to State Government.

The Ombudsman shall, after every six months, report to the State Government, the number and nature of complaints received, the action taken and orders passed in relation to such complaints and such report shall be published on the website of the Ombudsman and a copy thereof be forwarded to the Central Government.

CHAPTER IX
PENALTIES

24. Penalty for failure to comply with orders of Ombudsman.

Whoever fails to comply with any order given by an Ombudsman within such time as may be specified in such order shall be liable to pay a fine which may extend upto ten thousand rupees and in case the failure continues, with an additional fine which may extend to five thousand rupees for every day during which the failure continues.

25. Prohibition of victimization.

No person shall subject any other person or persons to any detriment on the ground that such person or persons have taken any of the following actions namely:—

(*a*) made complaint under this Act;

(*b*) brought proceedings under this Act against any person;

(*c*) furnished any information or produced any document to a person exercising or performing any power or function under this Act; or

(*d*) appeared as a witness in a proceeding under this Act.

26. Court to try offences.

No court other than the court of Judicial Magistrate First Class shall take cognizance of an offence under this Act.

CHAPTER X
MISCELLANEOUS

27. Act to have overriding effect.

The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time in force or in any instrument having effect by virtue of any law other than this Act.

28. Protection of action taken in good faith.

No suit, prosecution or other legal proceeding shall lie against the Central Government, the State Government, the Ombudsman or any member thereof or any officer or other employee or person acting under the direction either of the Central Government, the State Government, or Ombudsman in respect of anything which is in good faith done or intended to be done in pursuance of this Act or any rules or guidelines made thereunder or in respect of the publication by or under the authority of the Central Government, the State Government or Ombudsman.

29. Delegation of powers.

The Central Government or the State Government, as the case may be, may, by general or special order, direct that any power exercisable by it under this Act shall, in such circumstances and under such conditions, if any, as may be mentioned in the order, be exercisable also by an officer subordinate to that Government or the local authority.

30. Central Government to make guidelines.

The Central Government may, by notification, make guidelines consistent with this Act and any rules thereunder, generally to carry out the provisions of this Act.

31. Power to remove difficulties.

(*1*) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act, as may appear to be necessary for removing the difficulty:

Provided that no order shall be made under this section after the expiry of the period of two years from the date of commencement of this Act.

(*2*) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

32. Power of Central Government to make Rules.

(*1*) The Central Government may, by notification, make rules to carry out the provisions of this Act.

(*2*) Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in

two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

33. Power of State Governments to make Rules.

(*1*) The State Government may, by notification, make rules for carrying out the provisions of this Act.

(*2*) Every rule made by the State Government under this Act shall be laid, as soon as may be, after it is made before the Legislature of that State.

STATEMENT OF OBJECTS AND REASONS

Although tuberculosis is a preventable and treatable disease, yet it continues to be a serious public health epidemic in India. India bears the highest tuberculosis burden in the world, accounting for 23 per cent. of the global incidence of active tuberculosis patients. It is estimated that 1,400 Indians die every day due to tuberculosis. Since India is a signatory to the World Health Organization's 'End TB Strategy' and the United Nations' Sustainable Development Goals, the Ministry of Health and Family Welfare has formulated the National Strategic Plan to eliminate Tuberculosis by 2025.

To supplement the strategies outlined within this Plan, the Bill aims to address all aspects of the diagnosis, treatment, prevention and control of the spread of tuberculosis as well as the rights of the patients seeking care. It mandates the creation of a National Tuberculosis Elimination Board, which will be the apex body directing all efforts to combat the disease along with State-level Boards. It also provides for appointment of an Ombudsman to address the grievances of patients and related stakeholders.

The Bill prohibits certain discriminatory acts that stigmatize patients and their families and mandates the Central Government and State Governments to undertake welfare measures to provide financial, nutritional and psycho-social support to patients from vulnerable sections of the population. To facilitate the tracking of tuberculosis treatment and care, the Bill makes it mandatory for both public and private hospitals and clinics to notify tuberculosis patients under their care on the web-based NIKSHAY portal and encourage all patients seeking care to enroll under Aadhaar. Tuberculosis is India's most severe public health crisis and combating it will require the collective and sustained effort of all stakeholders. The Bill aims to ensure that India will achieve its goal to eliminate tuberculosis by 2025 and it seeks to achieve the above objects.

Hence this Bill.

NEW DELHI; KIRIT PREMJIBHAI SOLANKI

November 27, 2017.

FINANCIAL MEMORANDUM

Clause 4 of the Bill provides that the Central Government and every State Government, as the case may be, shall take all measures as it deems necessary and expedient for the prevention of spread of tuberculosis, in accordance with the guidelines. Clause 5 provides for measures to be taken by the Central Government or the State Government for providing Molecular Testing methods for diagnosis and daily dosage treatment for those living with Multi-drug Resistant (MDR-TB) Tuberculosis. Clause 10 provides for every State Government to carry out identification of the poor and vulnerable sections of the population within the jurisdiction of each tuberculosis program. Clause 12 provides that the Central Government and every State Government to take measures to facilitate better access to welfare, access to persons infected or affected by tuberculosis including nutritional support, financial support and social support.Clause 15 provides that the Central Government shall constitute a Board to be known as the National Tuberculosis Elimination Board. Clause 17 provides for constitution of the State Tuberculosis Elimination Boards. Clause 18 provides for appointment of Ombudsman. The Bill, therefore, if enacted, will involve expenditure from the Consolidated Fund of India. It is likely to involve an annual recurring expenditure of about rupees one hundred crore from the Consolidated Fund of India. A non-recurring expenditure of about rupees fifty crore is also likely to be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 4 of the Bill empowers the Central Government to make guidelines consistent with the proposed legislation and rules thereunder to carry out its provisions. Clause 32 of the Bill empowers the Central Government to make rules for carrying out the provisions of this Act. As matters in respect of which rules may be made under the aforesaid provisions are matters of procedure and administrative detail only, the delegation of legislative power is, therefore, of a normal character.

LOK SABHA

———

A

BILL

to provide for the prevention, diagnosis, treatment and control of the spread of tuberculosis and for the protection of the rights of patients affected by the tuberculosis disease and for matters connected therewith or incidental thereto.

———

(Dr. Kirit Premjibhai Solanki, M.P.)

GMGIPMRND—2721LS(S3)—15-12-2017.

THE TUBERCULOSIS (PREVENTION AND ERADICATION) BILL, 2018

AS INTRODUCED IN LOK SABHA

Bill No. 213 of 2018

THE TUBERCULOSIS (PREVENTION AND ERADICATION) BILL, 2018

B*y*

SHRIMATI SUPRIYA SULE, M.P.

A

BILL

to establish a Tuberculosis Prevention Authority for prevention and complete eradication of tuberculosis and for all matters connected therewith and incidental thereto.

WHEREAS India ratified the World Health Organisation Framework Convention on Tobacco Control in 2005,

BE it enacted by Parliament in the Sixty-ninth Year of the Republic of India as follows:—

1. Short title, extent and commencement.

(*1*) This Act may be called the Tuberculosis (Prevention and Eradication) Act, 2018.

(*2*) It extends to the whole of India.

(*3*) It shall come into force on such date, as the Central Government may, by notification in the Official Gazette, appoint.

2. Definitions.

In this Act, unless the context otherwise requires,—

(*a*) "annual report" means a report giving the details of developmental activities taken up over the year by the Authority and detailing about targets set and achieved;

(*b*) "appropriate Government" means in the case of a State, the Government of that State and in all other cases, the Central Government.

(*c*) "Authority" means the Tuberculosis Prevention Authority constituted under section 3;

(*d*) "company" means an entity registered under the Companies Act, 2013;

(*e*) "prescribed" means prescribed by the rules made under this Act;

(*f*) "tuberculosis" means an infectious disease caused by a bacterium, Mycobacterium Tuberculosis that is spread through the air; and

(*g*) "society" means an entity registered as society under the Societies Registration Act, 1860.

3. Constitution of the Tuberculosis Prevention Authority.

(*1*) **With effect from such date as the Central Government may, by notification in the Official Gazette specify, there shall be constituted an Authority to be known as the Tuberculosis Prevention Authority for carrying out the purposes of this Act.**

(*2*) The Authority consist of,—

(*a*) Minister of State, Union Ministry of Health and Family Welfare—Chairperson, *ex officio*;

(*b*) Minister of State, Union Ministry of Women and Child Development—Vice- Chairperson, *ex officio;*

(c) Director General of Health Services, Union Ministry of Health and Family Welfare—member, *ex-officio*;

(*d*) Secretaries of the Union Ministies of Women and Child Development, Health and Family Welfare and Statistics and Programme Implementation—members, *ex officio*;

(*e*) Chairperson, National Commission for Women—member, *ex-officio*; and

(*f*) Director, National Institute of Health and Family Welfare—member, *ex-officio*.

(*2*) The Central Government shall appoint such number of officers and staff as it considers necessary for the functioning of the Authority.

(*3*) The salary, allowances and terms of conditions of services of officers and staff of the authority shall be such, as may be prescribed.

4. Meetings of the Authority.

(*1*) The Authority shall meet at such times and places and shall observe such rules of procedure in regard to transaction of business at its meetings as may be prescribed by the Central Government.

(*2*) The expenditure incurred to attend meetings by the Members referred to in sub-clauses (*a*) to (*f*) of section 3, shall be borne by their concerned controlling authorities.

5. Functions of the Authority.

(*1*) The Authority shall discharge such functions as may be necessary for prevention and eradication of tuberculosis in the country.

(*2*) Without prejudice to the generality of forgoing provisions, the authority shall,—
(*a*) formulate a Charter outlining its objectives along with roadmap to eradicate tuberculosis, within one year of its constitution;
(*b*) disseminate any necessary knowledge and information collected on the control of tuberculosis to the State Governments to be disseminated to tuberculosis Control Centres;
(*c*) undertake a baseline study to collect comprehensive data about causes of tuberculosis, risk factors and vulnerable population, within one year of setting up of the Authority.
(*d*) direct the appropriate Government to assist in conducting the baseline study;
(*e*) direct the State Governments to establish Tuberculosis (TB) Control Centres at district level within one year of the commencement of this Act;
(*f*) direct healthcare service providers to follow the standard tuberculosis diagnosis and treatment protocol; and
(*g*) undertake such other functions as may be assigned to it, from time to time for carrying out the purposes of this Act.

6. Cost-free screening and treatment of tuberculosis.

(*1*) The tuberculosis Control Centres shall provide free screening of tuberculosis and cost-free treatment to the patients, until complete recovery from the disease.
(*2*) The State Government shall also provide healthcare coupons to patients diagnosed with tuberculosis, which may be redeemed for cost-free treatment at private hospitals.

7. Mobile tuberculosis vans for active screening.

(*1*) The State Government shall provide for mobile tuberculosis vans for active screening of tuberculosis, especially in remote rural areas.
(*2*) The patient screened tuberculosis positive with the mobile vanas, shall be referred to the nearest tuberculosis Control Centres for follow-up care and treatment with the assistance from the appropriate Government.

8. Mobile tuberculosis vaccine immunization drive.

The State Government shall undertake mobile tuberculosis immunization drive to vaccinate children who were either not vaccinated or underwent incomplete vaccination.

9. Air borne infection control in high risk areas.

The State Government shall direct the concerned authorities to undertake air borne infection control in high risk and vulnerable areas.

10. Nutritional support to tuberculosis patients.

The appropriate Government shall provide additional nutritional support to tuberculosis patients at tuberculosis Control Centres, to incentivise patients in increasing their adherence to treatment and reduce drop outs.

11. Funding research on new drugs and diagnostic tools for tuberculosis.

The Central Government shall issue notification mandating the registered companies and societies manufacturing and distributing tobacco related products, to contribute five per cent. of their annual sales value for research on new drugs and diagnostic tools for tuberculosis.

12. Facilities for treating drug resistant strain of tuberculosis.

The State Governmetn shall provide extensive facilities at the primary health centres and tuberculosis Control Centres for diagnosis and treatment of drug resistant strain of tuberculosis.

13. Outreach activities to increase awareness of tuberculosis.

(*1*) The appropriate Government shall undertake outreach activities to communicate to citizens of the factors contributing to tuberculosis, symptoms of tuberculosis and its ill effects, especially in rual areas.
(*2*) The nurses and the staff at the tuberculosis Control Centres shall educate the tuberculosis patients on the cough etiquette.
(*3*) The appropriate Government shall nobilise the local population in increasing awareness of tuberculosis in citizens.

14. Tobacco cessation services.

The appropriate Government shall provide for tobacco cessation counselling services at all tuberculosis Control Centres.

15. Awareness in women of ill effects of tobacco consumption on reproductive health.

The appropriate Government shall—

(*a*) undertake outreach and communication activities to increase awareness in women, especially in rural areas, of ill effects of tobacco consumption on their reproductive health and babies;
(*b*) provide for tobacco cessation counselling services at all antenatal clinics and primary health centres; and
(*c*) increrase awareness in rural households about the lethal potential of indoor air pollution from chulhas, and undertake necessary steps to curb the same.

16. State's budget for tuberculosis control to be indexed so its health and development indicators.

(*1*) The Central Government while allocating resources to a State Government for tuberculosis control, shall take into consideration the health and development indicators alongwith the past years spending potential of that State.
(*2*) The Central Government shall increase the proportion of health sector budget to at least three per cent. of Gross Domestic Product by the year 2020.

17. Annual report and its laying before the parliament.

(*1*) The Authority shall prepare once every year, as may be prescribed, an annual report giving the summary of its activities, including schemes it has undertaken and recommended to the Government over the year and it shall contain statements of annual accounts of the Authority.
(*2*) A copy of the report shall be forwarded to the Central Government, and the Central Government shall lay the report before each House of Parliament.

18. Central Government to provide funds.

The Central Government, will from time to time provide, after due appropriation made by Parliament by law in this behalf, requisite funds for carrying out the purposes of this Act.

19. Power to remove difficulties.

If any difficulty arises in giving effect to the provisions of this Act, the Central Governments, in consultation with the State Governments, may make such order or give such direction, not inconsistent with the provisions of this Act, as appears to it to be necessary or expedient for the removal of any difficulty:
Provided that no such orders shall be made after the expiry of the period of three years from the date of commencement of this Act.

20. Power to make rules.

(*1*) The Central Government may, by notification in the Official Gazette, make rules for carrying out the pruposes of this Act.
(*2*) Every rule made under this section shall be laid, as soon as may be after it is made, before each Houses of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both the Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annualment shall be without prejudice to the validity of anything previously done under that rule.

STATEMENT OF OBJECTS AND REASONS

As per the statistics of World Health Organisation, India accounts for half a million deaths annually due to tuberculosis. The data from the Central Bureau of Health Intelligence also identifies tuberculosis as the leading cause of deaths in the country, accounting for 63,297 deaths in 2015. The Bill provides for free screening and treatment of tuberculosis at tuberculosis Control Centres established at district level in every state. The patients are also provided with an alternative of healthcare coupons that can be redeemed at any private hospital for free tuberculosis related treatment and care. Mobile tuberculosis vans are provided for active screening of tuberculosis in high risk population, especially in rural areas. Tuberculosis positive patients thus screened are referred to the nearest tuberculosis Control Centres for follow-up treatment and care. The Bill directs the State Government to undertake
mobile tuberculosis immunization dirve to vaccinate children. The Bill also directs the government to undertake air borne infection control activities in areas vulnerable to disease. The Bill aims to reduce drop outs from treatment and increase the patients compliance, through provision of nutritional supplements at tuberculosis Control Centres. To fund research in new drugs and diagnostic tools for tuberculosis, the Bill mandates all private and government companies involved in manufacture and distribution of tobacco related products, to contribute five per cent. of their annual sales value. The Bill also proposes 100% tax onall tobacco and tobacco related products, including smokeless tobacco like ghutka etc. The Bill has provision to mobilise local population to increase outreach to citizens about factors contributing to tuberculosis, symptoms of tuberculosis, cough etiquette. As per the Global Report 2017 of the World Health Organisation,

India accounts for 24 per cent. of global cases of multi-drug resistant tuberculosis. The Bill provides for active screening and extensive facilities for treatment of multi-drug resistant strain of tuberculosis at tuberculosis Control Centres.

Tobacco use is one of the main causes of tuberculosis, contributing to 7.9 per cent of tuberculosis related deaths in the country. Research has shown that providing tobacco cessation services to tobacco users, has proved to reduce the disease burden of tuberculosis.

Recognising tobacco as a major contributor to tuberculosis, the Bill provides for integration of tobacco cessation counselling services at all tuberculosis Control Centre. As per the World Health Organisation statistics, India is home to second highest number of women smokers globally. According to the National Family Health Survey-3, the proportion of children with low birth weight, is greater among children born to mothers who use tobacco. The Bill also has provision to educate women of the ill effects of tobacco consumption on their reproductive health, provide for tobacco cessation couselling services at all antenatal clinics and primary health centres. The Bill also provides for measures to curb indoor air pollution created by *chulhas* (used in rural areas for cooking purposes).

In 2016-17, health sector budget accounted for a mere 1.5 per cent, of the Gross Domestic Product. The Bill provides for increasing the health budget to at least three per cent. of Gross Domestic Product in next two years. The Bill stipulates that a State's budget for tuberculosis control must be indexed to the respective State's health and development indicators, along with its past years spending profile. The Bill thus champions for the control, prevention and complete eradication of tuberculosis in the country, by mandating free of cost diagnosis and treatment for tuberculosis.

Hence this Bill.

NEW DELHI; SUPRIYA SULE

November 22, 2018.

FINANCIAL MEMORANDUM

Clasue 3 of the Bill provides for the constitution of the Tuberculosis Prevention Authority and also appointment of such number of officers and staffs for its functioning. Clause 5 provides for establishment of Tuberculosis Control Centre. Clause 6 provides for free screening and cost-free treatment to the patients. Clause 7 provides for mobile tuberculosis vans for active screening of tuberculosis. Clause 8 provides for mobile tuberculosis immunization drive.

Clause 11 provides for funding research on new drugs and diagnostic tools for tuberculosis.

Clause 12 provides for facilities for treating drugs resistant strain of tuberculosis.

Clause 18 makes it obligatory for the Central Government to provide requisite funds for carrying out the purposes of this Billl. The Bill, therefore, if enacted, will involve recurring expenditure of five hundred crore rupees per annum which shall be charged from the Consolidated Fund of India.

A non-recurring expenditure to the tune of rupees one hundred crore is also likely to be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 20 of the Bill empowers the Central Government to make necessary rules for carrying out the purposes of the Bill. As the rules will relate to matters of details only, the delegation of legislative power is of normal character.

LOK SABHA

————

A

BILL

to establish a Tuberculosis Prevention Authority for prevention and complete eradication of tuberculosis and for all matters connected therewith and incidental thereto.

————

(Shrimati Supriya Sule, M.P.)

MGIPMRND—2189LS(S3)—18-12-2018.

THE VACCINATION (REPEAL) BILL, 2000

As Introduced in Rajya Sabha

Bill No. LXXVII of 2000

THE VACCINATION(REPEAL)BILL,2000

A Bill

to repeal the Vaccination Act, 1880

Be it enacted by parliament in the Fifty-first Year of Republic of India as follows:-

1.Short Title:

1. This Act may be called the Vaccination (Repeal)Act, 2000.
2. The Vaccination Act, 1880 is hereby repealed.

STATEMENT OF OBJECTS AND REASONS

The Vaccination Act,1880 pertains to small-pox vaccination, Small-pox was once a major killer throught the world. A vast international campaign by the World Health Organisation between the year 1967 and 1979 led to the eradication of small-pox. On 5th July,1975-India was declared small-pox free by International Commission for Assessment of Small-pox Eradication. On 8th May, 1980 the World Health Organisation declared the global eradication of small-pox. All member States of the World Health Organisation had officially discontinued compulsory vaccination of small-pox with effect from 1982. The Commission on review of Administrative Laws under the Chairmanship of Shri P.C>Jain has, inter alia, recommended the repeal of the Vaccination Act, 1880. The Vaccination Act,1880 is no longer relevant and needs to be repealed.

2. The Bill seeks to repeal the aforesaid Act.

C.P.Thakur

New Delhi. The 17th November, 2000

VACCINATION (REPEAL) ACT, 2000.

RAJYA SABHA

The following Bills were introduced in the Rajya Sabha on the 15th December, 2000:—

I

BnxNo. LXXVIIOF2000

A Bill to repeal the Vaccination Act, 1880.

BE it enacted by Parliament in the Fifty-first Year of the Republic of India as follows:—

1. Short Title

1. This Act may be called the Vaccination (Repeal) Act, 2000.
2. The Vaccination Act, 1880 is hereby repealed.

STATEMENT OF OBJECTS AND REASONS

The Vaccination Act, 1880 pertains to small-pox vaccination. Small-pox was once a major killer throughout the world. A vast international campaign by the World Health Organisation between the years 1967 and 1979 led to the eradication of small-pox. On 5th July, 1975, India was proclaimed to be no longer a small-pox endemic country and in April, 1977 India was declared small-pox free by International Commission for Assessment of Small-pox Eradication. On 8th May, 1980 the World Health Organisation declared the global eradication of small-pox. All member States of the World Health Organisation had officially discontinued compulsory vaccination of small-pox with effect from 1982. The Commission on Review of Administrative Laws under the Chairmanship of Shri P.C. Jain has, *inter alia,* recommended the repeal of the Vaccination Act, 1880. The Vaccination Act, 1880 is no longer relevant and needs to be repealed.

2. The Bill seeks to repeal the aforesaid Act.

C.P. THAKUR.

रजिस्ट्री सं० डी०एल०-33004/2000 REGISTERED NO. DL-33004/2000

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II — खण्ड 2
PART II — Section 2
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं० 57] नई दिल्ली, शुक्रवार, दिसम्बर 15, 2000 / अग्रहायण 24, 1922
No. 57] NEW DELHI, FRIDAY, DECEMBER 15, 2000 / AGRAHAYANA 24, 1922

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

RAJYA SABHA

The following Bills were introduced in the Rajya Sabha on the 15th December, 2000:—

I

BILL NO. LXXVII OF 2000

A Bill to repeal the Vaccination Act, 1880.

BE it enacted by Parliament in the Fifty-first Year of the Republic of India as follows:—

1. This Act may be called the Vaccination (Repeal) Act, 2000. Short title.

2. The Vaccination Act, 1880 is hereby repealed. Repeal of Act 13 of 1880.

List of references

1.The Constitution of India
2.Draft National Health Bill 2009–*http://mohfw.nic.in/NRHM/Draft_Health_Bill/General/Draft_National_Bill.*
3.. Disaster Management Act 2005
4. Gazette notifications of various legislations
5.Official websites of relevant ministries.